

**(h) Authorization of appropriations**

To carry out subsections (a), (b), (c)(1), and (d), there are authorized to be appropriated \$4,900,000 for each of fiscal years 2015 through 2019.

(July 1, 1944, ch. 373, title III, §399NN, as added Pub. L. 111-148, title X, §10413(b), Mar. 23, 2010, 124 Stat. 991; amended Pub. L. 113-265, §2, Dec. 18, 2014, 128 Stat. 2942.)

## AMENDMENTS

2014—Subsec. (h). Pub. L. 113-265 substituted “\$4,900,000 for each of fiscal years 2015 through 2019” for “\$9,000,000 for each of the fiscal years 2010 through 2014”.

## SUBCHAPTER III—NATIONAL RESEARCH INSTITUTES

## CODIFICATION

Title IV of the Public Health Service Act, comprising this subchapter, was originally enacted by act July 1, 1944, ch. 373, 58 Stat. 707, at which time title IV related solely to the National Cancer Institute. Because of the extensive amendments, reorganization of the subject matter, and expansion of title IV by the acts listed below, title IV is shown herein as having been added by Pub. L. 99-158, without reference to intervening amendments.

The provisions of title IV as originally enacted were subsequently redesignated as part A of title IV and amended, and parts B to I of title IV were added and amended by the following acts: June 16, 1948, ch. 481, 62 Stat. 464; June 24, 1948, ch. 621, 62 Stat. 598; Aug. 15, 1950, ch. 714, 64 Stat. 443; Oct. 5, 1961, Pub. L. 87-395, 75 Stat. 824; Oct. 17, 1962, Pub. L. 87-838, 76 Stat. 1072; Aug. 16, 1968, Pub. L. 90-489, 82 Stat. 771; Oct. 30, 1970, Pub. L. 91-515, 84 Stat. 1297; Dec. 23, 1971, Pub. L. 92-218, 85 Stat. 778; May 19, 1972, Pub. L. 92-305, 86 Stat. 162; Sept. 19, 1972, Pub. L. 92-423, 86 Stat. 679; Apr. 22, 1974, Pub. L. 93-270, 88 Stat. 90; May 14, 1974, Pub. L. 93-282, 88 Stat. 126; May 31, 1974, Pub. L. 93-296, 88 Stat. 184; July 12, 1974, Pub. L. 93-348, 88 Stat. 342; July 23, 1974, Pub. L. 93-352, 88 Stat. 358; July 23, 1974, Pub. L. 93-354, 88 Stat. 373; Jan. 4, 1975, Pub. L. 93-640, 88 Stat. 2217; July 29, 1975, Pub. L. 94-63, 89 Stat. 304; Nov. 28, 1975, Pub. L. 94-135, 89 Stat. 713; Apr. 21, 1976, Pub. L. 94-273, 90 Stat. 375; Apr. 22, 1976, Pub. L. 94-278, 90 Stat. 401; Oct. 19, 1976, Pub. L. 94-562, 90 Stat. 2645; Aug. 1, 1977, Pub. L. 95-83, 91 Stat. 383; Nov. 9, 1978, Pub. L. 95-622, 92 Stat. 3412; Nov. 9, 1978, Pub. L. 95-623, 92 Stat. 3443; July 10, 1979, Pub. L. 96-32, 93 Stat. 82; Oct. 7, 1980, Pub. L. 96-398, 94 Stat. 1564; Dec. 17, 1980, Pub. L. 96-538, 94 Stat. 3183; Aug. 13, 1981, Pub. L. 97-35, 95 Stat. 358; Apr. 26, 1984, Pub. L. 98-24, 97 Stat. 175.

Title IV was subsequently amended generally and completely reorganized by Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 822.

## PART A—NATIONAL INSTITUTES OF HEALTH

**§ 281. Organization of National Institutes of Health****(a) Relation to Public Health Service**

The National Institutes of Health is an agency of the Service.

**(b) National research institutes and national centers**

The following agencies of the National Institutes of Health are national research institutes or national centers:

- (1) The National Cancer Institute.
- (2) The National Heart, Lung, and Blood Institute.
- (3) The National Institute of Diabetes and Digestive and Kidney Diseases.

(4) The National Institute of Arthritis and Musculoskeletal and Skin Diseases.

(5) The National Institute on Aging.

(6) The National Institute of Allergy and Infectious Diseases.

(7) The Eunice Kennedy Shriver National Institute of Child Health and Human Development.

(8) The National Institute of Dental and Craniofacial Research.

(9) The National Eye Institute.

(10) The National Institute of Neurological Disorders and Stroke.

(11) The National Institute on Deafness and Other Communication Disorders.

(12) The National Institute on Alcohol Abuse and Alcoholism.

(13) The National Institute on Drug Abuse.

(14) The National Institute of Mental Health.

(15) The National Institute of General Medical Sciences.

(16) The National Institute of Environmental Health Sciences.

(17) The National Institute of Nursing Research.

(18) The National Institute of Biomedical Imaging and Bioengineering.

(19) The National Human Genome Research Institute.

(20) The National Library of Medicine.

(21) The National Center for Advancing Translational Sciences.

(22) The John E. Fogarty International Center for Advanced Study in the Health Sciences.

(23) The National Center for Complementary and Integrative Health.

(24) The National Institute on Minority Health and Health Disparities.

(25) Any other national center that, as an agency separate from any national research institute, was established within the National Institutes of Health as of the day before January 15, 2007.

**(c) Division of Program Coordination, Planning, and Strategic Initiatives****(1) In general**

Within the Office of the Director of the National Institutes of Health, there shall be a Division of Program Coordination, Planning, and Strategic Initiatives (referred to in this subsection as the “Division”).

**(2) Offices within Division****(A) Offices**

The following offices are within the Division: The Office of AIDS Research, the Office of Research on Women’s Health, the Office of Behavioral and Social Sciences Research, the Office of Disease Prevention, the Office of Dietary Supplements, and any other office located within the Office of the Director of NIH as of the day before January 15, 2007. In addition to such offices, the Director of NIH may establish within the Division such additional offices or other administrative units as the Director determines to be appropriate.

**(B) Authorities**

Each office in the Division—

(i) shall continue to carry out the authorities that were in effect for the office before January 15, 2007; and

(ii) shall, as determined appropriate by the Director of NIH, support the Division with respect to the authorities described in section 282(b)(7) of this title.

**(d) Organization**

**(1) Number of institutes and centers**

In the National Institutes of Health, the number of national research institutes and national centers may not exceed a total of 27, including any such institutes or centers established under authority of paragraph (2) or under authority of this subchapter as in effect on the day before January 15, 2007.

**(2) Reorganization of institutes**

**(A) In general**

The Secretary may establish in the National Institutes of Health one or more additional national research institutes to conduct and support research, training, health information, and other programs with respect to any particular disease or groups of diseases or any other aspect of human health if—

(i) the Secretary determines that an additional institute is necessary to carry out such activities; and

(ii) the additional institute is not established before the expiration of 180 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate written notice of the determination made under clause (i) with respect to the institute.

**(B) Additional authority**

The Secretary may reorganize the functions of any national research institute and may abolish any national research institute if the Secretary determines that the institute is no longer required. A reorganization or abolition may not take effect under this paragraph before the expiration of 180 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate written notice of the reorganization or abolition.

**(3) Reorganization of Office of Director**

Notwithstanding subsection (c), the Director of NIH may, after a series of public hearings, and with the approval of the Secretary, reorganize the offices within the Office of the Director, including the addition, removal, or transfer of functions of such offices, and the establishment or termination of such offices, if the Director determines that the overall management and operation of programs and activities conducted or supported by such offices would be more efficiently carried out under such a reorganization.

**(4) Internal reorganization of institutes and centers**

Notwithstanding any conflicting provisions of this subchapter, the director of a national

research institute or a national center may, after a series of public hearings and with the approval of the Director of NIH, reorganize the divisions, centers, or other administrative units within such institute or center, including the addition, removal, or transfer of functions of such units, and the establishment or termination of such units, if the director of such institute or center determines that the overall management and operation of programs and activities conducted or supported by such divisions, centers, or other units would be more efficiently carried out under such a reorganization.

**(e) Scientific Management Review Board for periodic organizational reviews**

**(1) In general**

Not later than 60 days after January 15, 2007, the Secretary shall establish an advisory council within the National Institutes of Health to be known as the Scientific Management Review Board (referred to in this subsection as the “Board”).

**(2) Duties**

**(A) Reports on organizational issues**

The Board shall provide advice to the appropriate officials under subsection (d) regarding the use of the authorities established in paragraphs (2), (3), and (4) of such subsection to reorganize the National Institutes of Health (referred to in this subsection as “organizational authorities”). Not less frequently than once each 7 years, the Board shall—

(i) determine whether and to what extent the organizational authorities should be used; and

(ii) issue a report providing the recommendations of the Board regarding the use of the authorities and the reasons underlying the recommendations.

**(B) Certain responsibilities regarding reports**

The activities of the Board with respect to a report under subparagraph (A) shall include the following:

(i) Reviewing the research portfolio of the National Institutes of Health (referred to in this subsection as “NIH”) in order to determine the progress and effectiveness and value of the portfolio and the allocation among the portfolio activities of the resources of NIH.

(ii) Determining pending scientific opportunities, and public health needs, with respect to research within the jurisdiction of NIH.

(iii) For any proposal for organizational changes to which the Board gives significant consideration as a possible recommendation in such report—

(I) analyzing the budgetary and operational consequences of the proposed changes;

(II) taking into account historical funding and support for research activities at national research institutes and centers that have been established recently relative to national research in-

stitutes and centers that have been in existence for more than two decades;

(III) estimating the level of resources needed to implement the proposed changes;

(IV) assuming the proposed changes will be made and making a recommendation for the allocation of the resources of NIH among the national research institutes and national centers; and

(V) analyzing the consequences for the progress of research in the areas affected by the proposed changes.

**(C) Consultation**

In carrying out subparagraph (A), the Board shall consult with—

(i) the heads of national research institutes and national centers whose directors are not members of the Board;

(ii) other scientific leaders who are officers or employees of NIH and are not members of the Board;

(iii) advisory councils of the national research institutes and national centers;

(iv) organizations representing the scientific community; and

(v) organizations representing patients.

**(3) Composition of Board**

The Board shall consist of the Director of NIH, who shall be a permanent nonvoting member on an ex officio basis, and an odd number of additional members, not to exceed 21, all of whom shall be voting members. The voting members of the Board shall be the following:

(A) Not fewer than 9 officials who are directors of national research institutes or national centers. The Secretary shall designate such officials for membership and shall ensure that the group of officials so designated includes directors of—

(i) national research institutes whose budgets are substantial relative to a majority of the other institutes;

(ii) national research institutes whose budgets are small relative to a majority of the other institutes;

(iii) national research institutes that have been in existence for a substantial period of time without significant organizational change under subsection (d);

(iv) as applicable, national research institutes that have undergone significant organization changes under such subsection, or that have been established under such subsection, other than national research institutes for which such changes have been in place for a substantial period of time; and

(v) national centers.

(B) Members appointed by the Secretary from among individuals who are not officers or employees of the United States. Such members shall include—

(i) individuals representing the interests of public or private institutions of higher education that have historically received funds from NIH to conduct research; and

(ii) individuals representing the interests of private entities that have received funds

from NIH to conduct research or that have broad expertise regarding how the National Institutes of Health functions, exclusive of private entities to which clause (i) applies.

**(4) Chair**

The Chair of the Board shall be selected by the Secretary from among the members of the Board appointed under paragraph (3)(B). The term of office of the Chair shall be 2 years.

**(5) Meetings**

**(A) In general**

The Board shall meet at the call of the Chair or upon the request of the Director of NIH, but not fewer than 5 times with respect to issuing any particular report under paragraph (2)(A). The location of the meetings of the Board is subject to the approval of the Director of NIH.

**(B) Particular forums**

Of the meetings held under subparagraph (A) with respect to a report under paragraph (2)(A)—

(i) one or more shall be directed toward the scientific community to address scientific needs and opportunities related to proposals for organizational changes under subsection (d), or as the case may be, related to a proposal that no such changes be made; and

(ii) one or more shall be directed toward consumer organizations to address the needs and opportunities of patients and their families with respect to proposals referred to in clause (i).

**(C) Availability of information from forums**

For each meeting under subparagraph (B), the Director of NIH shall post on the Internet site of the National Institutes of Health a summary of the proceedings.

**(6) Compensation; term of office**

The provisions of subsections (b)(4) and (c) of section 284a of this title apply with respect to the Board to the same extent and in the same manner as such provisions apply with respect to an advisory council referred to in such subsections, except that the reference in such subsection (c) to 4 years regarding the term of an appointed member is deemed to be a reference to 5 years.

**(7) Reports**

**(A) Recommendations for changes**

Each report under paragraph (2)(A) shall be submitted to—

(i) the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives;

(ii) the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate;

(iii) the Secretary; and

(iv) officials with organizational authorities, other than any such official who served as a member of the Board with respect to the report involved.

**(B) Availability to public**

The Director of NIH shall post each report under paragraph (2) on the Internet site of the National Institutes of Health.

**(C) Report on Board activities**

Not later than 18 months after January 15, 2007, the Board shall submit to the committees specified in subparagraph (A) a report describing the activities of the Board.

**(f) Organizational changes per recommendation of Scientific Management Review Board****(1) In general**

With respect to an official who has organizational authorities within the meaning of subsection (e)(2)(A), if a recommendation to the official for an organizational change is made in a report under such subsection, the official shall, except as provided in paragraphs (2), (3), and (4) of this subsection, make the change in accordance with the following:

(A) Not later than 100 days after the report is submitted under subsection (e)(7)(A), the official shall initiate the applicable public process required in subsection (d) toward making the change.

(B) The change shall be fully implemented not later than the expiration of the 3-year period beginning on the date on which such process is initiated.

**(2) Inapplicability to certain reorganizations**

Paragraph (1) does not apply to a recommendation made in a report under subsection (e)(2)(A) if the recommendation is for—

(A) an organizational change under subsection (d)(2) that constitutes the establishment, termination, or consolidation of one or more national research institutes or national centers; or

(B) an organizational change under subsection (d)(3).

**(3) Objection by Director of NIH****(A) In general**

Paragraph (1) does not apply to a recommendation for an organizational change made in a report under subsection (e)(2)(A) if, not later than 90 days after the report is submitted under subsection (e)(7)(A), the Director of NIH submits to the committees specified in such subsection a report providing that the Director objects to the change, which report includes the reasons underlying the objection.

**(B) Scope of objection**

For purposes of subparagraph (A), an objection by the Director of NIH may be made to the entirety of a recommended organizational change or to 1 or more aspects of the change. Any aspect of a change not objected to by the Director in a report under subparagraph (A) shall be implemented in accordance with paragraph (1).

**(4) Congressional review**

An organizational change under subsection (d)(2) that is initiated pursuant to paragraph (1) shall be carried out by regulation in accordance with the procedures for substantive rules under section 553 of title 5. A rule under the preceding sentence shall be considered a major rule for purposes of chapter 8 of such title (relating to congressional review of agency rulemaking).

**(g) Definitions**

For purposes of this subchapter:

(1) The term “Director of NIH” means the Director of the National Institutes of Health.

(2) The terms “national research institute” and “national center” mean an agency of the National Institutes of Health that is—

(A) listed in subsection (b) and not terminated under subsection (d)(2)(A); or

(B) established by the Director of NIH under such subsection.

**(h) References to NIH**

For purposes of this subchapter, a reference to the National Institutes of Health includes its agencies.

(July 1, 1944, ch. 373, title IV, § 401, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 822; amended Pub. L. 100-553, § 2(1), Oct. 28, 1988, 102 Stat. 2769; Pub. L. 100-607, title I, § 101(1), Nov. 4, 1988, 102 Stat. 3048; Pub. L. 100-690, title II, § 2613(b)(2), Nov. 18, 1988, 102 Stat. 4238; Pub. L. 102-321, title I, § 121(a), July 10, 1992, 106 Stat. 358; Pub. L. 103-43, title XV, §§ 1501(1), 1511(b)(1), 1521(1), June 10, 1993, 107 Stat. 172, 179, 180; Pub. L. 103-417, § 13(b), Oct. 25, 1994, 108 Stat. 4335; Pub. L. 105-277, div. A, § 101(f) [title II, § 212, title VI, § 601(k)], Oct. 21, 1998, 112 Stat. 2681-337, 2681-359, 2681-388; Pub. L. 106-525, title I, § 101(b)(1), Nov. 22, 2000, 114 Stat. 2501; Pub. L. 106-580, § 3(e), Dec. 29, 2000, 114 Stat. 3091; Pub. L. 109-482, title I, §§ 101(a), (b), 108(a), Jan. 15, 2007, 120 Stat. 3675, 3676, 3697; Pub. L. 110-154, § 1(b)(1), Dec. 21, 2007, 121 Stat. 1827; Pub. L. 111-148, title X, § 10334(c)(3)(A), Mar. 23, 2010, 124 Stat. 974; Pub. L. 112-74, div. F, title II, § 221(a)(2), (c)(2)(B), Dec. 23, 2011, 125 Stat. 1087, 1089; Pub. L. 113-235, div. G, title II, § 224(1), Dec. 16, 2014, 128 Stat. 2490.)

## AMENDMENTS

2014—Subsec. (b)(23). Pub. L. 113-235 substituted “National Center for Complementary and Integrative Health” for “National Center for Complementary and Alternative Medicine”.

2011—Subsec. (b)(21). Pub. L. 112-74, § 221(a)(2), substituted “National Center for Advancing Translational Sciences” for “National Center for Research Resources”.

Subsec. (c)(2)(A). Pub. L. 112-74, § 221(c)(2)(B), struck out “the Office of Rare Diseases,” after “the Office of Dietary Supplements,”.

2010—Subsec. (b)(24). Pub. L. 111-148 substituted “Institute” for “Center”.

2007—Subsec. (b)(7). Pub. L. 110-154 substituted “Eunice Kennedy Shriver National Institute of Child Health and Human Development” for “National Institute of Child Health and Human Development”.

Pub. L. 109-482, § 101(a), reenacted section catchline without change and amended text generally, substituting provisions consisting of subssecs. (a) to (d)(1) for former subssecs. (a) to (d) which related to: in subsec. (a), relationship to Public Health Service; in subsec. (b), list of national research institutes that were agencies; in subsec. (c), establishment of additional institutes and reorganization or abolition of institutes; and, in subsec. (d), definition of “national research institute”. See below.

Subsec. (d)(2). Pub. L. 109-482, § 108(a), added after subsec. (d)(1) provisions identical to text of subsec. (c) prior to amendment by Pub. L. 109-482, § 101(a), redesignated such provisions as par. (2), added par. heading, redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively, added subpar. headings, in subpar. (A), redesignated former subpars. (A) and (B) as cls. (i)

and (ii), respectively, in cl. (ii), substituted “Health, Education, Labor, and Pensions” for “Labor and Human Resources” and “clause (i)” for “subparagraph (A)”, and, in subpar. (B), substituted “Health, Education, Labor, and Pensions” for “Labor and Human Resources”.

Subsec. (d)(3), (4). Pub. L. 109-482, §101(b)(1), added pars. (3) and (4).

Subsecs. (e) to (h). Pub. L. 109-482, §101(b)(2), added subsecs. (e) to (h).

2000—Subsec. (b)(1)(R). Pub. L. 106-580 added subpar. (R).

Subsec. (b)(2)(F). Pub. L. 106-525, §101(b)(1)(A), realigned margins.

Subsec. (b)(2)(G). Pub. L. 106-525, §101(b)(1)(B), added subpar. (G).

1998—Subsec. (b)(1)(H). Pub. L. 105-277, §101(f) [title II, §212], substituted “National Institute of Dental and Craniofacial Research” for “National Institute of Dental Research”.

Subsec. (b)(2)(F). Pub. L. 105-277, §101(f) [title VI, §601(k)], added subpar. (F).

1994—Subsec. (b)(2)(E). Pub. L. 103-417 added subpar. (E).

1993—Subsec. (b)(1)(Q). Pub. L. 103-43, §1511(b)(1)(A), added subpar. (Q).

Subsec. (b)(2)(B). Pub. L. 103-43, §1501(1), amended subpar. (B) generally, substituting “National Center for Research Resources” for “Division of Research Resources”.

Subsec. (b)(2)(D). Pub. L. 103-43, §§1511(b)(1)(B), 1521(1), added subpar. (D) and struck out former subpar. (D) which read as follows: “The National Center for Nursing Research.”

1992—Subsec. (b)(1)(N) to (P). Pub. L. 102-321 added subpars. (N) to (P).

1988—Subsec. (b)(1)(J), (M). Pub. L. 100-553 and Pub. L. 100-607 made identical amendments, striking out “and Communicative” after “Neurological” in subpar. (J), and adding subpar. (M). Pub. L. 100-690 amended subsec. (b)(1) to read as if the amendments by Pub. L. 100-607 had not been enacted.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Pub. L. 109-482, title I, §109, Jan. 15, 2007, 120 Stat. 3697, provided that: “This title [see Tables for classification] and the amendments made by this title apply only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years.”

#### EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106-525, title VI, §603, Nov. 22, 2000, 114 Stat. 2511, provided that: “This Act [enacting subpart 6 (§287c-31 et seq.) of part E of this subchapter and sections 293e, 296e-1, and 299a-1 of this title, amending sections 281, 296f, 299a, 299c-6, and 300u-6 of this title, repealing section 283b of this title, and enacting provisions set out as notes under sections 201, 287c-31, 293e, and 3501 of this title] and the amendments made by this Act take effect October 1, 2000, or upon the date of the enactment of this Act [Nov. 22, 2000], whichever occurs later.”

#### EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102-321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as a note under section 236 of this title.

#### EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by Pub. L. 100-690, see section 2613(b)(1) of Pub. L. 100-690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

#### CONSTRUCTION OF 2007 AMENDMENT

Pub. L. 109-482, title I, §102(g), Jan. 15, 2007, 120 Stat. 3685, provided that: “This Act [see Tables for classification] and the amendments made by this Act may not be

construed as affecting the authorities of the national research institutes and national centers that were in effect under the Public Health Service Act [42 U.S.C. 201 et seq.] on the day before the date of the enactment of this Act [Jan. 15, 2007], subject to the authorities of the Secretary of Health and Human Services and the Director of NIH under section 401 of the Public Health Service Act [42 U.S.C. 281] (as amended by section 101 of this Act). For purposes of the preceding sentence, the terms ‘national research institute’, ‘national center’, and ‘Director of NIH’ have the meanings given such terms in such section 401.”

#### STUDY OF THE USE OF CENTERS OF EXCELLENCE AT THE NATIONAL INSTITUTES OF HEALTH

Pub. L. 107-84, §7, Dec. 18, 2001, 115 Stat. 829, required the Secretary of Health and Human Services to contract, not later than 60 days after Dec. 18, 2001, with the Institute of Medicine to conduct a study on the impact of, need for, and other issues associated with Centers of Excellence at the National Institutes of Health and complete the study and submit a report not later than one year after the date of the contract.

#### REPORT ON MEDICAL USES OF BIOLOGICAL AGENTS IN DEVELOPMENT OF DEFENSES AGAINST BIOLOGICAL WARFARE

Pub. L. 103-43, title XIX, §1904, June 10, 1993, 107 Stat. 203, directed Secretary of Health and Human Services, in consultation with Secretary of Defense and with heads of other appropriate executive agencies, to report to Congress, not later than 12 months after June 10, 1993, on the appropriateness and impact of the National Institutes of Health assuming responsibility for the conduct of all Federal research, development, testing, and evaluation functions relating to medical countermeasures against biowarfare threat agents.

#### RESEARCH ON LUPUS ERYTHEMATOSUS

Pub. L. 99-158, §5, Nov. 20, 1985, 99 Stat. 880, as amended by Pub. L. 102-531, title III, §312(f), Oct. 27, 1992, 106 Stat. 3506, directed Secretary of Health and Human Resources to establish a Lupus Erythematosus Coordinating Committee to plan, develop, coordinate, and implement comprehensive Federal initiatives in research on Lupus Erythematosus, provided for composition of committee and meetings, and directed Committee to prepare a report for Congress on its activities, to be submitted not later than 18 months after Nov. 20, 1985, with Committee to terminate one month after the report was submitted.

#### INTERAGENCY COMMITTEE ON LEARNING DISABILITIES

Pub. L. 99-158, §9, Nov. 20, 1985, 99 Stat. 882, directed Director of the National Institutes of Health, not later than 90 days after Nov. 20, 1985, to establish an Interagency Committee on Learning Disabilities to review and assess Federal research priorities, activities, and findings regarding learning disabilities (including central nervous system dysfunction in children), provided for composition of the Committee, directed Committee to report to Congress on its activities not later than 18 months after Nov. 20, 1985, and provided that the Committee terminate 90 days after submission of the report.

### § 282. Director of National Institutes of Health

#### (a) Appointment

The National Institutes of Health shall be headed by the Director of NIH who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

**(b) Duties and authority**

In carrying out the purposes of section 241 of this title, the Secretary, acting through the Director of NIH—

(1) shall carry out this subchapter, including being responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

(2) shall coordinate and oversee the operation of the national research institutes, national centers, and administrative entities within the National Institutes of Health;

(3) shall, in consultation with the heads of the national research institutes and national centers, be responsible for program coordination across the national research institutes and national centers, including conducting priority-setting reviews, to ensure that the research portfolio of the National Institutes of Health is balanced and free of unnecessary duplication, and takes advantage of collaborative, cross-cutting research;

(4) shall assemble accurate data to be used to assess research priorities, including—

(A) information to better evaluate scientific opportunity, public health burdens, and progress in reducing health disparities; and

(B) data on study populations of clinical research, funded by or conducted at each national research institute and national center, which—

(i) specifies the inclusion of—

(I) women;

(II) members of minority groups;

(III) relevant age categories, including pediatric subgroups; and

(IV) other demographic variables as the Director of the National Institutes of Health determines appropriate;

(ii) is disaggregated by research area, condition, and disease categories; and

(iii) is to be made publicly available on the Internet website of the National Institutes of Health;

(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health, and through the development, implementation, and updating of the strategic plan developed under subsection (m);

(6) shall ensure that the resources of the National Institutes of Health are sufficiently allocated for research projects identified in strategic plans;

(7)(A) shall, through the Division of Program Coordination, Planning, and Strategic Initiatives—

(i) identify research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between 2 or more national research institutes or national centers, or

would otherwise benefit from strategic coordination and planning;

(ii) include information on such research in reports under section 283 of this title; and

(iii) in the case of such research supported with funds referred to in subparagraph (B)—

(I) require as appropriate that proposals include milestones and goals for the research;

(II) require that the proposals include timeframes for funding of the research; and

(III) ensure appropriate consideration of proposals for which the principal investigator is an individual who has not previously served as the principal investigator of research conducted or supported by the National Institutes of Health;

(B)(i) may, with respect to funds reserved under section 282a(c)(1) of this title for the Common Fund, allocate such funds to the national research institutes and national centers for conducting and supporting research that is identified under subparagraph (A); and

(ii) shall, with respect to funds appropriated to the Common Fund pursuant to section 282a(a)(2) of this title, allocate such funds to the national research institutes and national centers for making grants for pediatric research that is identified under subparagraph (A); and

(C) may assign additional functions to the Division in support of responsibilities identified in subparagraph (A), as determined appropriate by the Director;

(8) shall, in coordination with the heads of the national research institutes and national centers, ensure that such institutes and centers—

(A) preserve an emphasis on investigator-initiated research project grants, including with respect to research involving collaboration between 2 or more such institutes or centers;

(B) when appropriate, maximize investigator-initiated research project grants in their annual research portfolios;

(C) foster collaboration between clinical research projects funded by the respective national research institutes and national centers that—

(i) conduct research involving human subjects; and

(ii) collect similar data; and

(D) encourage the collaboration described in subparagraph (C) to—

(i) allow for an increase in the number of subjects studied; and

(ii) utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities;

(9) shall ensure that research conducted or supported by the National Institutes of Health is subject to review in accordance with section 289a of this title and that, after such review, the research is reviewed in accordance with section 289a-1(a)(2) of this title by the appropriate advisory council under section 284a of this title before the research proposals are approved for funding;

(10) shall have authority to review and approve the establishment of all centers of excellence recommended by the national research institutes;

(11)(A) shall oversee research training for all of the national research institutes and National Research Service Awards in accordance with section 288 of this title; and

(B) may conduct and support research training—

(i) for which fellowship support is not provided under section 288 of this title; and

(ii) that does not consist of residency training of physicians or other health professionals;

(12) may, from funds appropriated under section 282a(b) of this title, reserve funds to provide for research on matters that have not received significant funding relative to other matters, to respond to new issues and scientific emergencies, and to act on research opportunities of high priority;

(13) may, subject to appropriations Acts, collect and retain registration fees obtained from third parties to defray expenses for scientific, educational, and research-related conferences;

(14) for the national research institutes and administrative entities within the National Institutes of Health—

(A) may acquire, construct, improve, repair, operate, and maintain, at the site of such institutes and entities, laboratories, and other research facilities, other facilities, equipment, and other real or personal property, and

(B) may acquire, without regard to section 8141 of title 40, by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

(15) may secure resources for research conducted by or through the National Institutes of Health;

(16) may, without regard to the provisions of title 5 governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups and scientific program advisory committees as are needed to carry out the requirements of this subchapter and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups;

(17) may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

(18) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(19) may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

(20) may accept voluntary and uncompensated services;

(21) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this subchapter;

(22) may appoint physicians, dentists, and other health care professionals, subject to the provisions of title 5 relating to appointments and classifications in the competitive service, and may compensate such professionals subject to the provisions of chapter 74 of title 38;

(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development;

(24) implement the Cures Acceleration Network described in section 287a of this title; and

(25) may require recipients of National Institutes of Health awards to share scientific data, to the extent feasible, generated from such National Institutes of Health awards in a manner that is consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

(A) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

(B) proprietary interests, confidential commercial information, and the intellectual property rights of the funding recipient.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (16). The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

**(c) Availability of substances and organisms for research**

The Director of NIH may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

**(d) Services of experts or consultants; number; payment of expenses, conditions, recovery**

(1) The Director of NIH may obtain (in accordance with section 3109 of title 5, but without regard to the limitation in such section on the period of service) the services of not more than 220 experts or consultants, with scientific or other professional qualifications, for the National Institutes of Health.

(2)(A) Except as provided in subparagraph (B), experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, for their travel to and from their place of service and for other expenses associated with their assignment.

(B) Expenses specified in subparagraph (A) shall not be allowed in connection with the as-

signment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

**(e) Dissemination of research information**

The Director of NIH shall—

(1) advise the agencies of the National Institutes of Health on medical applications of research;

(2) coordinate, review, and facilitate the systematic identification and evaluation of, clinically relevant information from research conducted by or through the national research institutes;

(3) promote the effective transfer of the information described in paragraph (2) to the health care community and to entities that require such information;

(4) monitor the effectiveness of the activities described in paragraph (3); and

(5) ensure that, after January 1, 1994, all new or revised health education and promotion materials developed or funded by the National Institutes of Health and intended for the general public are in a form that does not exceed a level of functional literacy, as defined in the National Literacy Act of 1991 (Public Law 102-73).

**(f) Associate Director for Prevention; functions**

There shall be in the National Institutes of Health an Associate Director for Prevention. The Director of NIH shall delegate to the Associate Director for Prevention the functions of the Director relating to the promotion of the disease prevention research programs of the national research institutes and the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities, including elementary, secondary, and post-secondary schools. The Associate Director shall—

(1) annually review the efficacy of existing policies and techniques used by the national research institutes to disseminate the results of disease prevention and behavioral research programs; and

(2) recommend, coordinate, and oversee the modification or reconstruction of such policies and techniques to ensure maximum dissemination, using advanced technologies to the maximum extent practicable, of research results to such entities.

**(g) Transferred**

**(h) Increased participation of women and disadvantaged individuals in biomedical and behavioral research**

The Secretary, acting through the Director of NIH and the Directors of the agencies of the Na-

tional Institutes of Health, shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research.

**(i) Data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions**

(1)(A) The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (in this subsection referred to as the "data bank"). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

(B) The Secretary shall establish the data bank after consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

(3) The data bank shall include the following:

(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 355(i) of title 21, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for participation in the clinical trials, a description of the location of trial sites, a point of contact for those wanting to enroll in the trial, and a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children, and shall be in a form that can be readily understood by members of the public. Such information shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

(i) under a treatment investigational new drug application that has been submitted to

the Secretary under section 360bbb(c) of title 21; or

(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that such disclosure would not substantially interfere with such enrollment.

(5) Fees collected under section 379h of title 21 shall not be used in carrying out this subsection.

**(j) Expanded clinical trial registry data bank**

**(1) Definitions; requirement**

**(A) Definitions**

In this subsection:

**(i) Applicable clinical trial**

The term “applicable clinical trial” means an applicable device clinical trial or an applicable drug clinical trial.

**(ii) Applicable device clinical trial**

The term “applicable device clinical trial” means—

(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 360(k), 360e, or 360j(m) of title 21 against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and

(II) a pediatric postmarket surveillance as required under section 360l of title 21.

**(iii) Applicable drug clinical trial**

**(I) In general**

The term “applicable drug clinical trial” means a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 355 of title 21 or to section 262 of this title.

**(II) Clinical investigation**

For purposes of subclause (I), the term “clinical investigation” has the meaning given that term in section 312.3 of title 21, Code of Federal Regulations (or any successor regulation).

**(III) Phase I**

For purposes of subclause (I), the term “phase I” has the meaning given that term in section 312.21 of title 21, Code of

Federal Regulations (or any successor regulation).

**(iv) Clinical trial information**

The term “clinical trial information” means, with respect to an applicable clinical trial, those data elements that the responsible party is required to submit under paragraph (2) or under paragraph (3).

**(v) Completion date**

The term “completion date” means, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated.

**(vi) Device**

The term “device” means a device as defined in section 321(h) of title 21.

**(vii) Drug**

The term “drug” means a drug as defined in section 321(g) of title 21 or a biological product as defined in section 262 of this title.

**(viii) Ongoing**

The term “ongoing” means, with respect to a clinical trial of a drug or a device and to a date, that—

(I) 1 or more patients is enrolled in the clinical trial; and

(II) the date is before the completion date of the clinical trial.

**(ix) Responsible party**

The term “responsible party”, with respect to a clinical trial of a drug or device, means—

(I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulation)); or

(II) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this subsection for the submission of clinical trial information.

**(B) Requirement**

The Secretary shall develop a mechanism by which the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph (2).

**(2) Expansion of clinical trial registry data bank with respect to clinical trial information**

**(A) In general**

**(i) Expansion of data bank**

To enhance patient enrollment and provide a mechanism to track subsequent

progress of clinical trials, the Secretary, acting through the Director of NIH, shall expand, in accordance with this subsection, the clinical trials registry of the data bank described under subsection (i)(1) (referred to in this subsection as the “registry data bank”). The Director of NIH shall ensure that the registry data bank is made publicly available through the Internet.

**(ii) Content**

The clinical trial information required to be submitted under this paragraph for an applicable clinical trial shall include—

- (I) descriptive information, including—
- (aa) a brief title, intended for the lay public;
  - (bb) a brief summary, intended for the lay public;
  - (cc) the primary purpose;
  - (dd) the study design;
  - (ee) for an applicable drug clinical trial, the study phase;
  - (ff) study type;
  - (gg) the primary disease or condition being studied, or the focus of the study;
  - (hh) the intervention name and intervention type;
  - (ii) the study start date;
  - (jj) the expected completion date;
  - (kk) the target number of subjects;
- and
- (ll) outcomes, including primary and secondary outcome measures;

(II) recruitment information, including—

- (aa) eligibility criteria;
- (bb) gender;
- (cc) age limits;
- (dd) whether the trial accepts healthy volunteers;
- (ee) overall recruitment status;
- (ff) individual site status; and
- (gg) in the case of an applicable drug clinical trial, if the drug is not approved under section 355 of title 21 or licensed under section 262 of this title, specify whether or not there is expanded access to the drug under section 360bbb of title 21 for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

(III) location and contact information, including—

- (aa) the name of the sponsor;
- (bb) the responsible party, by official title; and
- (cc) the facility name and facility contact information (including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed); and

(IV) administrative data (which the Secretary may make publicly available as necessary), including—

- (aa) the unique protocol identification number;

(bb) other protocol identification numbers, if any; and

(cc) the Food and Drug Administration IND/IDE protocol number and the record verification date.

**(iii) Modifications**

The Secretary may by regulation modify the requirements for clinical trial information under this paragraph, if the Secretary provides a rationale for why such a modification improves and does not reduce such clinical trial information.

**(B) Format and structure**

**(i) Searchable categories**

The Director of NIH shall ensure that the public may, in addition to keyword searching, search the entries in the registry data bank by 1 or more of the following criteria:

(I) The disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

(II) The name of the intervention, including any drug or device being studied in the clinical trial.

(III) The location of the clinical trial.

(IV) The age group studied in the clinical trial, including pediatric subpopulations.

(V) The study phase of the clinical trial.

(VI) The sponsor of the clinical trial, which may be the National Institutes of Health or another Federal agency, a private industry source, or a university or other organization.

(VII) The recruitment status of the clinical trial.

(VIII) The National Clinical Trial number or other study identification for the clinical trial.

**(ii) Additional searchable category**

Not later than 18 months after September 27, 2007, the Director of NIH shall ensure that the public may search the entries of the registry data bank by the safety issue, if any, being studied in the clinical trial as a primary or secondary outcome.

**(iii) Other elements**

The Director of NIH shall also ensure that the public may search the entries of the registry data bank by such other elements as the Director deems necessary on an ongoing basis.

**(iv) Format**

The Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.

**(C) Data submission**

The responsible party for an applicable clinical trial, including an applicable drug clinical trial for a serious or life-threatening disease or condition, that is initiated after, or is ongoing on the date that is 90 days after, September 27, 2007, shall submit to the

Director of NIH for inclusion in the registry data bank the clinical trial information described in of<sup>1</sup> subparagraph (A)(ii) not later than the later of—

- (i) 90 days after September 27, 2007;
- (ii) 21 days after the first patient is enrolled in such clinical trial; or
- (iii) in the case of a clinical trial that is not for a serious or life-threatening disease or condition and that is ongoing on September 27, 2007, 1 year after September 27, 2007.

**(D) Posting of data**

**(i) Applicable drug clinical trial**

The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accordance with this paragraph is posted in the registry data bank not later than 30 days after such submission.

**(ii) Applicable device clinical trial**

The Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly in the registry data bank—

- (I) not earlier than the date of clearance under section 360(k) of title 21, or approval under section 360e or 360j(m) of title 21, as applicable, for a device that was not previously cleared or approved, and not later than 30 days after such date, unless the responsible party affirmatively requests that the Director of the National Institutes of Health publicly post such clinical trial information for an applicable device clinical trial prior to such date of clearance or approval; or
- (II) for a device that was previously cleared or approved, not later than 30 days after the clinical trial information under paragraph (3)(C) is required to be posted by the Secretary.

**(iii) Option to make certain clinical trial information available earlier**

The Director of the National Institutes of Health shall inform responsible parties of the option to request that clinical trial information for an applicable device clinical trial be publicly posted prior to the date of clearance or approval, in accordance with clause (ii)(I).

**(iv) Combination products**

An applicable clinical trial for a product that is a combination of drug, device, or biological product shall be considered—

- (I) an applicable drug clinical trial, if the Secretary determines under section 353(g) of title 21 that the primary mode of action of such product is that of a drug or biological product; or
- (II) an applicable device clinical trial, if the Secretary determines under such section that the primary mode of action of such product is that of a device.

**(3) Expansion of registry data bank to include results of clinical trials**

**(A) Linking registry data bank to existing results**

**(i) In general**

Beginning not later than 90 days after September 27, 2007, for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved, the Secretary shall ensure that the registry data bank includes links to results information as described in clause (ii) for such clinical trial—

- (I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or
- (II) not later than 30 days after the results information described in clause (ii) becomes publicly available.

**(ii) Required information**

**(I) FDA information**

The Secretary shall ensure that the registry data bank includes links to the following information:

- (aa) If an advisory committee considered at a meeting an applicable clinical trial, any posted Food and Drug Administration summary document regarding such applicable clinical trial.
- (bb) If an applicable drug clinical trial was conducted under section 355a or 355c of title 21, a link to the posted Food and Drug Administration assessment of the results of such trial.
- (cc) Food and Drug Administration public health advisories regarding the drug or device that is the subject of the applicable clinical trial, if any.
- (dd) For an applicable drug clinical trial, the Food and Drug Administration action package for approval document required under section 355(l)(2) of title 21.
- (ee) For an applicable device clinical trial, in the case of a premarket application under section 360e of title 21, the detailed summary of information respecting the safety and effectiveness of the device required under section 360j(h)(1) of title 21, or, in the case of a report under section 360(k) of title 21, the section 360(k) summary of the safety and effectiveness data required under section 807.95(d) of title 21, Code of Federal Regulations (or any successor regulation).

(II) NIH information

The Secretary shall ensure that the registry data bank includes links to the following information:

- (aa) Medline citations to any publications focused on the results of an applicable clinical trial.
- (bb) The entry for the drug that is the subject of an applicable drug clinical trial.

<sup>1</sup> So in original. The word "of" probably should not appear.

cal trial in the National Library of Medicine database of structured product labels, if available.

**(iii) Results for existing data bank entries**

The Secretary may include the links described in clause (ii) for data bank entries for clinical trials submitted to the data bank prior to September 27, 2007, as available.

**(B) Inclusion of results**

The Secretary, acting through the Director of NIH, shall—

(i) expand the registry data bank to include the results of applicable clinical trials (referred to in this subsection as the “registry and results data bank”);

(ii) ensure that such results are made publicly available through the Internet;

(iii) post publicly a glossary for the lay public explaining technical terms related to the results of clinical trials; and

(iv) in consultation with experts on risk communication, provide information with the information included under subparagraph (C) in the registry and results data bank to help ensure that such information does not mislead the patients or the public.

**(C) Basic results**

Not later than 1 year after September 27, 2007, the Secretary shall include in the registry and results data bank for each applicable clinical trial for a drug that is approved under section 355 of title 21 or licensed under section 262 of this title or a device that is cleared under section 360(k) of title 21 or approved under section 360e or 360j(m) of title 21, the following elements:

**(i) Demographic and baseline characteristics of patient sample**

A table of the demographic and baseline data collected overall and for each arm of the clinical trial to describe the patients who participated in the clinical trial, including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any.

**(ii) Primary and secondary outcomes**

The primary and secondary outcome measures as submitted under paragraph (2)(A)(ii)(I)(II), and a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial, including the results of scientifically appropriate tests of the statistical significance of such outcome measures.

**(iii) Point of contact**

A point of contact for scientific information about the clinical trial results.

**(iv) Certain agreements**

Whether there exists an agreement (other than an agreement solely to comply with applicable provisions of law protecting the privacy of participants) between the sponsor or its agent and the principal

investigator (unless the sponsor is an employer of the principal investigator) that restricts in any manner the ability of the principal investigator, after the completion date of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial.

**(D) Expanded registry and results data bank**

**(i) Expansion by rulemaking**

To provide more complete results information and to enhance patient access to and understanding of the results of clinical trials, not later than 3 years after September 27, 2007, the Secretary shall by regulation expand the registry and results data bank as provided under this subparagraph.

**(ii) Clinical trials**

**(I) Approved products**

The regulations under this subparagraph shall require the inclusion of the results information described in clause (iii) for—

(aa) each applicable drug clinical trial for a drug that is approved under section 355 of title 21 or licensed under section 262 of this title; and

(bb) each applicable device clinical trial for a device that is cleared under section 360(k) of title 21 or approved under section 360e or 360j(m) of title 21.

**(II) Unapproved products**

The regulations under this subparagraph shall establish whether or not the results information described in clause (iii) shall be required for—

(aa) an applicable drug clinical trial for a drug that is not approved under section 355 of title 21 and not licensed under section 262 of this title (whether approval or licensure was sought or not); and

(bb) an applicable device clinical trial for a device that is not cleared under section 360(k) of title 21 and not approved under section 360e or section 360j(m) of title 21 (whether clearance or approval was sought or not).

**(iii) Required elements**

The regulations under this subparagraph shall require, in addition to the elements described in subparagraph (C), information within each of the following categories:

(I) A summary of the clinical trial and its results that is written in non-technical, understandable language for patients, if the Secretary determines that such types of summary can be included without being misleading or promotional.

(II) A summary of the clinical trial and its results that is technical in nature, if the Secretary determines that such types of summary can be included without being misleading or promotional.

(III) The full protocol or such information on the protocol for the trial as may

be necessary to help to evaluate the results of the trial.

(IV) Such other categories as the Secretary determines appropriate.

**(iv) Results submission**

The results information described in clause (iii) shall be submitted to the Director of NIH for inclusion in the registry and results data bank as provided by subparagraph (E), except that the Secretary shall by regulation determine—

(I) whether the 1-year period for submission of clinical trial information described in subparagraph (E)(i) should be increased from 1 year to a period not to exceed 18 months;

(II) whether the clinical trial information described in clause (iii) should be required to be submitted for an applicable clinical trial for which the clinical trial information described in subparagraph (C) is submitted to the registry and results data bank before the effective date of the regulations issued under this subparagraph; and

(III) in the case when the clinical trial information described in clause (iii) is required to be submitted for the applicable clinical trials described in clause (ii)(II), the date by which such clinical trial information shall be required to be submitted, taking into account—

(aa) the certification process under subparagraph (E)(iii) when approval, licensure, or clearance is sought; and

(bb) whether there should be a delay of submission when approval, licensure, or clearance will not be sought.

**(v) Additional provisions**

The regulations under this subparagraph shall also establish—

(I) a standard format for the submission of clinical trial information under this paragraph to the registry and results data bank;

(II) additional information on clinical trials and results that is written in non-technical, understandable language for patients;

(III) considering the experience under the pilot quality control project described in paragraph (5)(C), procedures for quality control, including using representative samples, with respect to completeness and content of clinical trial information under this subsection, to help ensure that data elements are not false or misleading and are non-promotional;

(IV) the appropriate timing and requirements for updates of clinical trial information, and whether and, if so, how such updates should be tracked;

(V) a statement to accompany the entry for an applicable clinical trial when the primary and secondary outcome measures for such clinical trial are submitted under paragraph (4)(A) after the date specified for the submission of such information in paragraph (2)(C); and

(VI) additions or modifications to the manner of reporting of the data elements established under subparagraph (C).

**(vi) Consideration of World Health Organization data set**

The Secretary shall consider the status of the consensus data elements set for reporting clinical trial results of the World Health Organization when issuing the regulations under this subparagraph.

**(vii) Public meeting**

The Secretary shall hold a public meeting no later than 18 months after September 27, 2007, to provide an opportunity for input from interested parties with regard to the regulations to be issued under this subparagraph.

**(E) Submission of results information**

**(i) In general**

Except as provided in clauses (iii), (iv), (v), and (vi) the responsible party for an applicable clinical trial that is described in clause (ii) shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraph (C) not later than 1 year, or such other period as may be provided by regulation under subparagraph (D), after the earlier of—

(I) the estimated completion date of the trial as described in paragraph (2)(A)(ii)(I)(jj);<sup>2</sup> or

(II) the actual date of completion.

**(ii) Clinical trials described**

An applicable clinical trial described in this clause is an applicable clinical trial subject to—

(I) paragraph (2)(C); and

(II)(aa) subparagraph (C); or

(bb) the regulations issued under subparagraph (D).

**(iii) Delayed submission of results with certification**

If the responsible party for an applicable clinical trial submits a certification that clause (iv) or (v) applies to such clinical trial, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) as required under the applicable clause.

**(iv) Seeking initial approval of a drug or device**

With respect to an applicable clinical trial that is completed before the drug is initially approved under section 355 of title 21 or initially licensed under section 262 of this title, or the device is initially cleared under section 360(k) or initially approved under section 360e or 360j(m) of title 21, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial in-

<sup>2</sup>So in original. The second closing parenthesis probably should not appear.

formation described in subparagraphs (C) and (D) not later than 30 days after the drug or device is approved under such section 355, licensed under such section 262, cleared under such section 360(k), or approved under such section 360e or 360j(m), as applicable.

**(v) Seeking approval of a new use for the drug or device**

**(I) In general**

With respect to an applicable clinical trial where the manufacturer of the drug or device is the sponsor of an applicable clinical trial, and such manufacturer has filed, or will file within 1 year, an application seeking approval under section 355 of title 21, licensing under section 262 of this title, or clearance under section 360(k), or approval under section 360e or 360j(m) of title 21 for the use studied in such clinical trial (which use is not included in the labeling of the approved drug or device), then the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) on the earlier of the date that is 30 days after the date—

(aa) the new use of the drug or device is approved under such section 355, licensed under such section 262, cleared under such section 360(k), or approved under such section 360e or 360j(m);

(bb) the Secretary issues a letter, such as a complete response letter, not approving the submission or not clearing the submission, a not approvable letter, or a not substantially equivalent letter for the new use of the drug or device under such section 355, 262, 360(k), 360e, or 360j(m); or

(cc) except as provided in subclause (III), the application or premarket notification under such section 355, 262, 360(k), 360e, or 360j(m) is withdrawn without resubmission for no less than 210 days.

**(II) Requirement that each clinical trial in application be treated the same**

If a manufacturer makes a certification under clause (iii) that this clause applies with respect to a clinical trial, the manufacturer shall make such a certification with respect to each applicable clinical trial that is required to be submitted in an application or report for licensure, approval, or clearance (under section 262 of this title or section 355, 360(k), 360e, or 360j(m) of title 21, as applicable) of the use studied in the clinical trial.

**(III) Two-year limitation**

The responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information subject to subclause (I) on the date that is 2 years after the date a certification under

clause (iii) was made to the Director of NIH, if an action referred to in item (aa), (bb), or (cc) of subclause (I) has not occurred by such date.

**(vi) Extensions**

The Director of NIH may provide an extension of the deadline for submission of clinical trial information under clause (i) if the responsible party for the trial submits to the Director a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted. The Director of NIH may grant more than one such extension for a clinical trial.

**(F) Notice to Director of NIH**

The Commissioner of Food and Drugs shall notify the Director of NIH when there is an action described in subparagraph (E)(iv) or item (aa), (bb), or (cc) of subparagraph (E)(v)(I) with respect to an application or a report that includes a certification required under paragraph (5)(B) of such action not later than 30 days after such action.

**(G) Posting of data**

The Director of NIH shall ensure that the clinical trial information described in subparagraphs (C) and (D) for an applicable clinical trial submitted in accordance with this paragraph is posted publicly in the registry and results database not later than 30 days after such submission.

**(H) Waivers regarding certain clinical trial results**

The Secretary may waive any applicable requirements of this paragraph for an applicable clinical trial, upon a written request from the responsible party, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is consistent with the protection of public health, or in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the waiver and provide an explanation for why the waiver was granted.

**(I) Adverse events**

**(i) Regulations**

Not later than 18 months after September 27, 2007, the Secretary shall by regulation determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for applicable clinical trials described in subparagraph (C) in a manner and form that is useful and not misleading to patients, physicians, and scientists.

**(ii) Default**

If the Secretary fails to issue the regulation required by clause (i) by the date that is 24 months after September 27, 2007, clause (iii) shall take effect.

**(iii) Additional elements**

Upon the application of clause (ii), the Secretary shall include in the registry and

results data bank for applicable clinical trials described in subparagraph (C), in addition to the clinical trial information described in subparagraph (C), the following elements:

**(I) Serious adverse events**

A table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

**(II) Frequent adverse events**

A table of anticipated and unanticipated adverse events that are not included in the table described in subclause (I) that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

**(iv) Posting of other information**

In carrying out clause (iii), the Secretary shall, in consultation with experts in risk communication, post with the tables information to enhance patient understanding and to ensure such tables do not mislead patients or the lay public.

**(v) Relation to subparagraph (C)**

Clinical trial information included in the registry and results data bank pursuant to this subparagraph is deemed to be clinical trial information included in such data bank pursuant to subparagraph (C).

**(4) Additional submissions of clinical trial information**

**(A) Voluntary submissions**

A responsible party for a clinical trial that is not an applicable clinical trial, or that is an applicable clinical trial that is not subject to paragraph (2)(C), may submit complete clinical trial information described in paragraph (2) or paragraph (3) provided the responsible party submits clinical trial information for each applicable clinical trial that is required to be submitted under section 262 of this title or under section 355, 360(k), 360e, or 360j(m) of title 21 in an application or report for licensure, approval, or clearance of the drug or device for the use studied in the clinical trial.

**(B) Required submissions**

**(i) In general**

Notwithstanding paragraphs (2) and (3) and subparagraph (A), in any case in which the Secretary determines for a specific clinical trial described in clause (ii) that posting in the registry and results data bank of clinical trial information for such clinical trial is necessary to protect the public health—

(I) the Secretary may require by notification that such information be submitted to the Secretary in accordance with paragraphs (2) and (3) except with regard to timing of submission;

(II) unless the responsible party submits a certification under paragraph

(3)(E)(iii), such information shall be submitted not later than 30 days after the date specified by the Secretary in the notification; and

(III) failure to comply with the requirements under subclauses (I) and (II) shall be treated as a violation of the corresponding requirement of such paragraphs.

**(ii) Clinical trials described**

A clinical trial described in this clause is—

(I) an applicable clinical trial for a drug that is approved under section 355 of title 21 or licensed under section 262 of this title or for a device that is cleared under section 360(k) of title 21 or approved under section 360e or section 360j(m) of title 21, whose completion date is on or after the date 10 years before September 27, 2007; or

(II) an applicable clinical trial that is described by both by<sup>3</sup> paragraph (2)(C) and paragraph (3)(D)(ii)(II).<sup>4</sup>

**(C) Updates to clinical trial data bank**

**(i) Submission of updates**

The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the registry and results data bank updates to reflect changes to the clinical trial information submitted under paragraph (2). Such updates—

(I) shall be provided not less than once every 12 months, unless there were no changes to the clinical trial information during the preceding 12-month period;

(II) shall include identification of the dates of any such changes;

(III) not later than 30 days after the recruitment status of such clinical trial changes, shall include an update of the recruitment status; and

(IV) not later than 30 days after the completion date of the clinical trial, shall include notification to the Director that such clinical trial is complete.

**(ii) Public availability of updates**

The Director of NIH shall make updates submitted under clause (i) publicly available in the registry data bank. Except with regard to overall recruitment status, individual site status, location, and contact information, the Director of NIH shall ensure that updates to elements required under subclauses (I) to (V) of paragraph (2)(A)(ii) do not result in the removal of any information from the original submissions or any preceding updates, and information in such databases is presented in a manner that enables users to readily access each original element submission and to track the changes made by the updates. The Director of NIH shall provide a link from the table of primary and secondary outcomes required under paragraph

<sup>3</sup>So in original.

<sup>4</sup>So in original. The second closing parenthesis probably should not appear.

(3)(C)(ii) to the tracked history required under this clause of the primary and secondary outcome measures submitted under paragraph (2)(A)(ii)(I)(II).

**(5) Coordination and compliance**

**(A) Clinical trials supported by grants from Federal agencies**

**(i) Grants from certain Federal agencies**

If an applicable clinical trial is funded in whole or in part by a grant from any agency of the Department of Health and Human Services, including the Food and Drug Administration, the National Institutes of Health, or the Agency for Healthcare Research and Quality, any grant or progress report forms required under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraphs (2) and (3).

**(ii) Verification by Federal agencies**

The heads of the agencies referred to in clause (i), as applicable, shall verify that the clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted under paragraphs (2) and (3) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

**(iii) Notice and opportunity to remedy**

If the head of an agency referred to in clause (i), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (ii), such agency head shall provide notice to such grantee of such non-compliance and allow such grantee 30 days to correct such non-compliance and submit the required clinical trial information.

**(iv) Consultation with other Federal agencies**

The Secretary shall—

(I) consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such research is an applicable clinical trial; and

(II) develop with such agencies procedures comparable to those described in clauses (i), (ii), and (iii) to ensure that clinical trial information for such applicable clinical trial is submitted under paragraphs (2) and (3).

**(B) Certification to accompany drug, biological product, and device submissions**

At the time of submission of an application under section 355 of title 21, section 360e of title 21, section 360j(m) of title 21, or section 262 of this title, or submission of a report under section 360(k) of title 21, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification

shall include the appropriate National Clinical Trial control numbers.

**(C) Quality control**

**(i) Pilot quality control project**

Until the effective date of the regulations issued under paragraph (3)(D), the Secretary, acting through the Director of NIH and the Commissioner of Food and Drugs, shall conduct a pilot project to determine the optimal method of verification to help to ensure that the clinical trial information submitted under paragraph (3)(C) is non-promotional and is not false or misleading in any particular under subparagraph (D). The Secretary shall use the publicly available information described in paragraph (3)(A) and any other information available to the Secretary about applicable clinical trials to verify the accuracy of the clinical trial information submitted under paragraph (3)(C).

**(ii) Notice of compliance**

If the Secretary determines that any clinical trial information was not submitted as required under this subsection, or was submitted but is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such noncompliance by submitting the required revised clinical trial information not later than 30 days after such notification.

**(D) Truthful clinical trial information**

**(i) In general**

The clinical trial information submitted by a responsible party under this subsection shall not be false or misleading in any particular.

**(ii) Effect**

Clause (i) shall not have the effect of—

(I) requiring clinical trial information with respect to an applicable clinical trial to include information from any source other than such clinical trial involved; or

(II) requiring clinical trial information described in paragraph (3)(D) to be submitted for purposes of paragraph (3)(C).

**(E) Public notices**

**(i) Notice of violations**

If the responsible party for an applicable clinical trial fails to submit clinical trial information for such clinical trial as required under paragraphs (2) or (3), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice—

(I) that the responsible party is not in compliance with this chapter by—

(aa) failing to submit required clinical trial information; or

(bb) submitting false or misleading clinical trial information;

(II) of the penalties imposed for the violation, if any; and

(III) whether the responsible party has corrected the clinical trial information in the registry and results data bank.

**(ii) Notice of failure to submit primary and secondary outcomes**

If the responsible party for an applicable clinical trial fails to submit the primary and secondary outcomes as required under section 2(A)(ii)(I)(II),<sup>5</sup> the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice that the responsible party is not in compliance by failing to register the primary and secondary outcomes in accordance with this chapter, and that the primary and secondary outcomes were not publicly disclosed in the database before conducting the clinical trial.

**(iii) Failure to submit statement**

The notice under clause (i) for a violation described in clause (i)(I)(aa) shall include the following statement: “The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.”.

**(iv) Submission of false information statement**

The notice under clause (i) for a violation described in clause (i)(I)(bb) shall include the following statement: “The entry for this clinical trial was found to be false or misleading and therefore not in compliance with the law.”.

**(v) Non-submission of statement**

The notice under clause (ii) for a violation described in clause (ii) shall include the following statement: “The entry for this clinical trial did not contain information on the primary and secondary outcomes at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.”.

**(vi) Compliance searches**

The Director of NIH shall provide that the public may easily search the registry and results data bank for entries that include notices required under this subparagraph.

**(6) Limitation on disclosure of clinical trial information**

**(A) In general**

Nothing in this subsection (or under section 552 of title 5) shall require the Secretary to publicly disclose, by any means other than the registry and results data bank, information described in subparagraph (B).

**(B) Information described**

Information described in this subparagraph is—

- (i) information submitted to the Director of NIH under this subsection, or information of the same general nature as (or

integrally associated with) the information so submitted; and

(ii) information not otherwise publicly available, including because it is protected from disclosure under section 552 of title 5.

**(7) Authorization of appropriations**

There are authorized to be appropriated to carry out this subsection \$10,000,000 for each fiscal year.

**(k) Day care for children of employees**

(1) The Director of NIH may establish a program to provide day care services for the employees of the National Institutes of Health similar to those services provided by other Federal agencies (including the availability of day care service on a 24-hour-a-day basis).

(2) Any day care provider at the National Institutes of Health shall establish a sliding scale of fees that takes into consideration the income and needs of the employee.

(3) For purposes regarding the provision of day care services, the Director of NIH may enter into rental or lease purchase agreements.

**(l) Council of Councils**

**(1) Establishment**

Not later than 90 days after January 15, 2007, the Director of NIH shall establish within the Office of the Director an advisory council to be known as the “Council of Councils” (referred to in this subsection as the “Council”) for the purpose of advising the Director on matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives, including making recommendations with respect to the conduct and support of research described in subsection (b)(7).

**(2) Membership**

**(A) In general**

The Council shall be composed of 27 members selected by the Director of NIH with approval from the Secretary from among the list of nominees under subparagraph (C).

**(B) Certain requirements**

In selecting the members of the Council, the Director of NIH shall ensure—

- (i) the representation of a broad range of disciplines and perspectives; and  
 (ii) the ongoing inclusion of at least 1 representative from each national research institute whose budget is substantial relative to a majority of the other institutes.

**(C) Nomination**

The Director of NIH shall maintain an updated list of individuals who have been nominated to serve on the Council, which list shall consist of the following:

- (i) For each national research institute and national center, 3 individuals nominated by the head of such institute or center from among the members of the advisory council of the institute or center, of which—  
 (I) two shall be scientists; and  
 (II) one shall be from the general public or shall be a leader in the field of pub-

<sup>5</sup>So in original. Probably should be “paragraph 2(A)(ii)(I)(II).”.

lic policy, law, health policy, economics, or management.

(ii) For each office within the Division of Program Coordination, Planning, and Strategic Initiatives, 1 individual nominated by the head of such office.

(iii) Members of the Council of Public Representatives.

### (3) Terms

#### (A) In general

The term of service for a member of the Council shall be 6 years, except as provided in subparagraphs (B) and (C).

#### (B) Terms of initial appointees

Of the initial members selected for the Council, the Director of NIH shall designate—

- (i) nine for a term of 6 years;
- (ii) nine for a term of 4 years; and
- (iii) nine for a term of 2 years.

#### (C) Vacancies

Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office.

### (m) National Institutes of Health Strategic Plan

#### (1) In general

Not later than 2 years after December 13, 2016, and at least every 6 years thereafter, the Director of the National Institutes of Health shall develop and submit to the appropriate committees of Congress and post on the Internet website of the National Institutes of Health, a coordinated strategy (to be known as the "National Institutes of Health Strategic Plan") to provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine.

#### (2) Requirements

The strategy under paragraph (1) shall—

(A) identify strategic research priorities and objectives across biomedical research, including—

(i) an assessment of the state of biomedical and behavioral research, including areas of opportunity with respect to basic, clinical, and translational research;

(ii) priorities and objectives to advance the treatment, cure, and prevention of health conditions;

(iii) emerging scientific opportunities, rising public health challenges, and scientific knowledge gaps; and

(iv) the identification of near-, mid-, and long-term scientific needs;

(B) consider, in carrying out subparagraph (A)—

(i) disease burden in the United States and the potential for return on investment to the United States;

(ii) rare diseases and conditions;

(iii) biological, social, and other determinants of health that contribute to health disparities; and

(iv) other factors the Director of National Institutes of Health determines appropriate;

(C) include multi-institute priorities, including coordination of research among institutes and centers;

(D) include strategic priorities for funding research through the Common Fund, in accordance with section 282a(c)(1)(C) of this title;

(E) address the National Institutes of Health's proposed and ongoing activities related to training and the biomedical workforce; and

(F) describe opportunities for collaboration with other agencies and departments, as appropriate.

#### (3) Use of plans

Strategic plans developed and updated by the national research institutes and national centers of the National Institutes of Health shall be prepared regularly and in such a manner that such plans will be informed by the strategic plans developed and updated under this subsection. Such plans developed by and updated by the national research institutes and national centers shall have a common template.

#### (4) Consultation

The Director of National Institutes of Health shall develop the strategic plan under paragraph (1) in consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders.

### (n) Unique research initiatives

#### (1) In general

The Director of NIH may approve, after consideration of a proposal under paragraph (2)(A), requests by the national research institutes and centers, or program officers within the Office of the Director to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects that carry out—

(A) the Precision Medicine Initiative under section 289g-5 of this title; or

(B) subsection (b)(7), except that not more than 50 percent of the funds available for a fiscal year through the Common Fund under section 282a(c)(1) of this title for purposes of carrying out such subsection (b)(7) may be used to engage in such other transactions.

#### (2) Requirements

The authority provided under this subsection may be used to conduct or support high impact cutting-edge research described in paragraph (1) using the other transactions authority described in such paragraph if the institute, center, or office—

(A) submits a proposal to the Director of NIH for the use of such authority before conducting or supporting the research, including why the use of such authority is essential to promoting the success of the project;

(B) receives approval for the use of such authority from the Director of NIH; and

(C) for each year in which the institute, center, or office has used such authority in accordance with this subsection, submits a report to the Director of NIH on the activities of the institute, center, or office relating to such research.

(July 1, 1944, ch. 373, title IV, § 402, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 823; amended Pub. L. 100-607, title I, § 111, Nov. 4, 1988, 102 Stat. 3052; Pub. L. 102-321, title I, § 163(b)(3), July 10, 1992, 106 Stat. 376; Pub. L. 103-43, title I, § 141(b), title II, §§ 201, 202, 206, 208, 210(b), (c), title III, § 303(b), June 10, 1993, 107 Stat. 139, 144, 148-150, 153; Pub. L. 105-115, title I, § 113(a), Nov. 21, 1997, 111 Stat. 2310; Pub. L. 105-362, title VI, § 601(a)(1)(A), Nov. 10, 1998, 112 Stat. 3285; Pub. L. 105-392, title IV, § 409, Nov. 13, 1998, 112 Stat. 3589; Pub. L. 107-109, § 15(c)(2), Jan. 4, 2002, 115 Stat. 1420; Pub. L. 109-482, title I, §§ 102(a)-(d), (f)(1)(A), 103(b)(1), Jan. 15, 2007, 120 Stat. 3681, 3683, 3684, 3687; Pub. L. 110-85, title III, § 304(a), title VIII, § 801(a), title XI, § 1104(2), Sept. 27, 2007, 121 Stat. 863, 904, 975; Pub. L. 110-316, title III, § 302, Aug. 14, 2008, 122 Stat. 3524; Pub. L. 111-148, title X, § 10409(b), Mar. 23, 2010, 124 Stat. 978; Pub. L. 112-74, div. F, title II, § 221(b)(5)(B), (d)(1), Dec. 23, 2011, 125 Stat. 1089, 1090; Pub. L. 113-94, § 3(a), Apr. 3, 2014, 128 Stat. 1086; Pub. L. 114-255, div. A, title II, §§ 2014(a), 2031(a), 2036(a), 2038(a), 2051, Dec. 13, 2016, 130 Stat. 1051, 1054, 1062, 1064, 1074.)

#### REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (b), is Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

The General Schedule, referred to in subsec. (b)(16), is set out under section 5332 of Title 5, Government Organization and Employees.

The National Literacy Act of 1991, referred to in subsec. (e)(5), is Pub. L. 102-73, July 25, 1991, 105 Stat. 333, which was repealed by Pub. L. 105-220, title II, § 251(a)(2), Aug. 7, 1998, 112 Stat. 1079. For complete classification of this Act to the Code, see Tables.

#### CODIFICATION

In subsec. (b)(14)(B), “section 8141 of title 40” substituted for “the Act of March 3, 1877 (40 U.S.C. 34)” on authority of Pub. L. 107-217, § 5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

#### AMENDMENTS

2016—Subsec. (b)(4). Pub. L. 114-255, § 2038(a)(1), amended par. (4) generally. Prior to amendment, text read as follows: “shall assemble accurate data to be used to assess research priorities, including information to better evaluate scientific opportunity, public health burdens, and progress in reducing minority and other health disparities;”.

Subsec. (b)(5). Pub. L. 114-255, § 2031(a)(1), inserted “, and through the development, implementation, and updating of the strategic plan developed under subsection (m)” before semicolon.

Subsec. (b)(8)(C), (D). Pub. L. 114-255, § 2038(a)(2), added subpars. (C) and (D).

Subsec. (b)(25). Pub. L. 114-255, § 2014(a), added par. (25).

Subsec. (j)(2)(D)(ii)(I). Pub. L. 114-255, § 2051(1), inserted “, unless the responsible party affirmatively requests that the Director of the National Institutes of Health publicly post such clinical trial information for an applicable device clinical trial prior to such date of clearance or approval” before semicolon.

Subsec. (j)(2)(D)(iii), (iv). Pub. L. 114-255, § 2051(2), added cls. (iii) and (iv).

Subsec. (m). Pub. L. 114-255, § 2031(a)(2), added subsec. (m).

Subsec. (n). Pub. L. 114-255, § 2036(a), added subsec. (n).

2014—Subsec. (b)(7). Pub. L. 113-94 amended par. (7) generally, enacting similar provisions and adding provisions relating to allocating funds appropriated pursuant to section 282a(a)(2) of this title for making grants for pediatric research.

2011—Subsec. (b)(24). Pub. L. 112-74, § 221(d)(1), substituted “287a” for “282d”.

Subsec. (g). Pub. L. 112-74, § 221(b)(5)(B), redesignated and transferred subsec. (g) of this section to subsec. (b) of section 285k of this title.

2010—Subsec. (b)(24). Pub. L. 111-148 added par. (24).

2008—Subsec. (j)(3)(C). Pub. L. 110-316, § 302(1), in introductory provisions, substituted “for each applicable clinical trial for a drug that is approved under section 355 of title 21 or licensed under section 262 of this title or a device that is cleared under section 360(k) of title 21 or approved under section 360e or 360j(m) of title 21, the following elements:” for “the following elements for drugs that are approved under section 355 of title 21 or licensed under section 262 of this title and devices that are cleared under section 360(k) of title 21 or approved under section 360e or 360j(m) of title 21:”.

Subsec. (j)(3)(I)(i), (iii). Pub. L. 110-316, § 302(2), substituted “applicable clinical trials described in subparagraph (C)” for “drugs described in subparagraph (C)”.

2007—Subsec. (a). Pub. L. 109-482, § 102(f)(1)(A), substituted “Director of NIH who shall” for “Director of the National Institutes of Health (hereafter in this subchapter referred to as the ‘Director of NIH’) who shall”.

Subsec. (b). Pub. L. 109-482, § 102(a)(5), substituted “paragraph (16)” for “paragraph (6)” in concluding provisions.

Subsec. (b)(1). Pub. L. 109-482, § 102(a)(6), added par. (1) and struck out former par. (1) which read as follows: “shall be responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;”.

Subsec. (b)(2), (3). Pub. L. 109-482, § 102(b), added pars. (2) and (3) and struck out former pars. (2) and (3) which read as follows:

“(2) shall coordinate and oversee the operation of the national research institutes and administrative entities within the National Institutes of Health;

“(3) shall assure that research at or supported by the National Institutes of Health is subject to review in accordance with section 289a of this title;”.

Subsec. (b)(4). Pub. L. 110-85, § 1104(2), inserted “minority and other” after “reducing”.

Pub. L. 109-482, § 102(b), added par. (4). Former par. (4) redesignated (14).

Subsec. (b)(5) to (22). Pub. L. 109-482, § 102(a)(1)-(4), (b), added pars. (5) to (13), redesignated former pars. (4) to (11) and (14) as (14) to (22), respectively, in par. (21) inserted “and” at end, and struck out former pars. (12) and (13) which read as follows:

“(12) after consultation with the Director of the Office of Research on Women’s Health, shall ensure that resources of the National Institutes of Health are sufficiently allocated for projects of research on women’s health that are identified under section 287d(b) of this title;

“(13) may conduct and support research training—

“(A) for which fellowship support is not provided under section 288 of this title; and

“(B) which does not consist of residency training of physicians or other health professionals; and”.

Subsec. (b)(23). Pub. L. 110-85, § 304(a), added par. (23).

Subsec. (i). Pub. L. 109-482, § 102(c), redesignated subsec. (j) as (i) and struck out former subsec. (i) which related to discretionary fund for use by the Director of NIH to carry out activities authorized in this chapter.

Subsec. (i)(5). Pub. L. 109-482, §103(b)(1), struck out first sentence which read as follows: "For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary."

Subsecs. (j), (k). Pub. L. 110-85, §801(a), added subsec. (j) and redesignated former subsec. (j) as (k). Former subsec. (k) redesignated (l).

Pub. L. 109-482, §102(c)(2), (d), added subsec. (k) and redesignated former subsec. (k) as (j).

Subsec. (l). Pub. L. 110-85, §801(a)(1), redesignated subsec. (k) as (l).

Pub. L. 109-482, §102(c)(1), struck out subsec. (l) which read as follows: "The Director of NIH shall carry out the program established in part F of subchapter X of this chapter (relating to interagency research on trauma)."

2002—Subsec. (j)(3)(A). Pub. L. 107-109, which directed the amendment of the first sentence of subsec. (j)(3)(A) by substituting "trial sites," for "trial sites, and" and "in the trial, and a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children," for "in the trial," was executed by making the substitutions in the second sentence, to reflect the probable intent of Congress.

1998—Subsec. (b)(13), (14). Pub. L. 105-392 added pars. (13) and (14).

Subsec. (f). Pub. L. 105-362 inserted "and" at end of par. (1), substituted a period for "; and" at end of par. (2), and struck out par. (3) which read as follows: "annually prepare and submit to the Director of NIH a report concerning the prevention and dissemination activities undertaken by the Associate Director, including—

"(A) a summary of the Associate Director's review of existing dissemination policies and techniques together with a detailed statement concerning any modification or restructuring, or recommendations for modification or restructuring, of such policies and techniques; and

"(B) a detailed statement of the expenditures made for the prevention and dissemination activities reported on and the personnel used in connection with such activities."

1997—Subsecs. (j) to (l). Pub. L. 105-115 added subsec. (j) and redesignated former subsecs. (j) and (k) as (k) and (l), respectively.

1993—Subsec. (b)(12). Pub. L. 103-43, §141(b), added par. (12).

Subsec. (e)(5). Pub. L. 103-43, §210(b), added par. (5).

Subsec. (f). Pub. L. 103-43, §201, substituted "other public and private entities, including elementary, secondary, and post-secondary schools. The Associate Director shall—" and pars. (1) to (3) for "other public and private entities. The Associate Director shall annually report to the Director of NIH on the prevention activities undertaken by the Associate Director. The report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities".

Subsec. (g). Pub. L. 103-43, §202, added subsec. (g).

Subsec. (h). Pub. L. 103-43, §206, added subsec. (h).

Subsec. (i). Pub. L. 103-43, §208, added subsec. (i).

Subsec. (j). Pub. L. 103-43, §210(c), added subsec. (j).

Subsec. (k). Pub. L. 103-43, §303(b), added subsec. (k).

1992—Subsec. (d)(1). Pub. L. 102-321 substituted "220" for "two hundred".

1988—Subsec. (b)(6). Pub. L. 100-607 inserted "and scientific program advisory committees" after "peer review groups".

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105-115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section

501 of Pub. L. 105-115, set out as a note under section 321 of Title 21, Food and Drugs.

#### EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102-321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as a note under section 236 of this title.

#### RULE OF CONSTRUCTION REGARDING CONTINUATION OF PROGRAMS

Pub. L. 109-482, title I, §103(c), Jan. 15, 2007, 120 Stat. 3689, provided that: "The amendment of a program by a provision of subsection (b) [amending this section and sections 283a, 283d, 283g to 283i, 284e to 284j, 284l, 284m, 285a-9, 285a-10, 285b-7a, 285b-7b, 285c-9, 285d-6a, 285d-8, 285e-10, 285e-10a, 285f-2, 285f-3, 285g-5, 285g-9, 285g-10, 285n, 285o, 285o-2, 285o-4, 285p, 285r, 286a-1, 287a-2, 287a-3, 287a-4, 287c-11, 287c-31 to 287c-33, 288, 288-1, and former 288-5a of this title and repealing sections 285a-8, 285b-8, 285e-11, and 286a-2 of this title] may not be construed as terminating the authority of the Federal agency involved to carry out the program."

#### CONFIDENTIALITY

Pub. L. 114-255, div. A, title II, §2014(b), Dec. 13, 2016, 130 Stat. 1051, provided that: "Nothing in the amendments made by subsection (a) [amending this section] authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, or [shall] be construed to require recipients of grants or cooperative agreements through the National Institutes of Health to share such information."

#### APPROPRIATE AGE GROUPINGS IN CLINICAL RESEARCH

Pub. L. 114-255, div. A, title II, §2038(i), Dec. 13, 2016, 130 Stat. 1067, provided that:

"(1) INPUT FROM EXPERTS.—Not later than 180 days after the date of enactment of this Act [Dec. 13, 2016], the Director of the National Institutes of Health shall convene a workshop of experts on pediatric and older populations to provide input on—

"(A) appropriate age groups to be included in research studies involving human subjects; and

"(B) acceptable justifications for excluding participants from a range of age groups from human subjects research studies.

"(2) POLICY UPDATES.—Not later than 180 days after the conclusion of the workshop under paragraph (1), the Director of the National Institutes of Health shall make a determination with respect to whether the policies of the National Institutes of Health on the inclusion of relevant age groups in clinical studies need to be updated, and shall update such policies as appropriate. In making the determination, the Director of the National Institutes of Health shall take into consideration whether such policies—

"(A) address the consideration of age as an inclusion variable in research involving human subjects; and

"(B) identify the criteria for justification for any age-related exclusions in such research.

"(3) PUBLIC AVAILABILITY OF FINDINGS AND CONCLUSIONS.—The Director of the National Institutes of Health shall—

"(A) make the findings and conclusions resulting from the workshop under paragraph (1) and updates to policies in accordance with paragraph (2), as applicable, available to the public on the Internet website of the National Institutes of Health; and

"(B) ensure that age-related data reported in the triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032 [of Pub. L. 114-255]) are made available to the public on the Internet website of the National Institutes of Health."

ENHANCING THE RIGOR AND REPRODUCIBILITY OF  
SCIENTIFIC RESEARCH

Pub. L. 114-255, div. A, title II, §2039, Dec. 13, 2016, 130 Stat. 1068, provided that:

“(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall convene a working group under the Advisory Committee to the Director of the National Institutes of Health (referred to in this section as the ‘Advisory Committee’), appointed under section 222 of the Public Health Service Act (42 U.S.C. 217a), to develop and issue recommendations through the Advisory Committee for a formal policy, which may incorporate or be informed by relevant existing and ongoing activities, to enhance rigor and reproducibility of scientific research funded by the National Institutes of Health.

“(b) CONSIDERATIONS.—In developing and issuing recommendations through the Advisory Committee under subsection (a), the working group established under such subsection shall consider, as appropriate—

“(1) preclinical experiment design, including analysis of sex as a biological variable;

“(2) clinical experiment design, including—

“(A) the diversity of populations studied for clinical research, with respect to biological, social, and other determinants of health that contribute to health disparities;

“(B) the circumstances under which summary information regarding biological, social, and other factors that contribute to health disparities should be reported; and

“(C) the circumstances under which clinical studies, including clinical trials, should conduct an analysis of the data collected during the study on the basis of biological, social, and other factors that contribute to health disparities;

“(3) applicable levels of rigor in statistical methods, methodology, and analysis;

“(4) data and information sharing in accordance with applicable privacy laws and regulations; and

“(5) any other matter the working group determines relevant.

“(c) POLICIES.—Not later than 18 months after the date of enactment of this Act, the Director of the National Institutes of Health shall consider the recommendations developed by the working group and issued by the Advisory Committee under subsection (a) and develop or update policies as appropriate.

“(d) REPORT.—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health shall issue a report to the Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives regarding recommendations developed under subsection (a) and any subsequent policy changes implemented, to enhance rigor and reproducibility in scientific research funded by the National Institutes of Health.

“(e) CONFIDENTIALITY.—Nothing in this section authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.”

DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC  
DEVICE AVAILABILITY

Pub. L. 110-85, title III, §305, Sept. 27, 2007, 121 Stat. 863, as amended by Pub. L. 112-144, title VI, §620(a), July 9, 2012, 126 Stat. 1064, provided that:

“(a) IN GENERAL.—

“(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of the enactment of this Act [Sept. 27, 2007], the Secretary of Health and Human Services shall issue a request for proposals for 1 or more grants or contracts to nonprofit consortia for

demonstration projects to promote pediatric device development.

“(2) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under paragraph (1), the Secretary shall make a determination on the grants or contracts under this section.

“(b) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit an application to the Secretary of Health and Human Services at such time, in such manner, and containing such information as the Secretary may require.

“(c) USE OF FUNDS.—A nonprofit consortium that receives a grant or contract under this section shall facilitate the development, production, and distribution of pediatric medical devices by—

“(1) encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;

“(2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;

“(3) connecting innovators and physicians to existing Federal and non-Federal resources, including resources from the Food and Drug Administration, the National Institutes of Health, the Small Business Administration, the Department of Energy, the Department of Education, the National Science Foundation, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institute of Standards and Technology;

“(4) assessing the scientific and medical merit of proposed pediatric device projects; and

“(5) providing assistance and advice as needed on business development, personnel training, prototype development, postmarket needs, and other activities consistent with the purposes of this section.

“(d) COORDINATION.—

“(1) NATIONAL INSTITUTES OF HEALTH.—Each consortium that receives a grant or contract under this section shall—

“(A) coordinate with the National Institutes of Health’s pediatric device contact point or office, designated under section 402(b)(23) of the Public Health Service Act [42 U.S.C. 282(b)(23)], as added by section 304(a) of this Act; and

“(B) provide to the National Institutes of Health any identified pediatric device needs that the consortium lacks sufficient capacity to address or those needs in which the consortium has been unable to stimulate manufacturer interest.

“(2) FOOD AND DRUG ADMINISTRATION.—Each consortium that receives a grant or contract under this section shall coordinate with the Commissioner of Food and Drugs and device companies to facilitate the application for approval or clearance of devices labeled for pediatric use.

“(3) EFFECTIVENESS AND OUTCOMES.—Each consortium that receives a grant or contract under this section shall annually report to the Secretary of Health and Human Services on the status of pediatric device development, production, and distribution that has been facilitated by the consortium.

“(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section \$5,250,000 for each of fiscal years 2013 through 2017.”

SURVEILLANCES

Pub. L. 110-85, title VIII, §801(c), Sept. 27, 2007, 121 Stat. 921, provided that: “Not later than 12 months after the date of the enactment of this Act [Sept. 27, 2007], the Secretary of Health and Human Services shall issue guidance on how the requirements of section 402(j) of the Public Health Service Act [42 U.S.C. 282(j)], as added by this section, apply to a pediatric post-market surveillance described in paragraph (1)(A)(ii)(II) of such section 402(j) that is not a clinical trial.”

## PREEMPTION

Pub. L. 110-85, title VIII, §801(d), Sept. 27, 2007, 121 Stat. 922, provided that:

“(1) IN GENERAL.—Upon the expansion of the registry and results data bank under section 402(j)(3)(D) of the Public Health Service Act [42 U.S.C. 282(j)(3)(D)], as added by this section, no State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.

“(2) RULE OF CONSTRUCTION.—The fact of submission of clinical trial information, if submitted in compliance with subsection (j) of section 402 of the Public Health Service Act (as amended by this section), that relates to a use of a drug or device not included in the official labeling of the approved drug or device shall not be construed by the Secretary of Health and Human Services or in any administrative or judicial proceeding, as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. The availability of clinical trial information through the registry and results data bank under such subsection (j), if submitted in compliance with such subsection, shall not be considered as labeling, adulteration, or misbranding of the drug or device under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)”

## COLLABORATION AND REPORT

Pub. L. 105-115, title I, §113(b), Nov. 21, 1997, 111 Stat. 2312, directed the Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs to collaborate to determine the feasibility of including device investigations within the scope of the data bank under subsec. (j) of this section, with the Secretary to report to Congress, not later than two years after Nov. 21, 1997, on the public health need, if any, for inclusion of device investigations within the scope of the data bank under subsec. (j), and on the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigations was required to be publicly disclosed.

## CHRONIC FATIGUE SYNDROME; EXPERTS AND RESEARCH REPRESENTATIVES ON ADVISORY COMMITTEES AND BOARDS

Pub. L. 103-43, title IX, §902(c), June 10, 1993, 107 Stat. 164, provided that: “The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall ensure that appropriate individuals with expertise in chronic fatigue syndrome or neuromuscular diseases and representative of a variety of disciplines and fields within the research community are appointed to appropriate National Institutes of Health advisory committees and boards.”

## THIRD-PARTY PAYMENTS REGARDING CERTAIN CLINICAL TRIALS AND CERTAIN LIFE-THREATENING ILLNESSES

Pub. L. 103-43, title XIX, §1901(a), June 10, 1993, 107 Stat. 200, provided that: “The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct a study for the purpose of—

“(1) determining the policies of third-party payors regarding the payment of the costs of appropriate health services that are provided incident to the participation of individuals as subjects in clinical trials conducted in the development of drugs with respect to acquired immune deficiency syndrome, cancer, and other life-threatening illnesses; and

“(2) developing recommendations regarding such policies.”

## PERSONNEL STUDY OF RECRUITMENT, RETENTION AND TURNOVER

Pub. L. 103-43, title XIX, §1905, June 10, 1993, 107 Stat. 203, directed Secretary of Health and Human Services,

acting through Director of National Institutes of Health, to conduct a study to review the retention, recruitment, vacancy and turnover rates of support staff, including firefighters, law enforcement, procurement officers, technicians, nurses and clerical employees, to ensure that National Institutes of Health is adequately supporting conduct of efficient, effective and high quality research for the American public, and to submit a report to Congress on results of such study not later than 1 year after June 10, 1993.

## CHRONIC PAIN CONDITIONS

Pub. L. 103-43, title XIX, §1907, June 10, 1993, 107 Stat. 204, directed Director of the National Institutes of Health to submit to Congress, not later than 2 years after June 10, 1993, a report and study on the incidence in the United States of cases of chronic pain, including chronic pain resulting from back injuries, reflex sympathetic dystrophy syndrome, temporomandibular joint disorder, post-herpetic neuropathy, painful diabetic neuropathy, phantom pain, and post-stroke pain, and the effect of such cases on the costs of health care in the United States.

## SUPPORT FOR BIOENGINEERING RESEARCH

Pub. L. 103-43, title XIX, §1912, June 10, 1993, 107 Stat. 206, directed Secretary of Health and Human Services, acting through Director of the National Institutes of Health, to conduct a study for the purpose of determining the sources and amounts of public and private funding devoted to basic research in bioengineering, including biomaterials sciences, cellular bioprocessing, tissue and rehabilitation engineering, evaluating whether that commitment is sufficient to maintain the innovative edge that the United States has in these technologies, evaluating the role of the National Institutes of Health or any other Federal agency to achieve a greater commitment to innovation in bioengineering, and evaluating the need for better coordination and collaboration among Federal agencies and between the public and private sectors, and, not later than 1 year after June 10, 1993, to prepare and submit to Committee on Labor and Human Resources of Senate, and Committee on Energy and Commerce of House of Representatives, a report containing the findings of the study together with recommendations concerning the enactment of legislation to implement the results of such study.

## MASTER PLAN FOR PHYSICAL INFRASTRUCTURE FOR RESEARCH

Pub. L. 103-43, title XX, §2002, June 10, 1993, 107 Stat. 208, directed Secretary of Health and Human Services, acting through Director of the National Institutes of Health, not later than June 1, 1994, to present to Congress a master plan to provide for replacement or refurbishment of less than adequate buildings, utility equipment and distribution systems (including the resources that provide electrical and other utilities, chilled water, air handling, and other services that the Secretary, acting through the Director, deemed necessary), roads, walkways, parking areas, and grounds that underpin the laboratory and clinical facilities of the National Institutes of Health, and provided that the plan could make recommendations for the undertaking of new projects that are consistent with the objectives of this section, such as encircling the National Institutes of Health Federal enclave with an adequate chilled water conduit.

## § 282a. Authorization of appropriations

## (a) In general

## (1) This subchapter

For purposes of carrying out this subchapter, there are authorized to be appropriated—

(A) \$30,331,309,000 for fiscal year 2007;

- (B) \$32,831,309,000 for fiscal year 2008;
- (C) such sums as may be necessary for fiscal year 2009;
- (D) \$34,851,000,000 for fiscal year 2018;
- (E) \$35,585,871,000 for fiscal year 2019; and
- (F) \$36,472,442,775 for fiscal year 2020.

**(2) Funding for 10-year pediatric research initiative through Common Fund**

For the purpose of carrying out section 282(b)(7)(B)(ii) of this title, there is authorized to be appropriated to the Common Fund, out of the 10-Year Pediatric Research Initiative Fund described in section 9008 of title 26, and in addition to amounts otherwise made available under paragraph (1) of this subsection and reserved under subsection (c)(1)(B)(i) of this section, \$12,600,000 for each of fiscal years 2014 through 2023.

**(b) Office of the Director**

Of the amount authorized to be appropriated under subsection (a) for a fiscal year, there are authorized to be appropriated for programs and activities under this subchapter carried out through the Office of the Director of NIH such sums as may be necessary for each of the fiscal years 2007 through 2009.

**(c) Trans-NIH research**

**(1) Common Fund**

**(A) Account**

For the purpose of allocations under section 282(b)(7)(B) of this title (relating to research identified by the Division of Program Coordination, Planning, and Strategic Initiatives), there is established an account to be known as the Common Fund.

**(B) Reservation**

**(i) In general**

Of the total amount appropriated under subsection (a)(1) for fiscal year 2007 or any subsequent fiscal year, the Director of NIH shall reserve an amount for the Common Fund, subject to any applicable provisions in appropriations Acts.

**(ii) Minimum amount**

For each fiscal year, the percentage constituted by the amount reserved under clause (i) relative to the total amount appropriated under subsection (a)(1) for such year may not be less than the percentage constituted by the amount so reserved for the preceding fiscal year relative to the total amount appropriated under subsection (a)(1) for such preceding fiscal year, subject to any applicable provisions in appropriations Acts.

**(C) Common Fund strategic planning report**

As part of the National Institutes of Health Strategic Plan required under section 282(m) of this title, the Secretary, acting through the Director of NIH, shall submit a report to the Congress containing a strategic plan for funding research described in section 282(b)(7)(A)(i) of this title (including personnel needs) through the Common Fund. Each such plan shall include the following:

(i) An estimate of the amounts determined by the Director of NIH to be appropriate for maximizing the potential of such research.

(ii) An estimate of the amounts determined by the Director of NIH to be sufficient only for continuing to fund research activities previously identified by the Division of Program Coordination, Planning, and Strategic Initiatives.

(iii) An estimate of the amounts determined by the Director of NIH to be necessary to fund research described in section 282(b)(7)(A)(i) of this title—

(I) that is in addition to the research activities described in clause (ii); and

(II) for which there is the most substantial need.

**(D) Evaluation**

During the 6-month period following the end of the first fiscal year for which the total amount reserved under subparagraph (B) is equal to 5 percent of the total amount appropriated under subsection (a)(1) for such fiscal year, the Secretary, acting through the Director of NIH, in consultation with the advisory council established under section 282(k) of this title, shall submit recommendations to the Congress for changes regarding amounts for the Common Fund.

**(2) Trans-NIH research reporting**

**(A) Limitation**

With respect to the total amount appropriated under subsection (a) for fiscal year 2008 or any subsequent fiscal year, if the head of a national research institute or national center fails to submit the report required by subparagraph (B) for the preceding fiscal year, the amount made available for the institute or center for the fiscal year involved may not exceed the amount made available for the institute or center for fiscal year 2006.

**(B) Reporting**

Not later than 2 years after December 13, 2016, the head of each national research institute or national center shall submit to the Director of the National Institutes of Health a report, to be included in the triennial report under section 283 of this title, on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers.

**(C) Determination**

For purposes of determining the amount or percentage of funds to be reported under subparagraph (B), any amounts made available to an institute or center under section 282(b)(7)(B) of this title shall be included.

**(D) Verification of amounts**

Upon receipt of each report submitted under subparagraph (B), the Director of NIH shall review and, in cases of discrepancy, verify the accuracy of the amounts specified in the report.

**(E) Waiver**

At the request of any national research institute or national center, the Director of NIH may waive the application of this paragraph to such institute or center if the Director finds that the conduct or support of research described in subparagraph (B) is inconsistent with the mission of such institute or center.

**(d) Transfer authority**

Of the total amount appropriated under subsection (a)(1) for a fiscal year, the Director of NIH may (in addition to the reservation under subsection (c)(1) for such year) transfer not more than 1 percent for programs or activities that are authorized in this subchapter and identified by the Director to receive funds pursuant to this subsection. In making such transfers, the Director may not decrease any appropriation account under subsection (a)(1) by more than 1 percent.

**(e) Rule of construction**

This section may not be construed as affecting the authorities of the Director of NIH under section 281 of this title.

(July 1, 1944, ch. 373, title IV, §402A, as added Pub. L. 109-482, title I, §103(a), Jan. 15, 2007, 120 Stat. 3685; amended Pub. L. 113-94, §3(b), Apr. 3, 2014, 128 Stat. 1087; Pub. L. 114-255, div. A, title II, §§2001, 2031(b), 2042(a), Dec. 13, 2016, 130 Stat. 1047, 1056, 1073.)

## AMENDMENTS

2016—Subsec. (a)(1)(D) to (F). Pub. L. 114-255, §2001, added subpars. (D) to (F).

Subsec. (c)(1)(C). Pub. L. 114-255, §2031(b), substituted “As part of the National Institutes of Health Strategic Plan required under section 282(m) of this title,” for “Not later than June 1, 2007, and every 2 years thereafter.”

Subsec. (c)(2)(B). Pub. L. 114-255, §2042(a)(1), amended subpar. (B) generally. Prior to amendment, text read as follows: “Not later than January 1, 2008, and each January 1st thereafter—

“(i) the head of each national research institute or national center shall submit to the Director of NIH a report on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

“(ii) the Secretary shall submit a report to the Congress identifying the percentage of funds made available by each national research institute and national center with respect to such fiscal year for conducting or supporting research described in clause (i).”

Subsec. (c)(2)(D), (E). Pub. L. 114-255, §2042(a)(2), substituted “(B)” for “(B)(i)”.

2014—Subsec. (a). Pub. L. 113-94, §3(b)(1)(B), which directed amendment of subsec. (a) by striking “For purposes of carrying out this subchapter” and inserting par. (1) designation, heading, and “For purposes of carrying out this subchapter”, was executed by striking “For the purpose of carrying out this subchapter” and making the insertions as directed, to reflect the probable intent of Congress.

Pub. L. 113-94, §3(b)(1)(A), redesignated pars. (1) to (3) as subpars. (A) to (C), respectively, and realigned margins.

Subsec. (a)(2). Pub. L. 113-94, §3(b)(1)(C), added par. (2). Former par. (2) redesignated subpar. (B) of par. (1).

Subsecs. (c)(1)(B), (D), (d). Pub. L. 113-94, §3(b)(2), substituted “subsection (a)(1)” for “subsection (a)” wherever appearing.

## EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

## SUPPLEMENT, NOT SUPPLANT; PROHIBITION AGAINST TRANSFER

Pub. L. 113-94, §3(c), Apr. 3, 2014, 128 Stat. 1087, provided that: “Funds appropriated pursuant to section 402A(a)(2) of the Public Health Service Act [42 U.S.C. 282a(a)(2)], as added by subsection (b)—

“(1) shall be used to supplement, not supplant, the funds otherwise allocated by the National Institutes of Health for pediatric research; and

“(2) notwithstanding any transfer authority in any appropriation Act, shall not be used for any purpose other than allocating funds for making grants as described in section 402(b)(7)(B)(ii) of the Public Health Service Act [42 U.S.C. 282(b)(7)(B)(ii)], as added by subsection (a).”

**§ 282b. Electronic coding of grants and activities**

The Secretary, acting through the Director of NIH, shall establish an electronic system to uniformly code research grants and activities of the Office of the Director and of all the national research institutes and national centers. The electronic system shall be searchable by a variety of codes, such as the type of research grant, the research entity managing the grant, and the public health area of interest. When permissible, the Secretary, acting through the Director of NIH, shall provide information on relevant literature and patents that are associated with research activities of the National Institutes of Health.

(July 1, 1944, ch. 373, title IV, §402B, as added Pub. L. 109-482, title I, §104(a)(3), Jan. 15, 2007, 120 Stat. 3689.)

## EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

**§ 282c. Public access to funded investigators' final manuscripts**

The Director of the National Institutes of Health (“NIH”) shall require in the current fiscal year and thereafter that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: *Provided*, That the NIH shall implement the public access policy in a manner consistent with copyright law.

(Pub. L. 111-8, div. F, title II, §217, Mar. 11, 2009, 123 Stat. 782.)

## CODIFICATION

Section was enacted as part of the Department of Health and Human Services Appropriations Act, 2009, and also as part of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2009, and the Omnibus Appro-

priations Act, 2009, and not as part of the Public Health Service Act which comprises this chapter.

#### § 282d. Transferred

##### CODIFICATION

Section, act July 1, 1944, ch. 373, title IV, §402C, as added Pub. L. 111-148, title X, §10409(d), Mar. 23, 2010, 124 Stat. 978, which related to the Cures Acceleration Network, was renumbered section 480 of act July 1, 1944, by Pub. L. 112-74, div. F, title II, §221(c)(1)(A), Dec. 23, 2011, 125 Stat. 1089, and transferred to section 287a of this title.

#### § 283. Triennial reports of Director of NIH

##### (a) In general

The Director of NIH shall submit to the Congress on a triennial basis a report in accordance with this section. The first report shall be submitted not later than 1 year after January 15, 2007. Each such report shall include the following information:

(1) An assessment of the state of biomedical and behavioral research.

(2) A description of the activities conducted or supported by the agencies of the National Institutes of Health and policies respecting the programs of such agencies.

(3) A description of intra-National Institutes of Health activities, including—

(A) identification of the percentage of funds made available by each national research institute and national center with respect to each applicable fiscal year for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

(B) recommendations for promoting coordination of information among the centers of excellence.

(4) A catalog of all the research activities of the agencies, prepared in accordance with the following:

(A) The catalog shall, for each such activity—

(i) identify the agency or agencies involved;

(ii) state whether the activity was carried out directly by the agencies or was supported by the agencies and describe to what extent the agency was involved; and

(iii) identify whether the activity was carried out through a center of excellence.

(B) In the case of clinical research, the catalog shall, as appropriate, identify study populations by demographic variables, including biological and social variables and relevant age categories (such as pediatric subgroups), and determinants of health, that contribute to research on minority health and health disparities.

(C) Research activities listed in the catalog shall include, where applicable, the following:

(i) Epidemiological studies and longitudinal studies.

(ii) Disease registries, information clear-houses, and other data systems.

(iii) Public education and information campaigns.

(iv) Training activities, including—

(I) National Research Service Awards and Clinical Transformation Science Awards;

(II) graduate medical education programs, including information on the number and type of graduate degrees awarded during the period in which the programs received funding under this subchapter;

(III) investigator-initiated awards for postdoctoral training and postdoctoral training funded through research grants;

(IV) a breakdown by demographic variables and other appropriate categories; and

(V) an evaluation and comparison of outcomes and effectiveness of various training programs.

(v) Clinical trials, including a breakdown of participation by study populations and demographic variables, including relevant age categories (such as pediatric subgroups), information submitted by each national research institute and national center to the Director of National Institutes of Health under section 289a-2(f) of this title, and such other information as may be necessary to demonstrate compliance with section 289a-2 of this title and other applicable requirements regarding inclusion of demographic groups.

(vi) Translational research activities with other agencies of the Public Health Service.

(5) A summary of the research activities throughout the agencies, which summary shall be organized by the following categories, where applicable:

(A) Cancer.

(B) Neurosciences.

(C) Life stages, human development, and rehabilitation.

(D) Organ systems.

(E) Autoimmune diseases.

(F) Genomics.

(G) Molecular biology and basic science.

(H) Technology development.

(I) Chronic diseases, including pain and palliative care.

(J) Infectious diseases and bioterrorism.

(K) Minority health and health disparities.

(L) Such additional categories as the Director determines to be appropriate.

(6) A review of each entity receiving funding under this subchapter in its capacity as a center of excellence (in this paragraph referred to as a "center of excellence"), including the following—

(A) an evaluation of the performance and research outcomes of each center of excellence; and

(B) recommendations for improving the effectiveness, efficiency, and outcomes of the centers of excellence.

##### (b) Requirement regarding disease-specific research activities

In a report under subsection (a), the Director of NIH, when reporting on research activities re-

lating to a specific disease, disorder, or other adverse health condition, shall—

- (1) present information in a standardized format;
- (2) identify the actual dollar amounts obligated for such activities; and
- (3) include a plan for research on the specific disease, disorder, or other adverse health condition, including a statement of objectives regarding the research, the means for achieving the objectives, a date by which the objectives are expected to be achieved, and justifications for revisions to the plan.

**(c) Additional reports**

In addition to reports required by subsections (a) and (b), the Director of NIH or the head of a national research institute or national center may submit to the Congress such additional reports as the Director or the head of such institute or center determines to be appropriate.

(July 1, 1944, ch. 373, title IV, § 403, as added Pub. L. 109-482, title I, § 104(a)(3), Jan. 15, 2007, 120 Stat. 3689; amended Pub. L. 110-85, title XI, § 1104(3), Sept. 27, 2007, 121 Stat. 975; Pub. L. 114-255, div. A, title II, § 2032, Dec. 13, 2016, 130 Stat. 1056.)

**PRIOR PROVISIONS**

A prior section 283, act July 1, 1944, ch. 373, title IV, § 403, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 826; amended Pub. L. 100-607, title I, § 112, Nov. 4, 1988, 102 Stat. 3052, required a biennial report by the Director to the President and Congress, prior to repeal by Pub. L. 109-482, title I, § 104(a)(3), Jan. 15, 2007, 120 Stat. 3689.

**AMENDMENTS**

2016—Pub. L. 114-255, § 2032(1), substituted “Triennial” for “Biennial” in section catchline.

Subsec. (a). Pub. L. 114-255, § 2032(2)(A), substituted “triennial” for “biennial” in introductory provisions.

Subsec. (a)(3). Pub. L. 114-255, § 2032(2)(B), amended par. (3) generally. Prior to amendment, par. (3) read as follows: “Classification and justification for the priorities established by the agencies, including a strategic plan and recommendations for future research initiatives to be carried out under section 282(b)(7) of this title through the Division of Program Coordination, Planning, and Strategic Initiatives.”

Subsec. (a)(4)(B). Pub. L. 114-255, § 2032(2)(C)(i), substituted “demographic variables, including biological and social variables and relevant age categories (such as pediatric subgroups), and determinants of health,” for “demographic variables and other variables”.

Subsec. (a)(4)(C)(v). Pub. L. 114-255, § 2032(2)(C)(ii), substituted “demographic variables, including relevant age categories (such as pediatric subgroups), information submitted by each national research institute and national center to the Director of National Institutes of Health under section 289a-2(f) of this title, and such” for “demographic variables and such” and “and other applicable requirements regarding inclusion of demographic groups” for “(regarding inclusion of women and minorities in clinical research)”.

Subsec. (a)(6). Pub. L. 114-255, § 2032(2)(D), substituted “the following—” for “the following:” in introductory provisions, “an evaluation” for “An evaluation” and “; and” for the period in subpar. (A), redesignated subpar. (C) as (B) and substituted “recommendations” for “Recommendations”, and struck out former subpars. (B) and (D), which read as follows:

“(B) Recommendations for promoting coordination of information among the centers of excellence.

“(D) If no additional centers of excellence have been funded under this subchapter since the previous

report under this section, an explanation of the reasons for not funding any additional centers.”

2007—Subsec. (a)(4)(C)(iv)(III). Pub. L. 110-85 inserted “and postdoctoral training funded through research grants” before semicolon at end.

**EFFECTIVE DATE**

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

**§ 283a. Annual reporting to increase interagency collaboration and coordination**

**(a) Collaboration with other HHS agencies**

On an annual basis, the Director of NIH shall submit to the Secretary a report on the activities of the National Institutes of Health involving collaboration with other agencies of the Department of Health and Human Services.

**(b) Clinical trials**

Each calendar year, the Director of NIH shall submit to the Commissioner of Food and Drugs a report that identifies each clinical trial that is registered during such calendar year in the databank of information established under section 282(i) of this title.

**(c) Human tissue samples**

On an annual basis, the Director of NIH shall submit to the Congress a report that describes how the National Institutes of Health and its agencies store and track human tissue samples.

**(d) First report**

The first report under subsections (a), (b), and (c) shall be submitted not later than 1 year after January 15, 2007.

(July 1, 1944, ch. 373, title IV, § 403A, as added Pub. L. 109-482, title I, § 104(a)(3), Jan. 15, 2007, 120 Stat. 3691.)

**PRIOR PROVISIONS**

A prior section 403A of act July 1, 1944, was renumbered section 403D and is classified to section 283a-3 of this title.

**EFFECTIVE DATE**

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

**§ 283a-1. Annual reporting to prevent fraud and abuse**

**(a) Whistleblower complaints**

**(1) In general**

On an annual basis, the Director of NIH shall submit to the Inspector General of the Department of Health and Human Services, the Secretary, the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate a report summarizing the activities of the National Institutes of Health relating to whistleblower complaints.

**(2) Contents**

For each whistleblower complaint pending during the year for which a report is submit-

ted under this subsection, the report shall identify the following:

- (A) Each agency of the National Institutes of Health involved.
- (B) The status of the complaint.
- (C) The resolution of the complaint to date.

**(b) First report**

The first report under subsection (a) shall be submitted not later than 1 year after January 15, 2007.

(July 1, 1944, ch. 373, title IV, §403B, as added Pub. L. 109-482, title I, §104(a)(3), Jan. 15, 2007, 120 Stat. 3691; amended Pub. L. 114-255, div. A, title II, §2042(b), Dec. 13, 2016, 130 Stat. 1073.)

AMENDMENTS

2016—Subsecs. (b), (c). Pub. L. 114-255 redesignated subsec. (c) as (b), substituted “subsection (a)” for “subsections (a) and (b)”, and struck out former subsec. (b), which related to annual report by the Director of NIH on experts and consultants whose services were obtained by the National Institutes of Health or its agencies.

EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

**§ 283a-2. Annual reporting regarding training of graduate students for doctoral degrees**

**(a) In general**

Each institution receiving an award under this subchapter for the training of graduate students for doctoral degrees shall annually report to the Director of NIH, with respect to graduate students supported by the National Institutes of Health at such institution—

- (1) the percentage of such students admitted for study who successfully attain a doctoral degree; and
- (2) for students described in paragraph (1), the average time between the beginning of graduate study and the receipt of a doctoral degree.

**(3)<sup>1</sup> Provision of information to applicants**

Each institution described in subsection (a) shall provide to each student submitting an application for a program of graduate study at such institution the information described in paragraphs (1) and (2) of such subsection with respect to the program or programs to which such student has applied.

(July 1, 1944, ch. 373, title IV, §403C, as added Pub. L. 109-482, title I, §104(a)(3), Jan. 15, 2007, 120 Stat. 3692; amended Pub. L. 110-85, title XI, §1104(5), Sept. 27, 2007, 121 Stat. 975; Pub. L. 114-255, div. A, title II, §2042(c), Dec. 13, 2016, 130 Stat. 1073.)

PRIOR PROVISIONS

A prior section 403C of act July 1, 1944, was renumbered section 403D and is classified to section 283a-3 of this title.

AMENDMENTS

2016—Subsec. (a)(2). Pub. L. 114-255 struck out “(not including any leaves of absence)” after “time”.

<sup>1</sup> So in original. Probably should be “(b)”.

2007—Subsec. (a). Pub. L. 110-85, §1104(5)(A), substituted “graduate students supported by the National Institutes of Health” for “each degree-granting program” in introductory provisions.

Subsec. (a)(1). Pub. L. 110-85, §1104(5)(B), inserted “such” after “percentage of”.

Subsec. (a)(2). Pub. L. 110-85, §1104(5)(C), inserted “(not including any leaves of absence)” after “average time”.

EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

**§ 283a-3. Establishment of program regarding DES**

**(a) In general**

The Director of NIH shall establish a program for the conduct and support of research and training, the dissemination of health information, and other programs with respect to the diagnosis and treatment of conditions associated with exposure to the drug diethylstilbestrol (in this section referred to as “DES”).

**(b) Education programs**

In carrying out subsection (a), the Director of NIH, after consultation with nonprofit private entities representing individuals who have been exposed to DES, shall conduct or support programs to educate health professionals and the public on the drug, including the importance of identifying and treating individuals who have been exposed to the drug.

**(c) Longitudinal studies**

After consultation with the Office of Research on Women’s Health, the Director of NIH, acting through the appropriate national research institutes, shall in carrying out subsection (a) conduct or support one or more longitudinal studies to determine the incidence of the following diseases or disorders in the indicated populations and the relationship of DES to the diseases or disorders:

- (1) In the case of women to whom (on or after January 1, 1938) DES was administered while the women were pregnant, the incidence of all diseases and disorders (including breast cancer, gynecological cancers, and impairments of the immune system, including autoimmune disease).
- (2) In the case of women exposed to DES in utero, the incidence of clear cell cancer (including recurrences), the long-term health effects of such cancer, and the effects of treatments for such cancer.
- (3) In the case of men and women exposed to DES in utero, the incidence of all diseases and disorders (including impairments of the reproductive and autoimmune systems).
- (4) In the case of children of men or women exposed to DES in utero, the incidence of all diseases and disorders.

**(d) Exposure to DES in utero**

For purposes of this section, an individual shall be considered to have been exposed to DES in utero if, during the pregnancy that resulted in the birth of such individual, DES was (on or

after January 1, 1938) administered to the biological mother of the individual.

(July 1, 1944, ch. 373, title IV, §403D, formerly §403A, as added Pub. L. 102-409, §2, Oct. 13, 1992, 106 Stat. 2092; amended Pub. L. 105-340, title I, §101(a), Oct. 31, 1998, 112 Stat. 3191; renumbered §403C and amended Pub. L. 109-482, title I, §§103(b)(2), 104(a)(1), Jan. 15, 2007, 120 Stat. 3687, 3689; renumbered §403D, Pub. L. 110-85, title XI, §1104(4), Sept. 27, 2007, 121 Stat. 975.)

#### CODIFICATION

Section was formerly classified to section 283a of this title prior to renumbering by Pub. L. 109-482.

#### AMENDMENTS

2007—Subsec. (e). Pub. L. 109-482, §103(b)(2), struck out subsec. (e) which read as follows: “In addition to any other authorization of appropriations available for the purpose of carrying out this section, there are authorized to be appropriated for such purpose such sums as may be necessary for each of the fiscal years 1993 through 2003.”

1998—Subsec. (e). Pub. L. 105-340 substituted “2003” for “1996”.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

### § 283b. Repealed. Pub. L. 106-525, title I, § 101(b)(2), Nov. 22, 2000, 114 Stat. 2501

Section, act July 1, 1944, ch. 373, title IV, §404, as added Pub. L. 103-43, title I, §151, June 10, 1993, 107 Stat. 139, related to the establishment and purpose of the Office of Research on Minority Health.

### § 283c. Office of Behavioral and Social Sciences Research

(a) There is established within the Office of the Director of NIH an office to be known as the Office of Behavioral and Social Sciences Research (in this section referred to as the “Office”). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

(b)(1) With respect to research on the relationship between human behavior and the development, treatment, and prevention of medical conditions, the Director of the Office shall—

(A) coordinate research conducted or supported by the agencies of the National Institutes of Health; and

(B) identify projects of behavioral and social sciences research that should be conducted or supported by the national research institutes, and develop such projects in cooperation with such institutes.

(2) Research authorized under paragraph (1) includes research on teen pregnancy, infant mortality, violent behavior, suicide, and homelessness. Such research does not include neurobiological research, or research in which the behavior of an organism is observed for the purpose of determining activity at the cellular or molecular level.

(July 1, 1944, ch. 373, title IV, §404A, as added Pub. L. 103-43, title II, §203(a), June 10, 1993, 107 Stat. 145.)

#### EFFECTIVE DATE

Pub. L. 103-43, title II, §203(c), June 10, 1993, 107 Stat. 146, provided that: “The amendment described in sub-

section (a) [enacting this section] is made upon the date of the enactment of this Act [June 10, 1993] and takes effect July 1, 1993. Subsection (b) [107 Stat. 145] takes effect on such date.”

### § 283d. Children’s Vaccine Initiative

The Secretary, in consultation with the Director of the National Vaccine Program under subchapter XIX and acting through the Directors of the National Institute for Allergy and Infectious Diseases, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Institute for Aging, and other public and private programs, shall carry out activities, which shall be consistent with the global Children’s Vaccine Initiative, to develop affordable new and improved vaccines to be used in the United States and in the developing world that will increase the efficacy and efficiency of the prevention of infectious diseases. In carrying out such activities, the Secretary shall, to the extent practicable, develop and make available vaccines that require fewer contacts to deliver, that can be given early in life, that provide long lasting protection, that obviate refrigeration, needles and syringes, and that protect against a larger number of diseases.

(July 1, 1944, ch. 373, title IV, §404B, as added Pub. L. 103-43, title II, §204, June 10, 1993, 107 Stat. 146; amended Pub. L. 109-482, title I, §103(b)(3), Jan. 15, 2007, 120 Stat. 3687; Pub. L. 110-154, §1(b)(2), Dec. 21, 2007, 121 Stat. 1827; Pub. L. 114-255, div. A, title II, §2042(d), Dec. 13, 2016, 130 Stat. 1073.)

#### AMENDMENTS

2016—Pub. L. 114-255 struck out subsec. (a) designation and heading “Development of New Vaccines” and subsec. (b). Prior to amendment, text of subsec. (b) read as follows: “In the report required in section 300aa-4 of this title, the Secretary, acting through the Director of the National Vaccine Program under subchapter XIX, shall include information with respect to activities and the progress made in implementing the provisions of this section and achieving its goals.”

2007—Subsec. (a). Pub. L. 110-154 substituted “Eunice Kennedy Shriver National Institute of Child Health and Human Development” for “National Institute for Child Health and Human Development”.

Subsec. (c). Pub. L. 109-482 struck out heading and text of subsec. (c). Text read as follows: “In addition to any other amounts authorized to be appropriated for activities of the type described in this section, there are authorized to be appropriated to carry out this section \$20,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.”

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

### § 283e. Plan for use of animals in research

#### (a) Preparation

The Director of NIH, after consultation with the committee established under subsection (e), shall prepare a plan—

(1) for the National Institutes of Health to conduct or support research into—

(A) methods of biomedical research and experimentation that do not require the use of animals;

(B) methods of such research and experimentation that reduce the number of animals used in such research;

(C) methods of such research and experimentation that produce less pain and distress in such animals; and

(D) methods of such research and experimentation that involve the use of marine life (other than marine mammals);

(2) for establishing the validity and reliability of the methods described in paragraph (1);

(3) for encouraging the acceptance by the scientific community of such methods that have been found to be valid and reliable; and

(4) for training scientists in the use of such methods that have been found to be valid and reliable.

**(b) Submission to Congressional committees**

Not later than October 1, 1993, the Director of NIH shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, the plan required in subsection (a) and shall begin implementation of the plan.

**(c) Periodic review and revision**

The Director of NIH shall periodically review, and as appropriate, make revisions in the plan required under subsection (a). A description of any revision made in the plan shall be included in the first biennial report under section 283 of this title that is submitted after the revision is made.

**(d) Dissemination of information**

The Director of NIH shall take such actions as may be appropriate to convey to scientists and others who use animals in biomedical or behavioral research or experimentation information respecting the methods found to be valid and reliable under subsection (a)(2).

**(e) Interagency Coordinating Committee on the Use of Animals in Research**

(1) The Director of NIH shall establish within the National Institutes of Health a committee to be known as the Interagency Coordinating Committee on the Use of Animals in Research (in this subsection referred to as the “Committee”).

(2) The Committee shall provide advice to the Director of NIH on the preparation of the plan required in subsection (a).

(3) The Committee shall be composed of—

(A) the Directors of each of the national research institutes (or the designees of such Directors); and

(B) representatives of the Environmental Protection Agency, the Food and Drug Administration, the Consumer Product Safety Commission, the National Science Foundation, and such additional agencies as the Director of NIH determines to be appropriate, which representatives shall include not less than one veterinarian with expertise in laboratory-animal medicine.

(July 1, 1944, ch. 373, title IV, §404C, as added Pub. L. 103-43, title II, §205(a), June 10, 1993, 107 Stat. 146; amended Pub. L. 112-74, div. F, title II, §221(d)(2), Dec. 23, 2011, 125 Stat. 1090.)

AMENDMENTS

2011—Subsec. (e)(3)(A). Pub. L. 112-74 struck out “and the Director of the Center for Research Resources” after “institutes”.

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104-14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

**§ 283f. Requirements regarding surveys of sexual behavior**

With respect to any survey of human sexual behavior proposed to be conducted or supported through the National Institutes of Health, the survey may not be carried out unless—

(1) the proposal has undergone review in accordance with any applicable requirements of sections 289 and 289a of this title; and

(2) the Secretary, in accordance with section 289a-1 of this title, makes a determination that the information expected to be obtained through the survey will assist—

(A) in reducing the incidence of sexually transmitted diseases, the incidence of infection with the human immunodeficiency virus, or the incidence of any other infectious disease; or

(B) in improving reproductive health or other conditions of health.

(July 1, 1944, ch. 373, title IV, §404D, as added Pub. L. 103-43, title II, §207, June 10, 1993, 107 Stat. 148.)

PROHIBITION AGAINST SHARP ADULT SEX SURVEY AND AMERICAN TEENAGE SEX SURVEY

Pub. L. 103-43, title XX, §2015, June 10, 1993, 107 Stat. 217, provided that: “The Secretary of Health and Human Services may not during fiscal year 1993 or any subsequent fiscal year conduct or support the SHARP survey of adult sexual behavior or the American Teenage Study of adolescent sexual behavior. This section becomes effective on the date of the enactment of this Act [June 10, 1993].”

**§ 283g. Muscular dystrophy; initiative through Director of National Institutes of Health**

**(a) Expansion, intensification, and coordination of activities**

**(1) In general**

The Director of NIH, in coordination with the Directors of the National Institute of Neurological Disorders and Stroke, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Heart, Lung, and Blood Institute, and the other national research institutes as appropriate, shall expand

and intensify programs of such Institutes with respect to research and related activities concerning various forms of muscular dystrophy, including Duchenne, Becker, congenital muscular dystrophy, limb-girdle muscular dystrophy, myotonic, facioscapulohumeral muscular dystrophy (referred to in this section as “FSHD”) and other forms of muscular dystrophy.

**(2) Coordination**

The Directors referred to in paragraph (1) shall jointly coordinate the programs referred to in such paragraph and consult with the Muscular Dystrophy Interagency Coordinating Committee established under section 6 of the MD-CARE Act.<sup>1</sup>

**(3) Allocations by Director of NIH**

The Director of NIH shall allocate the amounts appropriated to carry out this section for each fiscal year among the national research institutes referred to in paragraph (1).

**(b) Centers of excellence**

**(1) In general**

The Director of NIH shall award grants and contracts under subsection (a)(1) to public or nonprofit private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for centers of excellence regarding research on various forms of muscular dystrophy. Such centers of excellence shall be known as the “Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers”.

**(2) Research**

Each center under paragraph (1) shall supplement but not replace the establishment of a comprehensive research portfolio in all the muscular dystrophies. As a whole, the centers shall conduct basic and clinical research in all forms of muscular dystrophy including early detection, diagnosis, prevention, and treatment, including the fields of muscle biology, genetics, noninvasive imaging, cardiac and pulmonary function, and pharmacological and other therapies.

**(3) Coordination of centers**

The Director of NIH shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication and sharing of data between such centers.

**(4) Organization of centers**

Each center under paragraph (1) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of NIH.

**(5) Duration of support**

Support for a center established under paragraph (1) may be provided under this section for a period of not to exceed 5 years. Such period may be extended for 1 or more additional periods not exceeding 5 years if the operations

of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director of NIH and if such group has recommended to the Director that such period should be extended.

**(c) Facilitation of research**

The Director of NIH shall provide for a program under subsection (a)(1) under which samples of tissues and genetic materials that are of use in research on muscular dystrophy are donated, collected, preserved, and made available for such research. The program shall be carried out in accordance with accepted scientific and medical standards for the donation, collection, and preservation of such samples.

**(d) Coordinating Committee**

**(1) In general**

The Secretary shall establish the Muscular Dystrophy Coordinating Committee (referred to in this section as the “Coordinating Committee”) to coordinate activities across the National Institutes and with other Federal health programs and activities relating to the various forms of muscular dystrophy.

**(2) Composition**

The Coordinating Committee shall consist of not more than 18 members to be appointed by the Secretary, of which—

(A)  $\frac{2}{3}$  of such members shall represent governmental agencies, including the directors or their designees of each of the national research institutes involved in research with respect to muscular dystrophy and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, including the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Food and Drug Administration, and the Administration for Community Living and representatives of other governmental agencies that serve children and adults with muscular dystrophy, including the Department of Education and the Social Security Administration; and

(B)  $\frac{1}{3}$  of such members shall be public members, including a broad cross section of persons affected with muscular dystrophies including parents or legal guardians, affected individuals, researchers, and clinicians.

Members appointed under subparagraph (B) shall serve for a term of 3 years, and may serve for an unlimited number of terms if reappointed.

**(3) Chair**

**(A) In general**

With respect to muscular dystrophy, the Chair of the Coordinating Committee shall serve as the principal advisor to the Secretary, the Assistant Secretary for Health, and the Director of NIH, and shall provide advice to the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and to the heads of other relevant agencies. The Coordinating

<sup>1</sup> See References in Text note below.

Committee shall select the Chair for a term not to exceed 2 years.

**(B) Appointment**

The Chair of the Committee shall be appointed by and be directly responsible to the Secretary.

**(4) Administrative support; terms of service; other provisions**

The following shall apply with respect to the Coordinating Committee:

(A) The Coordinating Committee shall receive necessary and appropriate administrative support from the Department of Health and Human Services.

(B) The Coordinating Committee shall meet as appropriate as determined by the Secretary, in consultation with the chair,<sup>2</sup> but shall meet no fewer than two times per calendar year.

**(e) Plan for HHS activities**

**(1) In general**

Not later than 1 year after December 18, 2001, the Coordinating Committee shall develop a plan for conducting and supporting research and education on muscular dystrophy through the agencies represented on the Coordinating Committee pursuant to subsection (d)(2)(A) and shall periodically review and revise the plan. The plan shall—

(A) provide for a broad range of research and education activities relating to biomedical, epidemiological, psychosocial, public services, and rehabilitative issues, including studies of the impact of such diseases in rural and underserved communities, studies to demonstrate the cost-effectiveness of providing independent living resources and support to patients with various forms of muscular dystrophy, and studies to determine optimal clinical care interventions for adults with various forms of muscular dystrophy;

(B) identify priorities among the programs and activities of the National Institutes of Health regarding such diseases; and

(C) reflect input from a broad range of scientists, patients, and advocacy groups.

**(2) Certain elements of plan**

The plan under paragraph (1) shall, with respect to each form of muscular dystrophy, provide for the following as appropriate:

(A) Research to determine the reasons underlying the incidence and prevalence of various forms of muscular dystrophy.

(B) Basic research concerning the etiology and genetic links of the disease and potential causes of mutations.

(C) The development of improved screening techniques.

(D) Basic and clinical research for the development and evaluation of new treatments, including new biological agents and new clinical interventions to improve the health of those with muscular dystrophy.

(E) Information and education programs for health care professionals and the public.

**(f) Public input**

The Secretary shall, under subsection (a)(1), provide for a means through which the public can obtain information on the existing and planned programs and activities of the Department of Health and Human Services with respect to various forms of muscular dystrophy and through which the Secretary can receive comments from the public regarding such programs and activities.

**(g) Clinical research**

The Coordinating Committee may evaluate the potential need to enhance the clinical research infrastructure required to test emerging therapies for the various forms of muscular dystrophy by prioritizing the achievement of the goals related to this topic in the plan under subsection (e)(1).

(July 1, 1944, ch. 373, title IV, §404E, as added Pub. L. 107-84, §3, Dec. 18, 2001, 115 Stat. 824; amended Pub. L. 109-482, title I, §§103(b)(4), 104(b)(1)(A), Jan. 15, 2007, 120 Stat. 3687, 3692; Pub. L. 110-154, §1(b)(3), Dec. 21, 2007, 121 Stat. 1827; Pub. L. 110-361, §2, Oct. 8, 2008, 122 Stat. 4010; Pub. L. 113-166, §2, Sept. 26, 2014, 128 Stat. 1879.)

REFERENCES IN TEXT

Section 6 of the MD-CARE Act, referred to in subsec. (a)(2), is section 6 of Pub. L. 107-84, which was formerly set out as a note under section 247b-18 of this title and does not relate to establishment of a coordinating committee. However, subsec. (d) of this section contains provisions relating to the establishment of the Muscular Dystrophy Coordinating Committee.

PRIOR PROVISIONS

A prior section 283g, act July 1, 1944, ch. 373, title IV, §404E, as added Pub. L. 103-43, title II, §209, June 10, 1993, 107 Stat. 149, related to Office of Alternative Medicine, prior to repeal by Pub. L. 105-277, div. A, §101(f) [title VI, §601(1)], Oct. 21, 1998, 112 Stat. 2681-337, 2681-387.

AMENDMENTS

2014—Subsec. (a)(1). Pub. L. 113-166, §2(1), substituted “Musculoskeletal” for “Muscockeletal” and inserted “Becker, congenital muscular dystrophy, limb-girdle muscular dystrophy,” after “Duchenne.”

Subsec. (b)(2). Pub. L. 113-166, §2(2)(A), substituted “cardiac and pulmonary function, and pharmacological” for “genetics, pharmacological”.

Subsec. (b)(3). Pub. L. 113-166, §2(2)(B), inserted “and sharing of data” after “regular communication”.

Subsec. (d)(2). Pub. L. 113-166, §2(3)(A)(i), substituted “18” for “15” in introductory provisions.

Subsec. (d)(2)(A). Pub. L. 113-166, §2(3)(A)(ii), substituted “, the Food and Drug Administration, and the Administration for Community Living” for “and the Food and Drug Administration” and “including the Department of Education and the Social Security Administration” for “such as the Department of Education” and inserted “and adults” after “children”.

Subsec. (d)(4)(B). Pub. L. 113-166, §2(3)(B), inserted “, but shall meet no fewer than two times per calendar year” before period at end.

Subsec. (e)(1). Pub. L. 113-166, §2(4)(A)(i), substituted “through the agencies represented on the Coordinating Committee pursuant to subsection (d)(2)(A)” for “through the national research institutes” in introductory provisions.

Subsec. (e)(1)(A). Pub. L. 113-166, §2(4)(A)(ii), inserted “public services,” after “psychosocial,” and “, studies to demonstrate the cost-effectiveness of providing inde-

<sup>2</sup> So in original. Probably should be capitalized.

pendent living resources and support to patients with various forms of muscular dystrophy, and studies to determine optimal clinical care interventions for adults with various forms of muscular dystrophy” after “including studies of the impact of such diseases in rural and underserved communities”.

Subsec. (e)(2)(D). Pub. L. 113-166, §2(4)(B), inserted “and new clinical interventions to improve the health of those with muscular dystrophy” after “including new biological agents”.

2008—Subsec. (a)(1). Pub. L. 110-361, §2(b)(1), inserted “the National Heart, Lung, and Blood Institute,” after “the Eunice Kennedy Shriver National Institute of Child Health and Human Development.”

Subsec. (b)(1). Pub. L. 110-361, §2(b)(2), inserted at end “Such centers of excellence shall be known as the ‘Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers.’”

Subsec. (f). Pub. L. 110-361, §2(a), redesignated subsec. (g) as (f) and struck out former subsec. (f) which related to reports.

Subsec. (g). Pub. L. 110-361, §2(a), (b)(3), added subsec. (g) and redesignated former subsec. (g) as (f).

2007—Pub. L. 109-482, §104(b)(1)(A)(ii), which directed amendment of subsec. (b) by striking subsec. (f) and redesignating subsec. (g) as (f), could not literally be executed and was not executed in view of amendments by Pub. L. 110-361. See 2008 Amendment notes above.

Subsec. (a)(1). Pub. L. 110-154 substituted “Eunice Kennedy Shriver National Institute of Child Health and Human Development” for “National Institute of Child Health and Human Development”.

Subsec. (b)(3). Pub. L. 109-482, §104(b)(1)(A)(i), amended heading and text of par. (3) generally. Text read as follows: “The Director of NIH—

“(A) shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers; and

“(B) shall require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director.”

Subsec. (h). Pub. L. 109-482, §103(b)(4), struck out heading and text of subsec. (h). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2002 through 2006. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriations that is available for conducting or supporting through the National Institutes of Health research and other activities with respect to muscular dystrophy.”

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

### §§ 283h, 283i. Transferred

#### CODIFICATION

Section 283h, act July 1, 1944, ch. 373, title IV, §404F, as added Pub. L. 107-280, §3, Nov. 6, 2002, 116 Stat. 1989; amended Pub. L. 109-482, title I, §§103(b)(5), 104(b)(1)(B), Jan. 15, 2007, 120 Stat. 3687, 3693, which related to the Office of Rare Diseases, was renumbered section 481 of act July 1, 1944, by Pub. L. 112-74, div. F, title II, §221(c)(2)(A)(i), Dec. 23, 2011, 125 Stat. 1089, and transferred to section 287a-1 of this title.

Section 283i, act July 1, 1944, ch. 373, title IV, §404G, as added Pub. L. 107-280, §4, Nov. 6, 2002, 116 Stat. 1990; amended Pub. L. 109-482, title I, §103(b)(6), Jan. 15, 2007, 120 Stat. 3687, which related to rare disease regional centers of excellence, was renumbered section 481A of act July 1, 1944, by Pub. L. 112-74, div. F, title II, §221(c)(3), Dec. 23, 2011, 125 Stat. 1089, and transferred to section 287a-2 of this title.

### § 283j. Repealed. Pub. L. 114-255, div. A, title II, § 2042(f)(1), Dec. 13, 2016, 130 Stat. 1073

Section, July 1, 1944, ch. 373, title IV, §404H, as added Pub. L. 109-416, §2(b), Dec. 19, 2006, 120 Stat. 2821, required review and report on centers of excellence funded under this subchapter.

### § 283k. Biomedical and behavioral research facilities

#### (a) Modernization and construction of facilities

##### (1) In general

The Director of NIH, acting through the Office of the Director of NIH or the Director of the National Institute of Allergy and Infectious Diseases, may make grants or contracts to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities, subject to the provisions of this section.

##### (2) Construction and cost of construction

For purposes of this section, the terms “construction” and “cost of construction” include the construction of new buildings and the expansion, renovation, remodeling, and alteration of existing buildings, including architects’ fees, but do not include the cost of acquisition of land or off-site improvements.

#### (b) Scientific and technical review boards for merit-based review of proposals

##### (1) In general: approval as precondition to grants

###### (A) Establishment

There is established a Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities (referred to in this section as the “Board”).

###### (B) Requirement

The Director of NIH, acting through the Office of the Director of NIH, may approve an application for a grant under subsection (a) only if the Board has under paragraph (2) recommended the application for approval.

##### (2) Duties

###### (A) Advice

The Board shall provide advice to the Director of NIH and the Council of Councils established under section 282(l) of this title (in this section referred to as the “Council”) in carrying out this section.

###### (B) Determination of merit

In carrying out subparagraph (A), the Board shall make a determination of the merit of each application submitted for a grant under subsection (a), after consideration of the requirements established in subsection (c), and shall report the results of the determination to the Director of NIH and the Council. Such determinations shall be conducted in a manner consistent with procedures established under section 289a of this title.

###### (C) Amount

In carrying out subparagraph (A), the Board shall, in the case of applications rec-

ommended for approval, make recommendations to the Director and the Council on the amount that should be provided under the grant.

**(D) Annual report**

In carrying out subparagraph (A), the Board shall prepare an annual report for the Director of NIH and the Council describing the activities of the Board in the fiscal year for which the report is made. Each such report shall be available to the public, and shall—

- (i) summarize and analyze expenditures made under this section;
- (ii) provide a summary of the types, numbers, and amounts of applications that were recommended for grants under subsection (a) but that were not approved by the Director of NIH; and
- (iii) contain the recommendations of the Board for any changes in the administration of this section.

**(3) Membership**

**(A) In general**

Subject to subparagraph (B), the Board shall be composed of 15 members to be appointed by the Director of NIH, acting through the Office of the Director of NIH, and such ad-hoc or temporary members as the Director of NIH, acting through the Office of the Director of NIH, determines to be appropriate. All members of the Board, including temporary and ad-hoc members, shall be voting members.

**(B) Limitation**

Not more than three individuals who are officers or employees of the Federal Government may serve as members of the Board.

**(4) Certain requirements regarding membership**

In selecting individuals for membership on the Board, the Director of NIH, acting through the Office of the Director of NIH, shall ensure that the members are individuals who, by virtue of their training or experience, are eminently qualified to perform peer review functions. In selecting such individuals for such membership, the Director of NIH, acting through the Office of the Director of NIH, shall ensure that the members of the Board collectively—

- (A) are experienced in the planning, construction, financing, and administration of entities that conduct biomedical or behavioral research sciences;
- (B) are knowledgeable in making determinations of the need of entities for biomedical or behavioral research facilities, including such facilities for the dentistry, nursing, pharmacy, and allied health professions;
- (C) are knowledgeable in evaluating the relative priorities for applications for grants under subsection (a) in view of the overall research needs of the United States; and
- (D) are experienced with emerging centers of excellence, as described in subsection (c)(2).

**(5) Certain authorities**

**(A) Workshops and conferences**

In carrying out paragraph (2), the Board may convene workshops and conferences, and collect data as the Board considers appropriate.

**(B) Subcommittees**

In carrying out paragraph (2), the Board may establish subcommittees within the Board. Such subcommittees may hold meetings as determined necessary to enable the subcommittee to carry out its duties.

**(6) Terms**

**(A) In general**

Except as provided in subparagraph (B), each appointed member of the Board shall hold office for a term of 4 years. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of the term of the predecessor.

**(B) Staggered terms**

Members appointed to the Board shall serve staggered terms as specified by the Director of NIH, acting through the Office of the Director of NIH, when making the appointments.

**(C) Reappointment**

No member of the Board shall be eligible for reappointment to the Board until 1 year has elapsed after the end of the most recent term of the member.

**(7) Compensation**

Members of the Board who are not officers or employees of the United States shall receive for each day the members are engaged in the performance of the functions of the Board compensation at the same rate received by members of other national advisory councils established under this subchapter.

**(c) Requirements for grants**

**(1) In general**

The Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, may make a grant under subsection (a) only if the applicant for the grant meets the following conditions:

- (A) The applicant is determined by such Director to be competent to engage in the type of research for which the proposed facility is to be constructed.
- (B) The applicant provides assurances satisfactory to the Director that—
  - (i) for not less than 20 years after completion of the construction involved, the facility will be used for the purposes of the research for which it is to be constructed;
  - (ii) sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility;
  - (iii) sufficient funds will be available, when construction is completed, for the effective use of the facility for the research for which it is being constructed; and

(iv) the proposed construction will expand the applicant's capacity for research, or is necessary to improve or maintain the quality of the applicant's research.

(C) The applicant meets reasonable qualifications established by the Director with respect to—

(i) the relative scientific and technical merit of the applications, and the relative effectiveness of the proposed facilities, in expanding the capacity for biomedical or behavioral research and in improving the quality of such research;

(ii) the quality of the research or training, or both, to be carried out in the facilities involved;

(iii) the congruence of the research activities to be carried out within the facility with the research and investigator manpower needs of the United States; and

(iv) the age and condition of existing research facilities.

(D) The applicant has demonstrated a commitment to enhancing and expanding the research productivity of the applicant.

## **(2) Institutions of emerging excellence**

From the amount appropriated to carry out this section for a fiscal year up to \$50,000,000, the Director of NIH, acting through the Office of the Director of NIH, shall make available 25 percent of such amount, and from the amount appropriated to carry out this section for a fiscal year that is over \$50,000,000, the Director of NIH, acting through the Office of the Director of NIH, shall make available up to 25 percent of such amount, for grants under subsection (a) to applicants that in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:

(A) The applicant has a plan for research or training advancement and possesses the ability to carry out the plan.

(B) The applicant carries out research and research training programs that have a special relevance to a problem, concern, or unmet health need of the United States.

(C) The applicant has been productive in research or research development and training.

(D) The applicant—

(i) has been designated as a center of excellence under section 293c<sup>1</sup> of this title;

(ii) is located in a geographic area whose population includes a significant number of individuals with health status deficit, and the applicant provides health services to such individuals; or

(iii) is located in a geographic area in which a deficit in health care technology, services, or research resources may adversely affect the health status of the population of the area in the future, and the applicant is carrying out activities with respect to protecting the health status of such population.

## **(d) Requirement of application**

The Director of NIH, acting through the Office of the Director of NIH or the National Institute

of Allergy and Infectious Diseases, may make a grant under subsection (a) only if an application for the grant is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

## **(e) Amount of grant; payments**

### **(1) Amount**

The amount of any grant awarded under subsection (a) shall be determined by the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases,<sup>2</sup> except that such amount shall not exceed—

(A) 50 percent (or, in the case of the Institute, 75 percent) of the necessary cost of the construction of a proposed facility as determined by the Director; or

(B) in the case of a multipurpose facility, 40 percent (or, in the case of the Institute, 75 percent) of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

### **(2) Reservation of amounts**

On the approval of any application for a grant under subsection (a), the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, shall reserve, from any appropriation available for such grants, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with the construction progress, as the Director may determine appropriate. The reservation of any amount by the Director under this paragraph may be amended by the Director, either on the approval of an amendment of the application or on the revision of the estimated cost of construction of the facility.

### **(3) Exclusion of certain costs**

In determining the amount of any grant under subsection (a), there shall be excluded from the cost of construction an amount equal to the sum of—

(A) the amount of any other Federal grant that the applicant has obtained, or is assured of obtaining, with respect to construction that is to be financed in part by a grant authorized under this section; and

(B) the amount of any non-Federal funds required to be expended as a condition of such other Federal grant.

### **(4) Waiver of limitations**

The limitations imposed under paragraph (1) may be waived at the discretion of the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, for applicants meeting the conditions described in subsection (c).

### **(f) Recapture of payments**

If, not later than 20 years after the completion of construction for which a grant has been awarded under subsection (a)—

<sup>1</sup> See References in Text note below.

<sup>2</sup> So in original.

(1) in the case of an award by the Director of NIH, acting through the Office of the Director of NIH, the applicant or other owner of the facility shall cease to be a public or non profit<sup>3</sup> private entity; or

(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so),

the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

#### (g) Guidelines

Not later than 6 months after June 10, 1993, the Director of NIH, acting through the Office of the Director of NIH, after consultation with the Council, shall issue guidelines with respect to grants under subsection (a).

(July 1, 1944, ch. 373, title IV, §404I, formerly §481A, as added Pub. L. 103-43, title XV, §1502, June 10, 1993, 107 Stat. 173; amended Pub. L. 105-392, title I, §101(c), Nov. 13, 1998, 112 Stat. 3537; Pub. L. 106-505, title III, §303, Nov. 13, 2000, 114 Stat. 2330; Pub. L. 108-276, §2(b), July 21, 2004, 118 Stat. 841; Pub. L. 109-482, title I, §§103(b)(40), 104(b)(1)(M), Jan. 15, 2007, 120 Stat. 3688, 3693; renumbered §404I and amended Pub. L. 112-74, div. F, title II, §221(b)(1), Dec. 23, 2011, 125 Stat. 1087.)

#### REFERENCES IN TEXT

Section 293c of this title, referred to in subsec. (c)(2)(D)(i), does not contain provisions relating to designation as a center of excellence. See section 293 of this title.

#### CODIFICATION

Section was formerly classified to section 287a-2 of this title.

#### AMENDMENTS

2011—Subsec. (a)(1). Pub. L. 112-74, §221(b)(1)(B)(i), substituted “acting through the Office of the Director of NIH or the Director of the National Institute of Allergy and Infectious Diseases” for “acting through the Director of the Center or the Director of the National Institute of Allergy and Infectious Diseases”.

Subsec. (b)(1)(A). Pub. L. 112-74, §221(b)(1)(B)(vi)(I), struck out “within the Center” after “established”.

Subsec. (b)(1)(B). Pub. L. 112-74, §221(b)(1)(B)(v), substituted “Director of NIH, acting through the Office of the Director of NIH,” for “Director of the Center”.

Subsec. (b)(2)(A). Pub. L. 112-74, §221(b)(1)(B)(vi)(II)(aa), substituted “and the Council of Councils established under section 282(l) of this title (in this section referred to as the ‘Council’)” for “and the advisory council established under section 287a of this title (in this section referred to as the ‘Advisory Council’)”.

Pub. L. 112-74, §221(b)(1)(B)(iii), substituted “Director of NIH” for “Director of the Center”.

Subsec. (b)(2)(B). Pub. L. 112-74, §221(b)(1)(B)(vi)(II)(bb), struck out “Advisory” before “Council”.

Pub. L. 112-74, §221(b)(1)(B)(iii), substituted “Director of NIH” for “Director of the Center”.

Subsec. (b)(2)(C). Pub. L. 112-74, §221(b)(1)(B)(vi)(II)(bb), struck out “Advisory” before “Council”.

Subsec. (b)(2)(D). Pub. L. 112-74, §221(b)(1)(B)(vi)(II)(bb), struck out “Advisory” before “Council”.

Pub. L. 112-74, §221(b)(1)(B)(iii), substituted “Director of NIH” for “Director of the Center” in introductory provisions and cl. (ii).

Subsec. (b)(3)(A). Pub. L. 112-74, §221(b)(1)(B)(v), substituted “Director of NIH, acting through the Office of the Director of NIH,” for “Director of the Center” in two places.

Pub. L. 112-74, §221(b)(1)(B)(iv), struck out comma after “Director of the Center” the first place appearing.

Subsec. (b)(4). Pub. L. 112-74, §221(b)(1)(B)(v), substituted “Director of NIH, acting through the Office of the Director of NIH,” for “Director of the Center” in two places in introductory provisions.

Subsec. (b)(6)(B). Pub. L. 112-74, §221(b)(1)(B)(v), substituted “Director of NIH, acting through the Office of the Director of NIH,” for “Director of the Center”.

Subsec. (c)(1). Pub. L. 112-74, §221(b)(1)(B)(ii), substituted “Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases,” for “Director of the Center or the Director of the National Institute of Allergy and Infectious Diseases” in introductory provisions.

Subsec. (c)(2). Pub. L. 112-74, §221(b)(1)(B)(v), substituted “Director of NIH, acting through the Office of the Director of NIH,” for “Director of the Center” in two places in introductory provisions.

Subsec. (d). Pub. L. 112-74, §221(b)(1)(B)(ii), substituted “Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases,” for “Director of the Center or the Director of the National Institute of Allergy and Infectious Diseases”.

Subsec. (e). Pub. L. 112-74, §221(b)(1)(B)(ii), substituted “Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases,” for “Director of the Center or the Director of the National Institute of Allergy and Infectious Diseases” wherever appearing.

Subsec. (f)(1). Pub. L. 112-74, §221(b)(1)(B)(v), substituted “Director of NIH, acting through the Office of the Director of NIH,” for “Director of the Center”.

Pub. L. 112-74, §221(b)(1)(B)(iv), struck out comma after “Director of the Center”.

Subsec. (f)(2). Pub. L. 112-74, §221(b)(1)(B)(ii), substituted “Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases,” for “Director of the Center or the Director of the National Institute of Allergy and Infectious Diseases”.

Subsec. (g). Pub. L. 112-74, §221(b)(1)(B)(vii), substituted “after consultation with the Council” for “after consultation with the Advisory Council”.

Pub. L. 112-74, §221(b)(1)(B)(v), substituted “Director of NIH, acting through the Office of the Director of NIH,” for “Director of the Center”.

Pub. L. 112-74, §221(b)(1)(B)(iv), struck out comma after “Director of the Center”.

2007—Subsec. (c)(2). Pub. L. 109-482, §103(b)(40)(A), in introductory provisions, substituted “to carry out this section for a fiscal year up to” for “under subsection (i)(1) of this section for a fiscal year up to” and “to carry out this section for a fiscal year that” for “under such subsection for a fiscal year that”.

Subsec. (h). Pub. L. 109-482, §104(b)(1)(M), struck out subsec. (h) which required biennial report concerning the status of biomedical and behavioral research facilities and the availability and condition of laboratory equipment.

Subsec. (i). Pub. L. 109-482, §103(b)(40)(B), struck out subsec. (i) which authorized appropriations for the Na-

<sup>3</sup> So in original. Probably should be “nonprofit”.

tional Center for Research Resources and the National Institute of Allergy and Infectious Diseases.

2004—Subsec. (a)(1). Pub. L. 108-276, §2(b)(1), inserted “or the Director of the National Institute of Allergy and Infectious Diseases” after “Director of the Center”.

Subsec. (c)(1). Pub. L. 108-276, §2(b)(2)(A), inserted “or the Director of the National Institute of Allergy and Infectious Diseases” after “Director of the Center”.

Subsec. (c)(2). Pub. L. 108-276, §2(b)(2)(B), substituted “subsection (i)(1)” for “subsection (i)” in introductory provisions.

Subsec. (d). Pub. L. 108-276, §2(b)(3), inserted “or the Director of the National Institute of Allergy and Infectious Diseases” after “Director of the Center”.

Subsec. (e)(1). Pub. L. 108-276, §2(b)(4)(A)(i), inserted “or the Director of the National Institute of Allergy and Infectious Diseases” after “Director of the Center” in introductory provisions.

Subsec. (e)(1)(A). Pub. L. 108-276, §2(b)(4)(A)(ii), inserted “(or, in the case of the Institute, 75 percent)” after “50 percent”.

Subsec. (e)(1)(B). Pub. L. 108-276, §2(b)(4)(A)(iii), inserted “(or, in the case of the Institute, 75 percent)” after “40 percent”.

Subsec. (e)(2). Pub. L. 108-276, §2(b)(4)(B), inserted “or the Director of the National Institute of Allergy and Infectious Diseases” after “Director of the Center”.

Subsec. (e)(4). Pub. L. 108-276, §2(b)(4)(C), inserted “of the Center or the Director of the National Institute of Allergy and Infectious Diseases” after “Director”.

Subsec. (f)(1). Pub. L. 108-276, §2(b)(5)(A), inserted “in the case of an award by the Director of the Center,” before “the applicant”.

Subsec. (f)(2). Pub. L. 108-276, §2(b)(5)(B), inserted “of the Center or the Director of the National Institute of Allergy and Infectious Diseases” after “Director”.

Subsec. (i). Pub. L. 108-276, §2(b)(6), designated existing provisions as par. (1), inserted heading, substituted “For the purpose of carrying out this section with respect to the Center,” for “For the purpose of carrying out this section,” and added par. (2).

2000—Pub. L. 106-505 amended section generally, adding provisions requiring the Director to provide Congress with biennial status reports.

1998—Subsec. (c)(3)(D)(i). Pub. L. 105-392 substituted “part B of subchapter V of this chapter” for “section 293c of this title”.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### FINDINGS

Pub. L. 106-505, title III, §302, Nov. 13, 2000, 114 Stat. 2330, provided that: “Congress finds that—

“(1) the National Institutes of Health is the principal source of Federal funding for medical research at universities and other research institutions in the United States;

“(2) the National Institutes of Health has received a substantial increase in research funding from Congress for the purpose of expanding the national investment of the United States in behavioral and biomedical research;

“(3) the infrastructure of our research institutions is central to the continued leadership of the United States in medical research;

“(4) as Congress increases the investment in cutting-edge basic and clinical research, it is critical that Congress also examine the current quality of the laboratories and buildings where research is being conducted, as well as the quality of laboratory equipment used in research;

“(5) many of the research facilities and laboratories in the United States are outdated and inadequate;

“(6) the National Science Foundation found, in a 1998 report on the status of biomedical research fa-

cilities, that over 60 percent of research-performing institutions indicated that they had an inadequate amount of medical research space;

“(7) the National Science Foundation reports that academic institutions have deferred nearly \$11,000,000,000 in renovation and construction projects because of a lack of funds; and

“(8) future increases in Federal funding for the National Institutes of Health must include increased support for the renovation and construction of extramural research facilities in the United States and the purchase of state-of-the-art laboratory instrumentation.”

#### § 283I. Construction of regional centers for research on primates

(a) With respect to activities carried out by the Director of NIH, acting through the Office of the Director of NIH, to support regional centers for research on primates, the Director of NIH may, for each of the fiscal years 2000 through 2002, reserve from the amounts appropriated to carry out section 283k of this title such sums as necessary for the purpose of making awards of grants and contracts to public or nonprofit private entities to construct, renovate, or otherwise improve such regional centers. The reservation of such amounts for any fiscal year is subject to the availability of qualified applicants for such awards.

(b) The Director of NIH may not make a grant or enter into a contract under subsection (a) unless the applicant for such assistance agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such subsection, to make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount equal to not less than \$1 for each \$4 of Federal funds provided in such assistance.

(July 1, 1944, ch. 373, title IV, §404J, formerly §481B, as added Pub. L. 103-43, title XV, §1503, June 10, 1993, 107 Stat. 178; amended Pub. L. 105-392, title IV, §411, Nov. 13, 1998, 112 Stat. 3590; Pub. L. 106-505, title III, §304, Nov. 13, 2000, 114 Stat. 2335; Pub. L. 109-482, title I, §103(b)(41), Jan. 15, 2007, 120 Stat. 3688; renumbered §404J and amended Pub. L. 112-74, div. F, title II, §221(b)(2), Dec. 23, 2011, 125 Stat. 1088.)

#### CODIFICATION

Section was formerly classified to section 287a-3 of this title.

#### AMENDMENTS

2011—Subsec. (a). Pub. L. 112-74, §221(b)(2)(B), substituted “by the Director of NIH, acting through the Office of the Director of NIH,” for “by the National Center for Research Resources” and “283k” for “287a-2”.

2007—Subsec. (a). Pub. L. 109-482, which directed the substitution of “to carry out section 287a-2” for “under section 287a-2(h)”, was executed by making substitution for “under section 287a-2(i)”, to reflect the probable intent of Congress.

2000—Subsec. (a). Pub. L. 106-505, which directed the amendment of subsec. (a) by substituting “2000 through 2002, reserve from the amounts appropriated under section 287a-2(i) of this title such sums as necessary” for “1994” and all that follows through “\$5,000,000”, was executed by making the substitution for “1994 through 1996, reserve from the amounts appropriated under section 287a-2(h) of this title up to \$2,500,000”, to reflect

the probable intent of Congress and the amendment by Pub. L. 105-392. See 1998 Amendment note below.

1998—Subsec. (a). Pub. L. 105-392, in first sentence, substituted “may” for “shall” and “up to \$2,500,000” for “\$5,000,000”.

**EFFECTIVE DATE OF 2007 AMENDMENT**

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 283m. Sanctuary system for surplus chimpanzees**

**(a) In general**

The Secretary shall provide for the establishment and operation in accordance with this section of a system to provide for the lifetime care of chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by the National Institutes of Health, the Food and Drug Administration, or other agencies of the Federal Government, and with respect to which it has been determined by the Secretary that the chimpanzees are not needed for such research (in this section referred to as “surplus chimpanzees”).

**(b) Administration of sanctuary system**

The Secretary shall carry out this section, including the establishment of regulations under subsection (d), in consultation with the board of directors of the nonprofit private entity that receives the contract under subsection (e) (relating to the operation of the sanctuary system).

**(c) Acceptance of chimpanzees into system**

All surplus chimpanzees owned by the Federal Government shall be accepted into the sanctuary system. Subject to standards under subsection (d)(4), any chimpanzee that is not owned by the Federal Government can be accepted into the system if the owner transfers to the sanctuary system title to the chimpanzee.

**(d) Standards for permanent retirement of surplus chimpanzees**

**(1) In general**

Not later than 180 days after December 20, 2000, the Secretary shall by regulation establish standards for operating the sanctuary system to provide for the permanent retirement of surplus chimpanzees. In establishing the standards, the Secretary shall consider the recommendations of the board of directors of the nonprofit private entity that receives the contract under subsection (e), and shall consider the recommendations of the National Research Council applicable to surplus chimpanzees that are made in the report published in 1997 and entitled “Chimpanzees in Research—Strategies for Their Ethical Care, Management, and Use”.

**(2) Chimpanzees accepted into system**

With respect to chimpanzees that are accepted into the sanctuary system, standards under paragraph (1) shall include the following:

(A) A prohibition that the chimpanzees may not be used for research, except as authorized under paragraph (3).

(B) Provisions regarding the housing of the chimpanzees.

(C) Provisions regarding the behavioral well-being of the chimpanzees.

(D) A requirement that the chimpanzees be cared for in accordance with the Animal Welfare Act [7 U.S.C. 2131 et seq.].

(E) A requirement that the chimpanzees be prevented from breeding.

(F) A requirement that complete histories be maintained on the health and use in research of the chimpanzees.

(G) A requirement that the chimpanzees be monitored for the purpose of promptly detecting the presence in the chimpanzees of any condition that may be a threat to the public health or the health of other chimpanzees.

(H) A requirement that chimpanzees posing such a threat be contained in accordance with applicable recommendations of the Director of the Centers for Disease Control and Prevention.

(I) A prohibition that none of the chimpanzees may be subjected to euthanasia, except as in the best interests of the chimpanzee involved, as determined by the system and an attending veterinarian.

(J) A prohibition that the chimpanzees may not be discharged from the system.

(K) A provision that the Secretary may, in the discretion of the Secretary, accept into the system chimpanzees that are not surplus chimpanzees.

(L) Such additional standards as the Secretary determines to be appropriate.

**(3) Restrictions regarding research**

**(A) In general**

For purposes of paragraph (2)(A), standards under paragraph (1) shall provide that a chimpanzee accepted into the sanctuary system may not be used for studies or research, except that the chimpanzee may be used for noninvasive behavioral studies or medical studies based on information collected during the course of normal veterinary care that is provided for the benefit of the chimpanzee, provided that any such study involves minimal physical and mental harm, pain, distress, and disturbance to the chimpanzee and the social group in which the chimpanzee lives.

**(B) Additional restriction**

For purposes of paragraph (2)(A), a condition for the use in studies or research of a chimpanzee accepted into the sanctuary system is (in addition to conditions under subparagraph (A) of this paragraph) that the applicant for such use has not been fined for, or signed a consent decree for, any violation of the Animal Welfare Act [7 U.S.C. 2131 et seq.].

**(4) Non-Federal chimpanzees offered for acceptance into system**

With respect to a chimpanzee that is not owned by the Federal Government and is offered for acceptance into the sanctuary system, standards under paragraph (1) shall include the following:

(A) A provision that the Secretary may authorize the imposition of a fee for accepting such chimpanzee into the system, except as follows:

(i) Such a fee may not be imposed for accepting the chimpanzee if, on the day before December 20, 2000, the chimpanzee was owned by the nonprofit private entity that receives the contract under subsection (e) or by any individual sanctuary facility receiving a subcontract or grant under subsection (e)(1).

(ii) Such a fee may not be imposed for accepting the chimpanzee if the chimpanzee is owned by an entity that operates a primate center, and if the chimpanzee is housed in the primate center pursuant to the program for regional centers for research on primates that is carried out by the Director of NIH, acting through the Office of the Director of NIH.<sup>1</sup>

Any fees collected under this subparagraph are available to the Secretary for the costs of operating the system. Any other fees received by the Secretary for the long-term care of chimpanzees (including any Federal fees that are collected for such purpose and are identified in the report under section 3 of the Chimpanzee Health Improvement, Maintenance, and Protection Act) are available for operating the system, in addition to availability for such other purposes as may be authorized for the use of the fees.

(B) A provision that the Secretary may deny such chimpanzee acceptance into the system if the capacity of the system is not sufficient to accept the chimpanzee, taking into account the physical capacity of the system; the financial resources of the system; the number of individuals serving as the staff of the system, including the number of professional staff; the necessity of providing for the safety of the staff and of the public; the necessity of caring for accepted chimpanzees in accordance with the standards under paragraph (1); and such other factors as may be appropriate.

(C) A provision that the Secretary may deny such chimpanzee acceptance into the system if a complete history of the health and use in research of the chimpanzee is not available to the Secretary.

(D) Such additional standards as the Secretary determines to be appropriate.

**(e) Award of contract for operation of system**

**(1) In general**

Subject to the availability of funds pursuant to subsection (g), the Secretary shall make an award of a contract to a nonprofit private entity under which the entity has the responsibility of operating (and establishing, as applicable) the sanctuary system and awarding subcontracts or grants to individual sanctuary facilities that meet the standards under subsection (d).

**(2) Requirements**

The Secretary may make an award under paragraph (1) to a nonprofit private entity

only if the entity meets the following requirements:

(A) The entity has a governing board of directors that is composed and appointed in accordance with paragraph (3) and is satisfactory to the Secretary.

(B) The terms of service for members of such board are in accordance with paragraph (3).

(C) The members of the board serve without compensation. The members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the board.

(D) The entity has an executive director meeting such requirements as the Secretary determines to be appropriate.

(E) The entity makes the agreement described in paragraph (4) (relating to non-Federal contributions).

(F) The entity agrees to comply with standards under subsection (d).

(G) The entity agrees to make necropsy reports on chimpanzees in the sanctuary system available on a reasonable basis to persons who conduct biomedical or behavioral research, with priority given to such persons who are Federal employees or who receive financial support from the Federal Government for research.

(H) Such other requirements as the Secretary determines to be appropriate.

**(3) Board of directors**

For purposes of subparagraphs (A) and (B) of paragraph (2):

(A) The governing board of directors of the nonprofit private entity involved is composed and appointed in accordance with this paragraph if the following conditions are met:

(i) Such board is composed of not more than 13 voting members.

(ii) Such members include individuals with expertise and experience in the science of managing captive chimpanzees (including primate veterinary care), appointed from among individuals endorsed by organizations that represent individuals in such field.

(iii) Such members include individuals with expertise and experience in the field of animal protection, appointed from among individuals endorsed by organizations that represent individuals in such field.

(iv) Such members include individuals with expertise and experience in the zoological field (including behavioral primatology), appointed from among individuals endorsed by organizations that represent individuals in such field.

(v) Such members include individuals with expertise and experience in the field of the business and management of nonprofit organizations, appointed from among individuals endorsed by organizations that represent individuals in such field.

(vi) Such members include representatives from entities that provide accredita-

<sup>1</sup> So in original. Comma probably should not appear.

tion in the field of laboratory animal medicine.

(vii) Such members include individuals with expertise and experience in the field of containing biohazards.

(viii) Such members include an additional member who serves as the chair of the board, appointed from among individuals who have been endorsed for purposes of clause (ii), (iii), (iv), or (v).

(ix) None of the members of the board has been fined for, or signed a consent decree for, any violation of the Animal Welfare Act [7 U.S.C. 2131 et seq.].

(B) The terms of service for members of the board of directors are in accordance with this paragraph if the following conditions are met:

(i) The term of the chair of the board is 3 years.

(ii) The initial members of the board select, by a random method, one member from each of the six fields specified in subparagraph (A) to serve a term of 2 years and (in addition to the chair) one member from each of such fields to serve a term of 3 years.

(iii) After the initial terms under clause (ii) expire, each member of the board (other than the chair) is appointed to serve a term of 2 years.

(iv) An individual whose term of service expires may be reappointed to the board.

(v) A vacancy in the membership of the board is filled in the manner in which the original appointment was made.

(vi) If a member of the board does not serve the full term applicable to the member, the individual appointed to fill the resulting vacancy is appointed for the remainder of the term of the predecessor member.

#### (4) Requirement of matching funds

The agreement required in paragraph (2)(E) for a nonprofit private entity (relating to the award of the contract under paragraph (1)) is an agreement that, with respect to the costs to be incurred by the entity in establishing and operating the sanctuary system, the entity will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs, in cash or in kind, in an amount not less than the following, as applicable:

(A) For expenses associated with establishing the sanctuary system (as determined by the Secretary), 10 percent of such costs (\$1 for each \$9 of Federal funds provided under the contract under paragraph (1)).

(B) For expenses associated with operating the sanctuary system (as determined by the Secretary), 25 percent of such costs (\$1 for each \$3 of Federal funds provided under such contract).

#### (5) Establishment of contract entity

If the Secretary determines that an entity meeting the requirements of paragraph (2) does not exist, not later than 60 days after December 20, 2000, the Secretary shall, for pur-

poses of paragraph (1), make a grant for the establishment of such an entity, including paying the cost of incorporating the entity under the law of one of the States.

#### (f) Definitions

For purposes of this section:

##### (1) Permanent retirement

The term “permanent retirement”, with respect to a chimpanzee that has been accepted into the sanctuary system, means that under subsection (a) the system provides for the lifetime care of the chimpanzee, that under subsection (d)(2) the system does not permit the chimpanzee to be used in research (except as authorized under subsection (d)(3)) or to be euthanized (except as provided in subsection (d)(2)(I)), that under subsection (d)(2) the system will not discharge the chimpanzee from the system, and that under such subsection the system otherwise cares for the chimpanzee.

##### (2) Sanctuary system

The term “sanctuary system” means the system described in subsection (a).

##### (3) Secretary

The term “Secretary” means the Secretary of Health and Human Services.

##### (4) Surplus chimpanzees

The term “surplus chimpanzees” has the meaning given that term in subsection (a).

#### (g) Funding

##### (1) In general

Of the amount appropriated for the National Institutes of Health, there are authorized to be appropriated to carry out this section and for the care, maintenance, and transportation of all chimpanzees otherwise under the ownership or control of the National Institutes of Health, and to enable the National Institutes of Health to operate more efficiently and economically by decreasing the overall Federal cost of providing for the care, maintenance, and transportation of chimpanzees—

- (A) for fiscal year 2014, \$12,400,000;
- (B) for fiscal year 2015, \$11,650,000;
- (C) for fiscal year 2016, \$10,900,000;
- (D) for fiscal year 2017, \$10,150,000; and
- (E) for fiscal year 2018, \$9,400,000.

##### (2) Use of funds for other compliant facilities

With respect to amounts authorized to be appropriated by paragraph (1) for a fiscal year, the Secretary may use a portion of such amounts to make awards of grants or contracts to public or private entities operating facilities that, as determined by the Secretary in consultation with the board of directors of the nonprofit private entity that receives the contract under subsection (e), provide for the retirement of chimpanzees in accordance with the same standards that apply to the sanctuary system pursuant to regulations under subsection (d). Such an award may be expended for the expenses of operating the facilities involved.

##### (3) Biennial report

Not later than 180 days after November 27, 2013, the Director of the National Institutes of

Health shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations in the House of Representatives a report, to be updated biennially, regarding—

(A) the care, maintenance, and transportation of the chimpanzees under the ownership or control of the National Institutes of Health;

(B) costs related to such care, maintenance, and transportation, and any other related costs; and

(C) the research status of such chimpanzees.

(July 1, 1944, ch. 373, title IV, §404K, formerly §481C, as added Pub. L. 106-551, §2, Dec. 20, 2000, 114 Stat. 2752; amended Pub. L. 110-170, §2(a), Dec. 26, 2007, 121 Stat. 2465; renumbered §404K and amended Pub. L. 112-74, div. F, title II, §221(b)(3), Dec. 23, 2011, 125 Stat. 1088; Pub. L. 113-55, title III, §302(a), (c), Nov. 27, 2013, 127 Stat. 646, 647.)

#### REFERENCES IN TEXT

The Animal Welfare Act, referred to in subsecs. (d)(2)(D), (3)(B) and (e)(3)(A)(ix), is Pub. L. 89-544, Aug. 24, 1966, 80 Stat. 350, as amended, which is classified generally to chapter 54 (§2131 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 2131 of Title 7 and Tables.

Section 3 of the Chimpanzee Health Improvement, Maintenance, and Protection Act, referred to in subsec. (d)(4)(A), is section 3 of Pub. L. 106-551, which is set out as a note below.

#### CODIFICATION

Section was formerly classified to section 287a-3a of this title.

November 27, 2013, referred to in subsec. (g)(3), was in the original “the date enactment of this Act” (sic), which was translated as meaning the date of enactment of Pub. L. 113-55, which enacted par. (3), to reflect the probable intent of Congress.

#### AMENDMENTS

2013—Subsec. (g)(1). Pub. L. 113-55, §302(a)(1), amended par. (1) generally. Prior to amendment, text read as follows: “Of the amount appropriated under this chapter for fiscal year 2001 and each subsequent fiscal year, the Secretary, subject to paragraph (2), shall reserve a portion for purposes of the operation (and establishment, as applicable) of the sanctuary system and for purposes of paragraph (3), except that the Secretary may not for such purposes reserve any further funds from such amount after the aggregate total of the funds so reserved for such fiscal years reaches \$30,000,000. The purposes for which funds reserved under the preceding sentence may be expended include the construction and renovation of facilities for the sanctuary system.”

Subsec. (g)(2). Pub. L. 113-55, §302(a)(4), substituted “With respect to amounts authorized to be appropriated by paragraph (1)” for “With respect to amounts reserved under paragraph (1)” and “Secretary in consultation with the board of directors” for “board of directors”.

Pub. L. 113-55, §302(a)(2), (3), redesignated par. (3) as (2) and struck out former par. (2). Prior to amendment, text of par. (2) read as follows: “Funds may not be reserved for a fiscal year under paragraph (1) unless the amount appropriated under this chapter for such year equals or exceeds the amount appropriated under this chapter for fiscal year 1999.”

Subsec. (g)(3). Pub. L. 113-55, §302(c), added par. (3). Former par. (3) redesignated (2).

Pub. L. 113-55, §302(a)(3), redesignated par. (3) as (2). 2011—Subsec. (d)(4)(A)(ii). Pub. L. 112-74, §221(b)(3)(B), substituted “that is carried out by the Director of NIH, acting through the Office of the Director of NIH,” for “that is carried out by the National Center for Research Resources”.

2007—Subsec. (d)(2)(J). Pub. L. 110-170, §2(a)(1), struck out at end “If any chimpanzee is removed from a sanctuary facility for purposes of research authorized under paragraph (3)(A)(ii), the chimpanzee shall be returned immediately upon the completion of that research. All costs associated with the removal of the chimpanzee from the facility, with the care of the chimpanzee during such absence from the facility, and with the return of the chimpanzee to the facility shall be the responsibility of the entity that obtains approval under such paragraph regarding use of the chimpanzee and removes the chimpanzee from the sanctuary facility.”

Subsec. (d)(3)(A). Pub. L. 110-170, §2(a)(2)(A), substituted “except that the chimpanzee may be used for noninvasive behavioral studies” for “except as provided in clause (i) or (ii), as follows:

“(i) The chimpanzee may be used for noninvasive behavioral studies”

and struck out cl. (ii) which related to findings necessary before a chimpanzee may be used in research.

Subsec. (d)(3)(B), (C). Pub. L. 110-170, §2(a)(2)(B)-(D), redesignated subpar. (C) as (B), substituted “under subparagraph (A)” for “under subparagraphs (A) and (B)”, and struck out former subpar. (B) which related to approval of research design.

#### REPORT TO CONGRESS REGARDING NUMBER OF CHIMPANZEES AND FUNDING FOR CARE OF CHIMPANZEES

Pub. L. 106-551, §3, Dec. 20, 2000, 114 Stat. 2759, required the Secretary of Health and Human Services to submit a report to Congress, not later than 365 days after Dec. 20, 2000, about the chimpanzees that had been used, or bred or purchased for use, in research conducted or supported by the National Institutes of Health, the Food and Drug Administration, or other agencies of the Federal Government.

### § 283n. Shared Instrumentation Grant Program

#### (a) Requirements for grants

In determining whether to award a grant to an applicant under the Shared Instrumentation Grant Program, the Director of NIH, acting through the Office of the Director of NIH, shall consider—

(1) the extent to which an award for the specific instrument involved would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited;

(2) with respect to the instrument involved, the availability and commitment of the appropriate technical expertise within the major user group or the applicant institution for use of the instrumentation;

(3) the adequacy of the organizational plan for the use of the instrument involved and the internal advisory committee for oversight of the applicant, including sharing arrangements if any;

(4) the applicant’s commitment for continued support of the utilization and maintenance of the instrument; and

(5) the extent to which the specified instrument will be shared and the benefit of the proposed instrument to the overall research community to be served.

**(b) Peer review**

In awarding grants under the program described in subsection (a), the Director of NIH, acting through the Office of the Director of NIH, shall comply with the peer review requirements in section 289a of this title.

(July 1, 1944, ch. 373, title IV, § 404L, formerly Pub. L. 106-505, title III, § 305, Nov. 13, 2000, 114 Stat. 2335; renumbered July 1, 1944, ch. 373, title IV, § 404L, and amended Pub. L. 112-74, div. F, title II, § 221(b)(4), Dec. 23, 2011, 125 Stat. 1088.)

## CODIFICATION

Section was formerly set out as a note under section 287 of this title, prior to renumbering by Pub. L. 112-74.

## AMENDMENTS

2011—Pub. L. 112-74, § 221(b)(4)(B)(iii), substituted “Director of NIH, acting through the Office of the Director of NIH,” for “Director of the National Center for Research Resources” in subssecs. (a) and (b).

Subsec. (a). Pub. L. 112-74, § 221(b)(4)(B)(ii), substituted “under the Shared Instrumentation Grant Program” for “under the program described in subsection (a)” in introductory provisions.

Pub. L. 112-74, § 221(b)(4)(B)(i), redesignated subsec. (b) as (a) and struck out former subsec. (a). Prior to amendment, text of subsec. (a) read as follows: “There is authorized to be appropriated \$100,000,000 for fiscal year 2000, and such sums as may be necessary for each subsequent fiscal year, to enable the Secretary of Health and Human Services, acting through the Director of the National Center for Research Resources, to provide for the continued operation of the Shared Instrumentation Grant Program (initiated in fiscal year 1992 under the authority of section 287 of this title).”

Subsec. (b). Pub. L. 112-74, § 221(b)(4)(B)(iv), substituted “in subsection (a), the” for “in subsection (a)” and made technical amendment to reference in original act which appears in text as reference to section 289a of this title.

Pub. L. 112-74, § 221(b)(4)(B)(i), redesignated subsec. (c) as (b). Former subsec. (b) redesignated (a).

Subsec. (c). Pub. L. 112-74, § 221(b)(4)(B)(i), redesignated subsec. (c) as (b).

**§ 283o. Next generation of researchers****(a) Next generation of researchers initiative**

There shall be established within the Office of the Director of the National Institutes of Health, the Next Generation of Researchers Initiative (referred to in this section as the “Initiative”), through which the Director shall coordinate all policies and programs within the National Institutes of Health that are focused on promoting and providing opportunities for new researchers and earlier research independence.

**(b) Activities**

The Director of the National Institutes of Health, through the Initiative shall—

(1) promote policies and programs within the National Institutes of Health that are focused on improving opportunities for new researchers and promoting earlier research independence, including existing policies and programs, as appropriate;

(2) develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance

training and mentorship programs for researchers, and enhance workforce diversity;

(3) coordinate, as appropriate, with relevant agencies, professional and academic associations, academic institutions, and others, to improve and update existing information on the biomedical research workforce in order to inform programs related to the training, recruitment, and retention of biomedical researchers; and

(4) carry out other activities, including evaluation and oversight of existing programs, as appropriate, to promote the development of the next generation of researchers and earlier research independence.

(July 1, 1944, ch. 373, title IV, § 404M, as added Pub. L. 114-255, div. A, title II, § 2021(a), Dec. 13, 2016, 130 Stat. 1051.)

**§ 283p. Population focused research**

The Director of the National Institutes of Health shall, as appropriate, encourage efforts to improve research related to the health of sexual and gender minority populations, including by—

(1) facilitating increased participation of sexual and gender minority populations in clinical research supported by the National Institutes of Health, and reporting on such participation, as applicable;

(2) facilitating the development of valid and reliable methods for research relevant to sexual and gender minority populations; and

(3) addressing methodological challenges.

(July 1, 1944, ch. 373, title IV, § 404N, as added Pub. L. 114-255, div. A, title II, § 2038(d), Dec. 13, 2016, 130 Stat. 1065.)

## REPORTING

Pub. L. 114-255, div. A, title II, § 2038(e), Dec. 13, 2016, 130 Stat. 1065, provided that:

“(1) IN GENERAL.—The Secretary, in collaboration with the Director of the National Institutes of Health, shall as appropriate—

“(A) continue to support research for the development of appropriate measures related to reporting health information about sexual and gender minority populations; and

“(B) not later than 2 years after the date of enactment of this Act [Dec. 13, 2016], disseminate and make public such measures.

“(2) NATIONAL ACADEMY OF MEDICINE RECOMMENDATIONS.—In developing the measures described in paragraph (1)(A), the Secretary shall take into account recommendations made by the National Academy of Medicine.”

**§ 283q. Eureka prize competitions****(a) In general**

Pursuant to the authorities and processes established under section 3719 of title 15, the Director of the National Institutes of Health shall support prize competitions for one or both of the following goals:

(1) Identifying and funding areas of biomedical science that could realize significant advancements through a prize competition.

(2) Improving health outcomes, particularly with respect to human diseases and conditions—

(A) for which public and private investment in research is disproportionately small

relative to Federal Government expenditures on prevention and treatment activities with respect to such diseases and conditions, such that Federal expenditures on health programs would be reduced;

(B) that are serious and represent a significant disease burden in the United States; or

(C) for which there is potential for significant return on investment to the United States.

**(b) Tracking; reporting**

The Director of the National Institutes of Health shall—

(1) collect information on—

(A) the effect of innovations funded through the prize competitions under this section in advancing biomedical science or improving health outcomes pursuant to subsection (a); and

(B) the effect of the innovations on Federal expenditures; and

(2) include the information collected under paragraph (1) in the triennial report under section 283 of this title (as amended by section 2032).

(Pub. L. 114–255, div. A, title II, §2002, Dec. 13, 2016, 130 Stat. 1047.)

REFERENCES IN TEXT

Section 2032, referred to in subsec. (b)(2), means section 2032 of Pub. L. 114–255.

CODIFICATION

Section was enacted as part of the 21st Century Cures Act, and not as part of the Public Health Service Act which comprises this chapter.

PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

**§ 284. Directors of national research institutes**

**(a) Appointment**

**(1) In general**

The Director of the National Cancer Institute shall be appointed by the President, and the Directors of the other national research institutes and national centers shall be appointed by the Secretary, acting through the Director of National Institutes of Health. Each Director of a national research institute or national center shall report directly to the Director of National Institutes of Health.

**(2) Appointment**

**(A) Term**

A Director of a national research institute or national center who is appointed by the Secretary, acting through the Director of National Institutes of Health, shall be appointed for 5 years.

**(B) Reappointment**

At the end of the term of a Director of a national research institute or national center, the Director may be reappointed in accordance with standards applicable to the relevant appointment mechanism. There shall be no limit on the number of terms that a Director may serve.

**(C) Vacancies**

If the office of a Director of a national research institute or national center becomes

vacant before the end of such Director's term, the Director appointed to fill the vacancy shall be appointed for a 5-year term starting on the date of such appointment.

**(D) Current directors**

Each Director of a national research institute or national center who is serving on December 13, 2016, shall be deemed to be appointed for a 5-year term under this subsection beginning on such date.

**(E) Rule of construction**

Nothing in this subsection shall be construed to limit the authority of the Secretary or the Director of National Institutes of Health to terminate the appointment of a director referred to in subparagraph (A) before the expiration of such director's 5-year term.

**(F) Nature of appointment**

Appointments and reappointments under this subsection shall be made on the basis of ability and experience as it relates to the mission of the National Institutes of Health and its components, including compliance with any legal requirement that the Secretary or Director of National Institutes of Health determines relevant.

**(3) Nonapplication of certain provision**

The restrictions contained in section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note) related to consultants and individual scientists appointed for limited periods of time shall not apply to Directors appointed under this subsection.

**(b) Duties and authority; grants, contracts, and cooperative agreements**

(1) In carrying out the purposes of section 241 of this title with respect to human diseases or disorders or other aspects of human health for which the national research institutes were established, the Secretary, acting through the Director of each national research institute—

(A) shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to—

(i) the maintenance of health,

(ii) the detection, diagnosis, treatment, and prevention of human diseases and disorders,

(iii) the rehabilitation of individuals with human diseases, disorders, and disabilities, and

(iv) the expansion of knowledge of the processes underlying human diseases, disorders, and disabilities, the processes underlying the normal and pathological functioning of the body and its organ systems, and the processes underlying the interactions between the human organism and the environment;

(B) may, subject to the peer review prescribed under section 289a(b) of this title and any advisory council review under section 284a(a)(3)(A)(i) of this title, conduct the research, investigations, experiments, dem-

onstrations, and studies referred to in subparagraph (A);

(C) shall, as appropriate, conduct and support research that has the potential to transform the scientific field, has inherently higher risk, and that seeks to address major current challenges;

(D) may conduct and support research training (i) for which fellowship support is not provided under section 288 of this title, and (ii) which is not residency training of physicians or other health professionals;

(E) may develop, implement, and support demonstrations and programs for the application of the results of the activities of the institute to clinical practice and disease prevention activities;

(F) may develop, conduct, and support public and professional education and information programs;

(G) may secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research;

(H) may make available the facilities of the institute to appropriate entities and individuals engaged in research activities and cooperate with and assist Federal and State agencies charged with protecting the public health;

(I) may accept unconditional gifts made to the institute for its activities, and, in the case of gifts of a value in excess of \$50,000, establish suitable memorials to the donor;

(J) may secure for the institute consultation services and advice of persons from the United States or abroad;

(K) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(L) may accept voluntary and uncompensated services; and

(M) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute.

The indemnification provisions of section 2354 of title 10 shall apply with respect to contracts entered into under this subsection and section 282(b) of this title.

(2) Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements. The Secretary, acting through the Director of each national research institute—

(A) may enter into a contract for research, training, or demonstrations only if the contract has been recommended after technical and scientific peer review required by regulations under section 289a of this title;

(B) may make grants and cooperative agreements under paragraph (1) for research, training, or demonstrations, except that—

(i) if the direct cost of the grant or cooperative agreement to be made does not exceed \$50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 289a of this title, and

(ii) if the direct cost of the grant or cooperative agreement to be made exceeds

\$50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 289a of this title and is recommended under section 284a(a)(3)(A)(ii) of this title by the advisory council for the national research institute involved; and

(C) shall, subject to section 300cc-40c(d)(2) of this title, receive from the President and the Office of Management and Budget directly all funds appropriated by the Congress for obligation and expenditure by the Institute.

(3) Before an award is made by a national research institute or by a national center for a grant for a research program or project (commonly referred to as an “R-series grant”), other than an award constituting a noncompetitive renewal of such a grant, or a noncompetitive administrative supplement to such a grant, the Director of such national research institute or national center shall, consistent with the peer review process—

(A) review and make the final decision with respect to making the award; and

(B) take into consideration, as appropriate—

(i) the mission of the national research institute or national center and the scientific priorities identified in the strategic plan under section 282(m) of this title;

(ii) programs or projects funded by other agencies on similar research topics; and

(iii) advice by staff and the advisory council or board of such national research institute or national center.

**(c) Coordination with other public and private entities; cooperation with other national research institutes; appointment of additional peer review groups**

In carrying out subsection (b), each Director of a national research institute—

(1) shall coordinate, as appropriate, the activities of the institute with similar programs of other public and private entities;

(2) shall cooperate with the Directors of the other national research institutes in the development and support of multidisciplinary research and research that involves more than one institute;

(3) may, in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

(A) establish technical and scientific peer review groups in addition to those appointed under section 282(b)(16) of this title; and

(B) appoint the members of peer review groups established under subparagraph (A); and

(4) may publish, or arrange for the publication of, information with respect to the purpose of the Institute without regard to section 501 of title 44.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (3).

(July 1, 1944, ch. 373, title IV, §405, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 826; amended

Pub. L. 100-607, title I, §116, Nov. 4, 1988, 102 Stat. 3053; Pub. L. 100-690, title II, §2613(c), Nov. 18, 1988, 102 Stat. 4239; Pub. L. 103-43, title III, §301(a)(1), (b), June 10, 1993, 107 Stat. 150; Pub. L. 109-482, title I, §102(f)(1)(B), Jan. 15, 2007, 120 Stat. 3685; Pub. L. 114-255, div. A, title II, §§2033(a), (b), 2036(c), Dec. 13, 2016, 130 Stat. 1057, 1058, 1063.)

## REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (c), is Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, as amended, which is set out in the Appendix to Title 5, Government Organization and Employees.

## AMENDMENTS

2016—Subsec. (a). Pub. L. 114-255, §2033(a), amended subsec. (a) generally. Prior to amendment, text read as follows: “The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes shall be appointed by the Secretary. Each Director of a national research institute shall report directly to the Director of NIH.”

Subsec. (b)(1)(C) to (M). Pub. L. 114-255, §2036(c), added par. (C) and redesignated former pars. (C) to (L) as (D) to (M), respectively.

Subsec. (b)(3). Pub. L. 114-255, §2033(b), added par. (3). 2007—Subsec. (c)(3)(A). Pub. L. 109-482 substituted “section 282(b)(16)” for “section 282(b)(6)”.

1993—Subsec. (b)(2)(C). Pub. L. 103-43, §301(a)(1), added subpar. (C).

Subsec. (c). Pub. L. 103-43, §301(b)(2), inserted concluding provisions relating to Federal Advisory Committee Act.

Subsec. (c)(3). Pub. L. 103-43, §301(b)(1), amended par. (3) generally. Prior to amendment, par. (3) read as follows: “may, in consultation with the advisory council for the Institute and the approval of the Director of NIH, establish and appoint technical and scientific peer review groups in addition to those established and appointed under section 282(b)(6) of this title; and”.

1988—Subsec. (b)(1). Pub. L. 100-607, §116(1), struck out “the” after “with respect to” in introductory provisions.

Subsec. (c)(3). Pub. L. 100-690 substituted “establish and appoint” and “established and appointed” for “establish” and “established”, respectively.

Pub. L. 100-607, §116(2)(A), amended par. (3) generally. Prior to amendment, par. (3) read as follows: “may, with the approval of the advisory council for the institute and the Director of NIH, appoint technical and scientific peer review groups in addition to those appointed under section 282(b)(6) of this title.”

Subsec. (c)(4). Pub. L. 100-607, §116(2)(C), added par. (4).

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

## EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-690 effective immediately after enactment of Pub. L. 100-607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100-690, set out as a note under section 242m of this title.

## ENHANCING THE CLINICAL AND TRANSLATIONAL SCIENCE AWARD

Pub. L. 109-482, title I, §106, Jan. 15, 2007, 120 Stat. 3696, provided that:

“(a) IN GENERAL.—In administering the Clinical and Translational Science Award, the Director of NIH shall establish a mechanism to preserve independent funding and infrastructure for pediatric clinical research centers by—

“(1) allowing the appointment of a secondary principal investigator under a single Clinical and Translational Science Award, such that a pediatric principal investigator may be appointed with direct authority over a separate budget and infrastructure for pediatric clinical research; or

“(2) otherwise securing institutional independence of pediatric clinical research centers with respect to finances, infrastructure, resources, and research agenda.

“(b) REPORT.—As part of the biennial report under section 403 of the Public Health Service Act [42 U.S.C. 283], the Director of NIH shall provide an evaluation and comparison of outcomes and effectiveness of training programs under subsection (a).

“(c) DEFINITION.—For purposes of this section, the term ‘Director of NIH’ has the meaning given such term in section 401 of the Public Health Service Act [42 U.S.C. 281].”

## § 284a. Advisory councils

## (a) Establishment; acceptance of conditional gifts; functions

(1) Except as provided in subsection (h), the Secretary shall appoint an advisory council for each national research institute which (A) shall advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute on matters related to the activities carried out by and through the institute and the policies respecting such activities, and (B) shall carry out the special functions prescribed by part C.

(2) Each advisory council for a national research institute may recommend to the Secretary acceptance, in accordance with section 238 of this title, of conditional gifts for study, investigation, or research respecting the diseases, disorders, or other aspect of human health with respect to which the institute was established, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the institute.

(3) Each advisory council for a national research institute—

(A)(i) may on the basis of the materials provided under section 289a(b)(2) of this title respecting research conducted at the institute, make recommendations to the Director of the institute respecting such research,

(ii) may review applications for grants and cooperative agreements for research or training and for which advisory council approval is required under section 284(b)(2) of this title and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspect of human health with respect to which the institute was established and with the approval of the Director of the institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

**(b) Membership; compensation**

(1) Each advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary. The ex officio members shall be nonvoting members.

(2) The ex officio members of an advisory council shall consist of—

(A) the Secretary, the Director of NIH, the Director of the national research institute for which the council is established, the Under Secretary for Health of the Department of Veterans Affairs or the Chief Dental Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of an advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including not less than two individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the national research institute for which the advisory council is established.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of an advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule.

**(c) Term of office; reappointment; vacancy**

The term of office of an appointed member of an advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term for 180 days after the date of such expiration. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

**(d) Chairman; term of office**

The chairman of an advisory council shall be selected by the Secretary from among the ap-

pointed members, except that the Secretary may select the Director of the national research institute for which the advisory council is established to be the chairman of the advisory council. The term of office of the chairman shall be two years.

**(e) Meetings**

The advisory council shall meet at the call of the chairman or upon the request of the Director of the national research institute for which it was established, but at least three times each fiscal year. The location of the meetings of each advisory council is subject to the approval of the Director of the national research institute for which the advisory council was established.

**(f) Appointment of executive secretary; training and orientation for new members**

The Director of the national research institute for which an advisory council is established shall designate a member of the staff of the institute to serve as the executive secretary of the advisory council. The Director of such institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of such institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

**(g) Comments and recommendations for inclusion in biennial report; additional reports**

Each advisory council may prepare, for inclusion in the biennial report made under section 284b<sup>1</sup> of this title, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the national research institute for which it was established in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the institute. Each advisory council may prepare such additional reports as it may determine appropriate.

**(h) Advisory councils in existence; application of section to National Cancer Advisory Board and advisory council to National Heart, Lung, and Blood Institute**

(1) Except as provided in paragraph (2), this section does not terminate the membership of any advisory council for a national research institute which was in existence on November 20, 1985. After November 20, 1985—

(A) the Secretary shall make appointments to each such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

(B) each advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

(C) the Director of each national research institute shall perform for such advisory council the functions prescribed by this section.

<sup>1</sup> See References in Text note below.

(2)(A) The National Cancer Advisory Board shall be the advisory council for the National Cancer Institute. This section applies to the National Cancer Advisory Board, except that—

(i) appointments to such Board shall be made by the President;

(ii) the term of office of an appointed member shall be 6 years;

(iii) of the members appointed to the Board not less than five members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors);

(iv) the chairman of the Board shall be selected by the President from the appointed members and shall serve as chairman for a term of two years;

(v) the ex officio members of the Board shall be nonvoting members and shall be the Secretary, the Director of the Office of Science and Technology Policy, the Director of NIH, the Under Secretary for Health of the Department of Veterans Affairs, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Science of the Department of Energy (or the designees of such officers); and

(vi) the Board shall meet at least four times each fiscal year.

(B) This section applies to the advisory council to the National Heart, Lung, and Blood Institute, except that the advisory council shall meet at least four times each fiscal year.

(July 1, 1944, ch. 373, title IV, § 406, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 828; amended Pub. L. 100-607, title I, § 117, Nov. 4, 1988, 102 Stat. 3053; Pub. L. 101-381, title I, § 102(1), Aug. 18, 1990, 104 Stat. 585; Pub. L. 102-405, title III, § 302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 103-43, title II, § 210(a), title XX, §§ 2008(b)(1), 2010(b)(2), June 10, 1993, 107 Stat. 149, 210, 214; Pub. L. 105-245, title III, § 309(b)(2)(C), Oct. 7, 1998, 112 Stat. 1853.)

#### REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (g), was repealed by Pub. L. 109-482, title I, § 104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

#### AMENDMENTS

1998—Subsec. (h)(2)(A)(v). Pub. L. 105-245 substituted “Science of the Department of Energy” for “Energy Research of the Department of Energy”.

1993—Subsec. (a)(2). Pub. L. 103-43, § 2010(b)(2), substituted “section 238” for “section 300aaa”.

Subsec. (b)(2)(A). Pub. L. 103-43, § 2008(b)(1)(A), substituted “Department of Veterans Affairs” for “Veterans’ Administration” in two places.

Subsec. (c). Pub. L. 103-43, § 210(a), substituted “for 180 days after the date of such expiration” for “until a successor has taken office”.

Subsec. (h)(2)(A)(v). Pub. L. 103-43, § 2008(b)(1)(B), substituted “Department of Veterans Affairs” for “Veterans’ Administration”.

1992—Subsecs. (b)(2)(A), (h)(2)(A)(v). Pub. L. 102-405 substituted “Under Secretary for Health” for “Chief Medical Director”.

1990—Subsec. (a)(2). Pub. L. 101-381 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

1988—Subsec. (b)(1). Pub. L. 100-607, § 117(a), inserted at end “The ex officio members shall be nonvoting members.”

Subsec. (b)(3)(A). Pub. L. 100-607, § 117(b), inserted “not less than two individuals who are leaders in the fields of” after “(including)”.

Subsec. (h)(2)(A)(v). Pub. L. 100-607, § 117(c), inserted “shall be nonvoting members and” after “Board” and substituted “the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Energy Research of the Department of Energy” for “and the Assistant Secretary of Defense for Health Affairs”.

#### TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

#### REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

#### § 284b. Repealed. Pub. L. 109-482, title I, § 104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693

Section, act July 1, 1944, ch. 373, title IV, § 407, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 831, related to biennial report and its contents.

#### EFFECTIVE DATE OF REPEAL

Repeal applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

#### § 284c. Certain uses of funds

(a)(1) Except as provided in paragraph (2), the sum of the amounts obligated in any fiscal year for administrative expenses of the National Institutes of Health may not exceed an amount which is 5.5 percent of the total amount appropriated for such fiscal year for the National Institutes of Health.

(2) Paragraph (1) does not apply to the National Library of Medicine, the National Center for Nursing Research, the John E. Fogarty International Center for Advanced Study in the Health Sciences, the Warren G. Magnuson Clinical Center, and the Office of Medical Applications of Research.

(3) For purposes of paragraph (1), the term “administrative expenses” means expenses in-

curred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

(b) For fiscal year 1989 and subsequent fiscal years, amounts made available to the National Institutes of Health shall be available for payment of nurses and allied health professionals in accordance with payment authorities, scheduling options, benefits, and other authorities provided under chapter 73 of title 38 for nurses of the Department of Veterans Affairs.

(July 1, 1944, ch. 373, title IV, § 408, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 831; amended Pub. L. 100-607, title I, § 118, Nov. 4, 1988, 102 Stat. 3053; Pub. L. 100-690, title II, § 2613(d), Nov. 18, 1988, 102 Stat. 4239; Pub. L. 103-43, title IV, § 403(b)(1), title XX, § 2008(b)(2), June 10, 1993, 107 Stat. 158, 211; Pub. L. 104-316, title I, § 122(a), Oct. 19, 1996, 110 Stat. 3836; Pub. L. 105-362, title VI, § 601(a)(1)(B), Nov. 10, 1998, 112 Stat. 3285.)

#### AMENDMENTS

1998—Subsec. (a)(4). Pub. L. 105-362 struck out par. (4) which read as follows: “Not later than December 31, 1987, and December 31 of each succeeding year, the Secretary shall report to the Congress the amount obligated in the fiscal year preceding such date for administrative expenses of the National Institutes of Health and the total amount appropriated for the National Institutes of Health for such fiscal year. The Secretary shall consult with the Comptroller General of the United States in preparing each report.”

1996—Subsec. (a)(3). Pub. L. 104-316 struck out at end “In identifying expenses incurred for such support and administration the Secretary shall consult with the Comptroller General of the United States.”

1993—Pub. L. 103-43 amended section catchline generally, redesignated subsec. (b) as (a) and par. (5) of subsec. (a) as (b), struck out former subsec. (a) which authorized appropriations in addition to amounts otherwise appropriated under this subchapter for the National Cancer Institute for programs other than under section 285a-1 of this title and for its program under section 285a-1 of this title and for the National Heart, Lung, and Blood Institute for programs other than under section 285b-1 of this title and for its program under section 285b-1 of this title, and substituted “Department of Veterans Affairs” for “Veterans’ Administration” in subsec. (b).

1988—Subsec. (a)(1), (2). Pub. L. 100-607, § 118(a), amended pars. (1) and (2) generally. Prior to amendment, pars. (1) and (2) read as follows:

“(1)(A) For the National Cancer Institute (other than its programs under section 285a-1 of this title), there are authorized to be appropriated \$1,194,000,000 for fiscal year 1986, \$1,270,000,000 for fiscal year 1987, and \$1,344,000,000 for fiscal year 1988.

“(B) For the programs under section 285a-1 of this title, there are authorized to be appropriated \$68,000,000 for fiscal year 1986, \$74,000,000 for fiscal year 1987, and \$80,000,000 for fiscal year 1988.

“(2)(A) For the National Heart, Lung, and Blood Institute (other than its programs under section 285b-1 of this title), there are authorized to be appropriated \$809,000,000 for fiscal year 1986, \$871,000,000 for fiscal year 1987, and \$927,000,000 for fiscal year 1988. Of the amount appropriated under this subsection for such fiscal year, not less than 15 percent of such amount shall be reserved for programs respecting diseases of the lung and not less than 15 percent of such amount shall be reserved for programs respecting blood diseases and blood resources.

“(B) For the programs under section 285b-1 of this title, there are authorized to be appropriated \$82,000,000

for fiscal year 1986, \$90,000,000 for fiscal year 1987, and \$98,000,000 for fiscal year 1988.”

Subsec. (a)(2)(B). Pub. L. 100-690 inserted a comma after “section 285b-1 of this title”.

Subsec. (b)(5). Pub. L. 100-607, § 118(b), added par. (5).

#### CHANGE OF NAME

National Center for Nursing Research changed to National Institute of Nursing Research by Pub. L. 103-43, title XV, § 1511, June 10, 1993, 107 Stat. 178.

#### EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-690 effective immediately after enactment of Pub. L. 100-607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100-690, set out as a note under section 242m of this title.

#### WARREN G. MAGNUSON CLINICAL CENTER; AVAILABILITY OF FUNDS FOR PAYMENT OF NURSES; RATE OF PAY AND OPTIONS AND BENEFITS

Pub. L. 99-349, title I, July 2, 1986, 100 Stat. 738, provided that: “Funds made available for fiscal year 1986 and hereafter to the Warren G. Magnuson Clinical Center of the National Institutes of Health shall be available for payment of nurses at the rates of pay and with schedule options and benefits authorized for the Veterans Administration pursuant to 38 U.S.C. 4107.”

### § 284d. Definitions

#### (a) Health service research

For purposes of this subchapter, the term “health services research” means research endeavors that study the impact of the organization, financing and management of health services on the quality, cost, access to and outcomes of care. Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions.

#### (b) Clinical research

As used in this subchapter, the term “clinical research” means patient oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, or epidemiologic or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials.

(July 1, 1944, ch. 373, title IV, § 409, as added Pub. L. 102-321, title I, § 121(b), July 10, 1992, 106 Stat. 358; amended Pub. L. 103-43, title XX, § 2016(a), June 10, 1993, 107 Stat. 218; Pub. L. 106-505, title II, § 206, Nov. 13, 2000, 114 Stat. 2329.)

#### AMENDMENTS

2000—Pub. L. 106-505 designated existing provisions as subsec. (a), inserted heading, and added subsec. (b).

1993—Pub. L. 103-43 inserted at end “Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions.”

#### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

**§ 284e. Research on osteoporosis, Paget's disease, and related bone disorders**

**(a) Establishment**

The Directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute on Aging, the National Institute of Dental Research, and the National Institute of Diabetes and Digestive and Kidney Diseases, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning osteoporosis, Paget's disease, and related bone disorders.

**(b) Coordination**

The Directors referred to in subsection (a) shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and the Interagency Task Force on Aging Research.

**(c) Information clearinghouse**

**(1) In general**

In order to assist in carrying out the purpose described in subsection (a), the Director of NIH shall provide for the establishment of an information clearinghouse on osteoporosis and related bone disorders to facilitate and enhance knowledge and understanding on the part of health professionals, patients, and the public through the effective dissemination of information.

**(2) Establishment through grant or contract**

For the purpose of carrying out paragraph (1), the Director of NIH shall enter into a grant, cooperative agreement, or contract with a nonprofit private entity involved in activities regarding the prevention and control of osteoporosis and related bone disorders.

(July 1, 1944, ch. 373, title IV, § 409A, as added Pub. L. 103-43, title III, § 302, June 10, 1993, 107 Stat. 151; amended Pub. L. 105-340, title I, § 102, Oct. 31, 1998, 112 Stat. 3192; Pub. L. 109-482, title I, § 103(b)(7), Jan. 15, 2007, 120 Stat. 3687.)

AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482 struck out heading and text of subsec. (d). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated \$40,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003."

1998—Subsec. (d). Pub. L. 105-340 substituted "through 2003" for "and 1996".

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 284f. Parkinson's disease**

**(a) In general**

The Director of NIH shall establish a program for the conduct and support of research and training with respect to Parkinson's disease (subject to the extent of amounts appropriated to carry out this section).

**(b) Inter-institute coordination**

**(1) In general**

The Director of NIH shall provide for the coordination of the program established under subsection (a) among all of the national research institutes conducting Parkinson's disease research.

**(2) Conference**

Coordination under paragraph (1) shall include the convening of a research planning conference not less frequently than once every 2 years. Each such conference shall prepare and submit to the Committee on Appropriations and the Committee on Labor and Human Resources of the Senate and the Committee on Appropriations and the Committee on Commerce of the House of Representatives a report concerning the conference.

**(c) Morris K. Udall research centers**

**(1) In general**

The Director of NIH is authorized to award Core Center Grants to encourage the development of innovative multidisciplinary research and provide training concerning Parkinson's disease. The Director is authorized to award not more than 10 Core Center Grants and designate each center funded under such grants as a Morris K. Udall Center for Research on Parkinson's Disease.

**(2) Requirements**

**(A) In general**

With respect to Parkinson's disease, each center assisted under this subsection shall—

- (i) use the facilities of a single institution or a consortium of cooperating institutions, and meet such qualifications as may be prescribed by the Director of the NIH; and
- (ii) conduct basic and clinical research.

**(B) Discretionary requirements**

With respect to Parkinson's disease, each center assisted under this subsection may—

- (i) conduct training programs for scientists and health professionals;
- (ii) conduct programs to provide information and continuing education to health professionals;
- (iii) conduct programs for the dissemination of information to the public;
- (iv) separately or in collaboration with other centers, establish a nationwide data system derived from patient populations with Parkinson's disease, and where possible, comparing relevant data involving general populations;
- (v) separately or in collaboration with other centers, establish a Parkinson's Disease Information Clearinghouse to facilitate and enhance knowledge and understanding of Parkinson's disease; and
- (vi) separately or in collaboration with other centers, establish a national education program that fosters a national focus on Parkinson's disease and the care of those with Parkinson's disease.

**(3) Stipends regarding training programs**

A center may use funds provided under paragraph (1) to provide stipends for scientists and

health professionals enrolled in training programs under paragraph (2)(B).

**(4) Duration of support**

Support of a center under this subsection may be for a period not exceeding five years. Such period may be extended by the Director of NIH for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

**(d) Morris K. Udall Awards for Excellence in Parkinson's Disease Research**

The Director of NIH is authorized to establish a grant program to support investigators with a proven record of excellence and innovation in Parkinson's disease research and who demonstrate potential for significant future breakthroughs in the understanding of the pathogenesis,<sup>1</sup> diagnosis, and treatment of Parkinson's disease. Grants under this subsection shall be available for a period of not to exceed 5 years.

(July 1, 1944, ch. 373, title IV, § 409B, as added Pub. L. 105-78, title VI, § 603(c), Nov. 13, 1997, 111 Stat. 1520; amended Pub. L. 109-482, title I, § 103(b)(8), Jan. 15, 2007, 120 Stat. 3687.)

AMENDMENTS

2007—Subsec. (a). Pub. L. 109-482, § 103(b)(8)(A), substituted “to carry out this section” for “under subsection (e) of this section”.

Subsec. (e). Pub. L. 109-482, § 103(b)(8)(B), struck out heading and text of subsec. (e). Text read as follows: “For the purpose of carrying out this section and section 241 of this title and this subchapter with respect to research focused on Parkinson's disease, there are authorized to be appropriated up to \$100,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 and 2000.”

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

ADDITIONAL GRANTS

Pub. L. 108-199, div. E, title II, § 217, Jan. 23, 2004, 118 Stat. 255, provided that: “Notwithstanding section 409B(c) of the Public Health Service Act [42 U.S.C. 284f(c)] regarding a limitation on the number of such grants, funds appropriated in this Act [div. E of Pub. L. 108-199, see Tables for classification] and Acts in fiscal years thereafter may be expended by the Director of the National Institutes of Health to award Core Center

Grants to encourage the development of innovative multidisciplinary research and provide training concerning Parkinson's disease. Each center funded under such grants shall be designated as a Morris K. Udall Center for Research on Parkinson's Disease.”

Similar provisions were contained in Pub. L. 108-7, div. G, title II, § 218, Feb. 20, 2003, 117 Stat. 326.

FINDING AND PURPOSE

Pub. L. 105-78, title VI, § 603(b), Nov. 13, 1997, 111 Stat. 1519, provided that:

“(1) FINDING.—Congress finds that to take full advantage of the tremendous potential for finding a cure or effective treatment, the Federal investment in Parkinson's disease must be expanded, as well as the coordination strengthened among the National Institutes of Health research institutes.

“(2) PURPOSE.—It is the purpose of this section [enacting this section] to provide for the expansion and coordination of research regarding Parkinson's disease, and to improve care and assistance for afflicted individuals and their family caregivers.”

**§ 284g. Expansion, intensification, and coordination of activities of National Institutes of Health with respect to research on autism spectrum disorder**

**(a) In general**

**(1) Expansion of activities**

The Director of NIH (in this section referred to as the “Director”) shall, subject to the availability of appropriations, expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism spectrum disorder, including basic and clinical research in fields including pathology, developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, and toxicology. Such research shall investigate the cause (including possible environmental causes), diagnosis or rule out, early detection, prevention, services, supports, intervention, and treatment of autism spectrum disorder.

**(2) Consolidation**

The Director may consolidate program activities under this section if such consolidation would improve program efficiencies and outcomes.

**(3) Administration of program; collaboration among agencies**

The Director shall carry out this section acting through the Director of the National Institute of Mental Health and in collaboration with any other agencies that the Director determines appropriate.

**(b) Centers of excellence**

**(1) In general**

The Director shall under subsection (a)(1) make awards of grants and contracts to public or nonprofit private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for centers of excellence regarding research on autism spectrum disorder.

**(2) Research**

Each center under paragraph (1) shall conduct basic and clinical research into autism

<sup>1</sup> So in original. Probably should be “pathogenesis.”

spectrum disorder. Such research should include investigations into the cause, diagnosis, early detection, prevention, control, and treatment of autism spectrum disorder. The centers, as a group, shall conduct research including the fields of developmental neurobiology, genetics, and psychopharmacology.

### (3) Services for patients

#### (A) In general

A center under paragraph (1) may expend amounts provided under such paragraph to carry out a program to make individuals aware of opportunities to participate as subjects in research conducted by the centers.

#### (B) Referrals and costs

A program under subparagraph (A) may, in accordance with such criteria as the Director may establish, provide to the subjects described in such subparagraph, referrals for health and other services, and such patient care costs as are required for research.

#### (C) Availability and access

The extent to which a center can demonstrate availability and access to clinical services shall be considered by the Director in decisions about awarding grants to applicants which meet the scientific criteria for funding under this section.

### (4) Organization of centers

Each center under paragraph (1) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director.

### (5) Number of centers; duration of support

#### (A) In general

The Director shall provide for the establishment of not less than five centers under paragraph (1).

#### (B) Duration

Support for a center established under paragraph (1) may be provided under this section for a period of not to exceed 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

### (c) Facilitation of research

The Director shall under subsection (a)(1) provide for a program under which samples of tissues and genetic materials that are of use in research on autism spectrum disorder are donated, collected, preserved, and made available for such research. The program shall be carried out in accordance with accepted scientific and medical standards for the donation, collection, and preservation of such samples.

### (d) Public input

The Director shall under subsection (a)(1) provide for means through which the public can ob-

tain information on the existing and planned programs and activities of the National Institutes of Health with respect to autism spectrum disorder and through which the Director can receive comments from the public regarding such programs and activities.

(July 1, 1944, ch. 373, title IV, § 409C, as added Pub. L. 106-310, div. A, title I, § 101, Oct. 17, 2000, 114 Stat. 1105; amended Pub. L. 109-416, §§ 2(a), 4(b), Dec. 19, 2006, 120 Stat. 2821, 2830; Pub. L. 109-482, title I, §§ 103(b)(9), 104(b)(1)(D), Jan. 15, 2007, 120 Stat. 3687, 3693.)

#### CODIFICATION

Another section 409C of act July 1, 1944, was renumbered section 409G and is classified to section 284k of this title.

#### AMENDMENTS

2007—Subsec. (b)(4) to (6). Pub. L. 109-482, § 104(b)(1)(D), redesignated pars. (5) and (6) as (4) and (5), respectively, and struck out heading and text of former par. (4). Text read as follows: “The Director shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers, and may require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director.”

Subsec. (e). Pub. L. 109-482, § 103(b)(9), which directed the striking of subsec. (e), could not be executed because of prior amendment by Pub. L. 109-416. See 2006 Amendment note below.

2006—Pub. L. 109-416, § 2(a)(1), substituted “autism spectrum disorder” for “autism” in section catchline.

Subsec. (a). Pub. L. 109-416, § 2(a)(3), added pars. (1) and (2), redesignated former par. (2) as (3), and struck out heading and text of former par. (1). Text read as follows: “The Director of NIH (in this section referred to as the ‘Director’) shall expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism.”

Subsec. (b)(1), (2). Pub. L. 109-416, § 2(a)(2), substituted “autism spectrum disorder” for “autism” in par. (1) and in two places in par. (2).

Subsecs. (c), (d). Pub. L. 109-416, § 2(a)(2), substituted “autism spectrum disorder” for “autism”.

Subsec. (e). Pub. L. 109-416, § 4(b), struck out heading and text of subsec. (e). Text read as follows: “There are authorized to be appropriated such sums as may be necessary to carry out this section. Amounts appropriated under this subsection are in addition to any other amounts appropriated for such purpose.”

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

### § 284h. Pediatric Research Initiative

#### (a) Establishment

The Secretary shall establish within the Office of the Director of NIH a Pediatric Research Initiative (referred to in this section as the “Initiative”) to conduct and support research that is directly related to diseases, disorders, and other conditions in children. The Initiative shall be headed by the Director of NIH.

#### (b) Purpose

The purpose of the Initiative is to provide funds to enable the Director of NIH—

- (1) to increase support for pediatric biomedical research within the National Insti-

tutes of Health to realize the expanding opportunities for advancement in scientific investigations and care for children;

(2) to enhance collaborative efforts among the Institutes to conduct and support multidisciplinary research in the areas that the Director deems most promising; and

(3) in coordination with the Food and Drug Administration, to increase the development of adequate pediatric clinical trials and pediatric use information to promote the safer and more effective use of prescription drugs in the pediatric population.

**(c) Duties**

In carrying out subsection (b), the Director of NIH shall—

(1) consult with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the other national research institutes, in considering their requests for new or expanded pediatric research efforts, and consult with the Administrator of the Health Resources and Services Administration and other advisors as the Director determines to be appropriate;

(2) have broad discretion in the allocation of any Initiative assistance among the Institutes, among types of grants, and between basic and clinical research so long as the assistance is directly related to the illnesses and conditions of children; and

(3) be responsible for the oversight of any newly appropriated Initiative funds and annually report to Congress and the public on the extent of the total funds obligated to conduct or support pediatric research across the National Institutes of Health, including the specific support and research awards allocated through the Initiative.

**(d) National Pediatric Research Network**

**(1) Network**

In carrying out the Initiative, the Director of NIH, in collaboration with the national research institutes and national centers that carry out activities involving pediatric research, shall support a National Pediatric Research Network in order to more effectively support pediatric research and optimize the use of Federal resources. Such National Pediatric Research Network may be comprised of, as appropriate—

(A) the pediatric research consortia receiving awards under paragraph (2); or

(B) other consortia, centers, or networks focused on pediatric research that are recognized by the Director of NIH and established pursuant to the authorities vested in the National Institutes of Health by other sections of this chapter.

**(2) Pediatric research consortia**

**(A) In general**

The Director of NIH shall award funding, including through grants, contracts, or other mechanisms, to public or private nonprofit entities for providing support for pediatric research consortia, including with respect to—

(i) basic, clinical, behavioral, or translational research to meet unmet needs for pediatric research; and

(ii) training researchers in pediatric research techniques in order to address unmet pediatric research needs.

**(B) Research**

The Director of NIH shall, as appropriate, ensure that—

(i) each consortium receiving an award under subparagraph (A) conducts or supports at least one category of research described in subparagraph (A)(i) and collectively such consortia conduct or support such categories of research; and

(ii) one or more such consortia provide training described in subparagraph (A)(ii).

**(C) Organization of consortium**

Each consortium receiving an award under subparagraph (A) shall—

(i) be formed from a collaboration of cooperating institutions;

(ii) be coordinated by a lead institution or institutions;

(iii) agree to disseminate scientific findings, including from clinical trials, rapidly and efficiently, as appropriate, to—

(I) other consortia;

(II) the National Institutes of Health;

(III) the Food and Drug Administration;

(IV) and<sup>1</sup> other relevant agencies; and

(iv) meet such requirements as may be prescribed by the Director of NIH.

**(D) Supplement, not supplant**

Any support received by a consortium under subparagraph (A) shall be used to supplement, and not supplant, other public or private support for activities authorized to be supported under this paragraph.

**(E) Duration of support**

Support of a consortium under subparagraph (A) shall be for a period of not to exceed 5 years. Such period may be extended at the discretion of the Director of NIH.

**(3) Coordination of consortia activities**

The Director of NIH shall, as appropriate—

(A) provide for the coordination of activities (including the exchange of information and regular communication) among the consortia established pursuant to paragraph (2); and

(B) require the periodic preparation and submission to the Director of reports on the activities of each such consortium.

**(4) Assistance with registries**

Each consortium receiving an award under paragraph (2)(A) may provide assistance, as appropriate, to the Centers for Disease Control and Prevention for activities related to patient registries and other surveillance systems upon request by the Director of the Centers for Disease Control and Prevention.

**(e) Research on pediatric rare diseases or conditions**

In making awards under subsection (d)(2) for pediatric research consortia, the Director of NIH

<sup>1</sup> So in original. The word “and” probably should appear at end of subcl. (III).

shall ensure that an appropriate number of such awards are awarded to such consortia that agree to—

- (1) consider pediatric rare diseases or conditions, or those related to birth defects; and
- (2) conduct or coordinate one or more multisite clinical trials of therapies for, or approaches to, the prevention, diagnosis, or treatment of one or more pediatric rare diseases or conditions.

**(f) Transfer of funds**

The Director of NIH may transfer amounts appropriated under this section to any of the Institutes for a fiscal year to carry out the purposes of the Initiative under this section.

(July 1, 1944, ch. 373, title IV, §409D, as added Pub. L. 106-310, div. A, title X, §1001, Oct. 17, 2000, 114 Stat. 1127; amended Pub. L. 109-482, title I, §103(b)(10), Jan. 15, 2007, 120 Stat. 3687; Pub. L. 110-154, §1(b)(4), Dec. 21, 2007, 121 Stat. 1827; Pub. L. 113-55, title II, §202, Nov. 27, 2013, 127 Stat. 644; Pub. L. 114-255, div. A, title II, §2071, Dec. 13, 2016, 130 Stat. 1083.)

CODIFICATION

Another section 409D of act July 1, 1944, was renumbered section 409H and is classified to section 284f of this title.

AMENDMENTS

2016—Subsec. (d)(1). Pub. L. 114-255, §2071(1), substituted “in collaboration with the national research institutes and national centers that carry out activities involving pediatric research, shall support” for “in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and in collaboration with other appropriate national research institutes and national centers that carry out activities involving pediatric research, may provide for the establishment of” in introductory provisions.

Subsec. (d)(2)(A), (E). Pub. L. 114-255, §2071(2), substituted “shall” for “may” in introductory provisions of par. (2)(A) and in first sentence of par. (2)(E).

2013—Subsecs. (d) to (f). Pub. L. 113-55 added subsecs. (d) and (e) and redesignated former subsec. (d) as (f).

2007—Subsec. (c)(1). Pub. L. 110-154 substituted “Eunice Kennedy Shriver National Institute of Child Health and Human Development” for “National Institute of Child Health and Human Development”.

Subsecs. (d), (e). Pub. L. 109-482 redesignated subsec. (e) as (d) and struck out heading and text of former subsec. (d). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated \$50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005.”

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 284i. Autoimmune diseases**

**(a) Expansion, intensification, and coordination of activities**

**(1) In general**

The Director of NIH shall expand, intensify, and coordinate research and other activities of the National Institutes of Health with respect to autoimmune diseases.

**(2) Allocations by Director of NIH**

With respect to amounts appropriated to carry out this section for a fiscal year, the Di-

rector of NIH shall allocate the amounts among the national research institutes that are carrying out paragraph (1).

**(3) Definition**

The term “autoimmune disease” includes, for purposes of this section such diseases or disorders with evidence of autoimmune pathogenesis<sup>1</sup> as the Secretary determines to be appropriate.

**(b) Coordinating Committee**

**(1) In general**

The Secretary shall ensure that the Autoimmune Diseases Coordinating Committee (referred to in this section as the “Coordinating Committee”) coordinates activities across the National Institutes and with other Federal health programs and activities relating to such diseases.

**(2) Composition**

The Coordinating Committee shall be composed of the directors or their designees of each of the national research institutes involved in research with respect to autoimmune diseases and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, including the Centers for Disease Control and Prevention and the Food and Drug Administration.

**(3) Chair**

**(A) In general**

With respect to autoimmune diseases, the Chair of the Committee shall serve as the principal advisor to the Secretary, the Assistant Secretary for Health, and the Director of NIH, and shall provide advice to the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and other relevant agencies.

**(B) Director of NIH**

The Chair of the Committee shall be directly responsible to the Director of NIH.

**(c) Plan for NIH activities**

**(1) In general**

Not later than 1 year after October 17, 2000, the Coordinating Committee shall develop a plan for conducting and supporting research and education on autoimmune diseases through the national research institutes and shall periodically review and revise the plan. The plan shall—

(A) provide for a broad range of research and education activities relating to biomedical, psychosocial, and rehabilitative issues, including studies of the disproportionate impact of such diseases on women;

(B) identify priorities among the programs and activities of the National Institutes of Health regarding such diseases; and

(C) reflect input from a broad range of scientists, patients, and advocacy groups.

**(2) Certain elements of plan**

The plan under paragraph (1) shall, with respect to autoimmune diseases, provide for the following as appropriate:

<sup>1</sup> So in original. Probably should be “pathogenesis”.

(A) Research to determine the reasons underlying the incidence and prevalence of the diseases.

(B) Basic research concerning the etiology and causes of the diseases.

(C) Epidemiological studies to address the frequency and natural history of the diseases, including any differences among the sexes and among racial and ethnic groups.

(D) The development of improved screening techniques.

(E) Clinical research for the development and evaluation of new treatments, including new biological agents.

(F) Information and education programs for health care professionals and the public.

### (3) Implementation of plan

The Director of NIH shall ensure that programs and activities of the National Institutes of Health regarding autoimmune diseases are implemented in accordance with the plan under paragraph (1).

(July 1, 1944, ch. 373, title IV, §409E, as added Pub. L. 106-310, div. A, title XIX, §1901, Oct. 17, 2000, 114 Stat. 1153; amended Pub. L. 109-482, title I, §§103(b)(11), 104(b)(1)(E), Jan. 15, 2007, 120 Stat. 3687, 3693.)

#### AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482, §104(b)(1)(E), struck out heading and text of subsec. (d). Text read as follows: “The Coordinating Committee under subsection (b)(1) of this section shall biennially submit to the Committee on Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate, a report that describes the research, education, and other activities on autoimmune diseases being conducted or supported through the national research institutes, and that in addition includes the following:

“(1) The plan under subsection (c)(1) of this section (or revisions to the plan, as the case may be).

“(2) Provisions specifying the amounts expended by the National Institutes of Health with respect to each of the autoimmune diseases included in the plan.

“(3) Provisions identifying particular projects or types of projects that should in the future be considered by the national research institutes or other entities in the field of research on autoimmune diseases.”

Subsec. (e). Pub. L. 109-482, §103(b)(11), struck out heading and text of subsec. (e). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriations that is available for conducting or supporting through the National Institutes of Health research and other activities with respect to autoimmune diseases.”

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

### § 284j. Muscular dystrophy research

#### (a) Coordination of activities

The Director of NIH shall expand and increase coordination in the activities of the National Institutes of Health with respect to research on muscular dystrophies, including Duchenne muscular dystrophy.

#### (b) Administration of program; collaboration among agencies

The Director of NIH shall carry out this section through the appropriate institutes, including the National Institute of Neurological Disorders and Stroke and in collaboration with any other agencies that the Director determines appropriate.

(July 1, 1944, ch. 373, title IV, §409F, as added Pub. L. 106-310, div. A, title XXII, §2201, Oct. 17, 2000, 114 Stat. 1157; amended Pub. L. 109-482, title I, §103(b)(12), Jan. 15, 2007, 120 Stat. 3687.)

#### AMENDMENTS

2007—Subsec. (c). Pub. L. 109-482 struck out heading and text of subsec. (c). Text read as follows: “There are authorized to be appropriated such sums as may be necessary to carry out this section for each of the fiscal years 2001 through 2005. Amounts appropriated under this subsection shall be in addition to any other amounts appropriated for such purpose.”

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

### § 284k. Clinical research

#### (a) In general

The Director of National Institutes of Health shall undertake activities to support and expand the involvement of the National Institutes of Health in clinical research.

#### (b) Requirements

In carrying out subsection (a), the Director of National Institutes of Health shall—

(1) consider the recommendations of the Division of Research Grants Clinical Research Study Group and other recommendations for enhancing clinical research; and

(2) establish intramural and extramural clinical research fellowship programs directed specifically at medical and dental students and a continuing education clinical research training program at the National Institutes of Health.

#### (c) Support for the diverse needs of clinical research

The Director of National Institutes of Health, in cooperation with the Directors of the Institutes, Centers, and Divisions of the National Institutes of Health, shall support and expand the resources available for the diverse needs of the clinical research community, including inpatient, outpatient, and critical care clinical research.

#### (d) Peer review

The Director of National Institutes of Health shall establish peer review mechanisms to evaluate applications for the awards and fellowships provided for in subsection (b)(2) and section 284l of this title. Such review mechanisms shall include individuals who are exceptionally qualified to appraise the merits of potential clinical research training and research grant proposals.

(July 1, 1944, ch. 373, title IV, §409G, formerly §409C, as added Pub. L. 106-505, title II, §203,

Nov. 13, 2000, 114 Stat. 2326; renumbered § 409G, Pub. L. 107-109, § 3(1), Jan. 4, 2002, 115 Stat. 1408.)

#### REFERENCES IN TEXT

Section 284I of this title, referred to in subsec. (d), was in the original “section 409D”, and was translated as meaning section 409D of act July 1, 1944, ch. 373, as added by section 204(b) of Pub. L. 106-505. Such section 409D was renumbered section 409H of act July 1, 1944, ch. 373, by Pub. L. 107-109, § 3(2), Jan. 4, 2002, 115 Stat. 1408. Another section 409D of act July 1, 1944, ch. 373, as added by section 1001 of Pub. L. 106-310, is classified to section 284h of this title.

#### FINDINGS AND PURPOSE

Pub. L. 106-505, title II, § 202, Nov. 13, 2000, 114 Stat. 2325, provided that:

“(a) FINDINGS.—Congress makes the following findings:

“(1) Clinical research is critical to the advancement of scientific knowledge and to the development of cures and improved treatment for disease.

“(2) Tremendous advances in biology are opening doors to new insights into human physiology, pathophysiology and disease, creating extraordinary opportunities for clinical research.

“(3) Clinical research includes translational research which is an integral part of the research process leading to general human applications. It is the bridge between the laboratory and new methods of diagnosis, treatment, and prevention and is thus essential to progress against cancer and other diseases.

“(4) The United States will spend more than \$1,200,000,000,000 on health care in 1999, but the Federal budget for health research at the National Institutes of Health was \$15,600,000,000 only 1 percent of that total.

“(5) Studies at the Institute of Medicine, the National Research Council, and the National Academy of Sciences have all addressed the current problems in clinical research.

“(6) The Director of the National Institutes of Health has recognized the current problems in clinical research and appointed a special panel, which recommended expanded support for existing National Institutes of Health clinical research programs and the creation of new initiatives to recruit and retain clinical investigators.

“(7) The current level of training and support for health professionals in clinical research is fragmented, undervalued, and underfunded.

“(8) Young investigators are not only apprentices for future positions but a crucial source of energy, enthusiasm, and ideas in the day-to-day research that constitutes the scientific enterprise. Serious questions about the future of life-science research are raised by the following:

“(A) The number of young investigators applying for grants dropped by 54 percent between 1985 and 1993.

“(B) The number of physicians applying for first-time National Institutes of Health research project grants fell from 1226 in 1994 to 963 in 1998, a 21 percent reduction.

“(C) Newly independent life-scientists are expected to raise funds to support their new research programs and a substantial proportion of their own salaries.

“(9) The following have been cited as reasons for the decline in the number of active clinical researchers, and those choosing this career path:

“(A) A medical school graduate incurs an average debt of \$85,619, as reported in the Medical School Graduation Questionnaire by the Association of American Medical Colleges (AAMC).

“(B) The prolonged period of clinical training required increases the accumulated debt burden.

“(C) The decreasing number of mentors and role models.

“(D) The perceived instability of funding from the National Institutes of Health and other Federal agencies.

“(E) The almost complete absence of clinical research training in the curriculum of training grant awardees.

“(F) Academic Medical Centers are experiencing difficulties in maintaining a proper environment for research in a highly competitive health care marketplace, which are compounded by the decreased willingness of third party payers to cover health care costs for patients engaged in research studies and research procedures.

“(10) In 1960, general clinical research centers were established under the Office of the Director of the National Institutes of Health with an initial appropriation of \$3,000,000.

“(11) Appropriations for general clinical research centers in fiscal year 1999 equaled \$200,500,000.

“(12) Since the late 1960s, spending for general clinical research centers has declined from approximately 3 percent to 1 percent of the National Institutes of Health budget.

“(13) In fiscal year 1999, there were 77 general clinical research centers in operation, supplying patients in the areas in which such centers operate with access to the most modern clinical research and clinical research facilities and technologies.

“(b) PURPOSE.—It is the purpose of this title [see Short Title of 2000 Amendments note set out under section 201 of this title] to provide additional support for and to expand clinical research programs.”

#### OVERSIGHT BY GAO

Pub. L. 106-505, title II, § 207, Nov. 13, 2000, 114 Stat. 2330, provided that, not later than 18 months after Nov. 13, 2000, the Comptroller General was to submit to Congress a report describing the extent to which the National Institutes of Health had complied with the amendments made by title II of Pub. L. 106-505.

#### § 284I. Enhancement awards

##### (a) Mentored Patient-Oriented Research Career Development Awards

###### (1) Grants

###### (A) In general

The Director of the National Institutes of Health shall make grants (to be referred to as “Mentored Patient-Oriented Research Career Development Awards”) to support individual careers in clinical research at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research.

###### (B) Use

Grants under subparagraph (A) shall be used to support clinical investigators in the early phases of their independent careers by providing salary and such other support for a period of supervised study.

###### (2) Applications

An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

##### (b) Mid-Career Investigator Awards in Patient-Oriented Research

###### (1) Grants

###### (A) In general

The Director of the National Institutes of Health shall make grants (to be referred to

as “Mid-Career Investigator Awards in Patient-Oriented Research”) to support individual clinical research projects at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research.

**(B) Use**

Grants under subparagraph (A) shall be used to provide support for mid-career level clinicians to allow such clinicians to devote time to clinical research and to act as mentors for beginning clinical investigators.

**(2) Applications**

An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director requires.

**(c) Graduate Training in Clinical Investigation Award**

**(1) In general**

The Director of the National Institutes of Health shall make grants (to be referred to as “Graduate Training in Clinical Investigation Awards”) to support individuals pursuing master’s or doctoral degrees in clinical investigation.

**(2) Applications**

An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

**(3) Limitations**

Grants under this subsection shall be for terms of 2 years or more and shall provide stipend, tuition, and institutional support for individual advanced degree programs in clinical investigation.

**(4) Definition**

As used in this subsection, the term “advanced degree programs in clinical investigation” means programs that award a master’s or Ph.D. degree in clinical investigation after 2 or more years of training in areas such as the following:

- (A) Analytical methods, biostatistics, and study design.
- (B) Principles of clinical pharmacology and pharmacokinetics.
- (C) Clinical epidemiology.
- (D) Computer data management and medical informatics.
- (E) Ethical and regulatory issues.
- (F) Biomedical writing.

**(d) Clinical Research Curriculum Awards**

**(1) In general**

The Director of the National Institutes of Health shall make grants (to be referred to as “Clinical Research Curriculum Awards”) to institutions for the development and support of programs of core curricula for training clinical investigators, including medical students. Such core curricula may include training in areas such as the following:

- (A) Analytical methods, biostatistics, and study design.
- (B) Principles of clinical pharmacology and pharmacokinetics.

(C) Clinical epidemiology.

(D) Computer data management and medical informatics.

(E) Ethical and regulatory issues.

(F) Biomedical writing.

**(2) Applications**

An application for a grant under this subsection shall be submitted by an individual institution or a consortium of institutions at such time as the Director may require. An institution may submit only one such application.

**(3) Limitations**

Grants under this subsection shall be for terms of up to 5 years and may be renewable.

(July 1, 1944, ch. 373, title IV, §409H, formerly §409D, as added Pub. L. 106-505, title II, §204(b), Nov. 13, 2000, 114 Stat. 2327; renumbered §409H, Pub. L. 107-109, §3(2), Jan. 4, 2002, 115 Stat. 1408; Pub. L. 109-482, title I, §103(b)(13), Jan. 15, 2007, 120 Stat. 3687.)

AMENDMENTS

2007—Subsec. (a)(3). Pub. L. 109-482, §103(b)(13)(A), struck out heading and text of par. (3). Text read as follows: “For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.”

Subsec. (b)(3). Pub. L. 109-482, §103(b)(13)(B), struck out heading and text of par. (3). Text read as follows: “For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.”

Subsec. (c)(5). Pub. L. 109-482, §103(b)(13)(C), struck out heading and text of par. (5). Text read as follows: “For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.”

Subsec. (d)(4). Pub. L. 109-482, §103(b)(13)(D), struck out heading and text of par. (4). Text read as follows: “For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.”

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 284m. Program for pediatric studies of drugs**

**(a) List of priority issues in pediatric therapeutics**

**(1) In general**

Not later than one year after September 27, 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs, biological products, or indications that require study. The list shall be revised every three years.

**(2) Consideration of available information**

In developing and prioritizing the list under paragraph (1), the Secretary—

(A) shall consider—

- (i) therapeutic gaps in pediatrics that may include developmental pharmacology,

pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

(ii) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

(iii) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators; and

(B) may consider the availability of qualified countermeasures (as defined in section 247d-6a of this title), security countermeasures (as defined in section 247d-6b of this title), and qualified pandemic or epidemic products (as defined in section 247d-6d of this title) to address the needs of pediatric populations, in consultation with the Assistant Secretary for Preparedness and Response, consistent with the purposes of this section.

**(b) Pediatric studies and research**

The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in paragraphs (1) and (2)(A) of subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.

**(c) Process for proposed pediatric study requests and labeling changes**

**(1) Submission of proposed pediatric study request**

The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a], or section 262(m) of this title, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(j)] or section 262(k) of this title; or

(ii) there is a submitted application that could be approved under the criteria of such section; and

(B) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food,

Drug, and Cosmetic Act [21 U.S.C. 355(b)(1)], and every three-year and five-year period referred to in subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355], or applicable twelve-year period referred to in section 262(k)(7) of this title, and any seven-year period referred to in section 527 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360cc] has ended for at least one form of the drug; and

(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

**(2) Written request to holders of approved applications**

The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified under subsection (a) to all holders of an approved application for the drug. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a] or section 262(m) of this title, including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.

**(3) Requests for proposals**

If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).

**(4) Disqualification**

A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).

**(5) Contracts, grants, or other funding mechanisms**

A contract, grant, or other funding may be awarded under this section only if a proposal is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

**(6) Reporting of studies**

**(A) In general**

On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submit-

ted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study, including a written request if issued.

**(B) Availability of reports**

Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(4)]) and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

**(C) Action by Commissioner**

The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).

**(7) Requests for labeling change**

During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and

(ii) publish in the Federal Register and through a posting on the Web site of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.

**(8) Dispute resolution**

**(A) Referral to Pediatric Advisory Committee**

If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Committee.

**(B) Action by the Pediatric Advisory Committee**

Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall—

(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

**(9) FDA determination**

Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

**(10) Failure to agree**

If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner of Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

**(11) No effect on authority**

Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

**(d) Dissemination of pediatric information**

Not later than one year after September 27, 2007, the Secretary, acting through the Director of the National Institutes of Health, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress.

**(e) Authorization of appropriations**

**(1) In general**

There are authorized to be appropriated to carry out this section, \$25,000,000 for each of fiscal years 2013 through 2017.

**(2) Availability**

Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.

(July 1, 1944, ch. 373, title IV, § 409I, as added Pub. L. 107-109, § 3(3), Jan. 4, 2002, 115 Stat. 1408; amended Pub. L. 108-155, § 3(b)(6), Dec. 3, 2003, 117 Stat. 1942; Pub. L. 109-482, title I, § 103(b)(14), Jan. 15, 2007, 120 Stat. 3687; Pub. L. 110-85, title V, § 502(b), Sept. 27, 2007, 121 Stat. 886; Pub. L. 111-148, title VII, § 7002(g)(2)(A), Mar. 23, 2010, 124 Stat. 820; Pub. L. 112-144, title V, §§ 507(d), 509(d), July 9, 2012, 126 Stat. 1045, 1049; Pub. L. 113-5, title III, § 307(b), Mar. 13, 2013, 127 Stat. 192.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(10), (11), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

AMENDMENTS

2013—Subsec. (a)(2). Pub. L. 113-5, § 307(b)(1), added par. (2) and struck out former par. (2). Prior to amend-

ment, text read as follows: “In developing and prioritizing the list under paragraph (1), the Secretary shall consider—

“(A) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

“(B) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

“(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.”

Subsec. (b). Pub. L. 113-5, §307(b)(2), substituted “paragraphs (1) and (2)(A) of subsection (a)” for “subsection (a)”.

2012—Subsec. (c)(1). Pub. L. 112-144, §509(d)(1)(A), inserted “or section 262(m) of this title,” after “Cosmetic Act”.

Subsec. (c)(1)(A)(i). Pub. L. 112-144, §509(d)(1)(B), inserted “or section 262(k) of this title” after “Cosmetic Act”.

Subsec. (c)(1)(B). Pub. L. 112-144, §509(d)(1)(C), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: “there is no patent protection or market exclusivity protection for at least one form of the drug under the Federal Food, Drug, and Cosmetic Act; and”.

Subsec. (c)(2). Pub. L. 112-144, §509(d)(2), struck out “for drugs lacking exclusivity” after “applications” in heading, and in text struck out “under section 505 of the Federal Food, Drug, and Cosmetic Act” after “for the drug” and substituted “505A of the Federal Food, Drug, and Cosmetic Act or section 262(m) of this title” for “505A of such Act”.

Subsec. (e)(1). Pub. L. 112-144, §507(d), substituted “to carry out this section, \$25,000,000 for each of fiscal years 2013 through 2017.” for “to carry out this section—

“(A) \$200,000,000 for fiscal year 2008; and

“(B) such sums as are necessary for each of the four succeeding fiscal years.”

2010—Subsec. (a)(1). Pub. L. 111-148 inserted “, biological products,” after “including drugs”.

2007—Pub. L. 110-85 amended section generally. Prior to amendment, section related to development of list of drugs for which pediatric studies are needed, award of contracts for pediatric studies, process for requesting contract proposals to conduct certain pediatric studies, reporting of completed studies, requests for labeling changes and dispute resolution, and recommendation by the Secretary for formulation changes.

Subsec. (d). Pub. L. 109-482 struck out subsec. (d) which related to authorization and availability of appropriations.

2003—Subsec. (c)(8), (9), (11). Pub. L. 108-155 struck out “Advisory Subcommittee of the Anti-Infective Drugs” before “Advisory Committee” wherever appearing.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108-155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108-155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

### § 284m-1. Pediatric Advisory Committee

#### (a) In general

The Secretary of Health and Human Services shall, under section 217a of this title or other appropriate authority, convene and consult an ad-

visory committee on pediatric therapeutics (including drugs and biological products) and medical devices (referred to in this section as the “advisory committee”).

#### (b) Purpose

##### (1) In general

The advisory committee shall advise and make recommendations to the Secretary, through the Commissioner of Food and Drugs, on matters relating to pediatric therapeutics (including drugs and biological products) and medical devices.

##### (2) Matters included

The matters referred to in paragraph (1) include—

(A) pediatric research conducted under sections 262, 284m, and 290b of this title and sections 351, 352, 355, 355a, 355c, 360(k), 360e, and 360j(m) of title 21;

(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions;

(C) the ethics, design, and analysis of clinical trials related to pediatric therapeutics (including drugs and biological products) and medical devices; and

(D) the development of countermeasures (as defined in section 360bbb-4(a) of title 21) for pediatric populations.

#### (c) Composition

The advisory committee shall include representatives of pediatric health organizations, pediatric researchers, relevant patient and patient-family organizations, and other experts selected by the Secretary.

#### (d) Continuation of Operation of Committee

Notwithstanding section 14 of the Federal Advisory Committee Act, the advisory committee shall continue to operate to carry out the advisory committee’s responsibilities under sections 355a, 355c, and 360j(m) of title 21.

(Pub. L. 107-109, §14, Jan. 4, 2002, 115 Stat. 1419, as amended by Pub. L. 108-155, §3(b)(2), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 110-85, title III, §306(b), title V, §502(d), Sept. 27, 2007, 121 Stat. 865, 889; Pub. L. 112-144, title V, §507(a), July 9, 2012, 126 Stat. 1045; Pub. L. 113-5, title III, §307(c), Mar. 13, 2013, 127 Stat. 192.)

#### REFERENCES IN TEXT

Section 14 of the Federal Advisory Committee Act, referred to in subsec. (d), is section 14 of Pub. L. 92-463, which is set out in the Appendix to Title 5, Government Organization and Employees.

#### CODIFICATION

Section was formerly set out as a note under section 284m of this title.

Section was enacted as part of the Best Pharmaceuticals for Children Act, and not as part of the Public Health Service Act which comprises this chapter.

#### AMENDMENTS

2013—Subsec. (b)(2)(D). Pub. L. 113-5 added subpar. (D).

2012—Subsec. (d). Pub. L. 112-144 substituted “to carry out the advisory committee’s responsibilities

under sections 355a, 355c, and 360j(m) of title 21” for “during the five-year period beginning on September 27, 2007”.

2007—Subsec. (a). Pub. L. 110–85, §306(b)(1), inserted “(including drugs and biological products) and medical devices” after “therapeutics”.

Subsec. (b)(1). Pub. L. 110–85, §306(b)(2)(A), inserted “(including drugs and biological products) and medical devices” after “therapeutics”.

Subsec. (b)(2)(A). Pub. L. 110–85, §306(b)(2)(B)(i), substituted “355c, 360(k), 360e, and 360j(m)” for “and 355c”.

Subsec. (b)(2)(B). Pub. L. 110–85, §306(b)(2)(B)(ii), added subpar. (B) and struck out former subpar. (B) which read as follows: “identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; and”.

Subsec. (b)(2)(C). Pub. L. 110–85, §306(b)(2)(B)(iii), inserted “(including drugs and biological products) and medical devices” after “therapeutics”.

Subsec. (d). Pub. L. 110–85, §502(d), added subsec. (d). 2003—Pub. L. 108–155, §3(b)(2)(A), struck out “Pharmacology” after “Pediatric” in section catchline.

Subsec. (a). Pub. L. 108–155, §3(b)(2)(D), substituted “therapeutics” for “pharmacology”.

Pub. L. 108–155, §3(b)(2)(B), inserted “or other appropriate authority” after “217a of this title”.

Subsec. (b)(1). Pub. L. 108–155, §3(b)(2)(D), substituted “therapeutics” for “pharmacology”.

Pub. L. 108–155, §3(b)(2)(C)(i), struck out “and in consultation with the Director of the National Institutes of Health” after “Commissioner of Food and Drugs”.

Subsec. (b)(2). Pub. L. 108–155, §3(b)(2)(C)(ii), substituted “355a, and 355c” for “and 355a”.

Subsec. (b)(2)(B), (C). Pub. L. 108–155, §3(b)(2)(D), substituted “therapeutics” for “pharmacology”.

#### EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108–155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

### § 284n. Certain demonstration projects

#### (a) Bridging the sciences

##### (1) In general

From amounts to be appropriated under section 282a(b) of this title, the Secretary of Health and Human Services, acting through the Director of NIH, (in this subsection referred to as the “Secretary”) in consultation with the Director of the National Science Foundation, the Secretary of Energy, and other agency heads when necessary, may allocate funds for the national research institutes and national centers to make grants for the purpose of improving the public health through demonstration projects for biomedical research at the interface between the biological, behavioral, and social sciences and the physical, chemical, mathematical, and computational sciences.

##### (2) Goals, priorities, and methods; interagency collaboration

The Secretary shall establish goals, priorities, and methods of evaluation for research under paragraph (1), and shall provide for interagency collaboration with respect to such research. In developing such goals, priorities, and methods, the Secretary shall ensure that—

(A) the research reflects the vision of innovation and higher risk with long-term payoffs; and

(B) the research includes a wide spectrum of projects, funded at various levels, with varying timeframes.

##### (3) Peer review

A grant may be made under paragraph (1) only if the application for the grant has undergone technical and scientific peer review under section 289a of this title and has been reviewed by the advisory council under section 282(k) of this title or has been reviewed by an advisory council composed of representatives from appropriate scientific disciplines who can fully evaluate the applicant.

#### (b) High-risk, high-reward research

##### (1) In general

From amounts to be appropriated under section 282a(b) of this title, the Secretary, acting through the Director of NIH, may allocate funds for the national research institutes and national centers to make awards of grants or contracts or to engage in other transactions for demonstration projects for high-impact, cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, and treatment of diseases and disorders. The head of a national research institute or national center may conduct or support such high-impact, cutting-edge research (with funds allocated under the preceding sentence or otherwise available for such purpose) if the institute or center gives notice to the Director of NIH beforehand and submits a report to the Director of NIH on an annual basis on the activities of the institute or center relating to such research.

##### (2) Special consideration

In carrying out the program under paragraph (1), the Director of NIH shall give special consideration to coordinating activities with national research institutes whose budgets are substantial relative to a majority of the other institutes.

##### (3) Administration of program

Activities relating to research described in paragraph (1) shall be designed by the Director of NIH or the head of a national research institute or national center, as applicable, to enable such research to be carried out with maximum flexibility and speed.

##### (4) Public-private partnerships

In providing for research described in paragraph (1), the Director of NIH or the head of a national research institute or national center, as applicable, shall seek to facilitate partnerships between public and private entities and shall coordinate when appropriate with the Foundation for the National Institutes of Health.

##### (5) Peer review

A grant for research described in paragraph (1) may be made only if the application for the grant has undergone technical and scientific peer review under section 289a of this title and has been reviewed by the advisory council under section 282(k) of this title.

**(c) Report to Congress**

Not later than the end of fiscal year 2009, the Secretary, acting through the Director of NIH, shall conduct an evaluation of the activities under this section and submit a report to the Congress on the results of such evaluation.

**(d) Definitions**

For purposes of this section, the terms “Director of NIH”, “national research institute”, and “national center” have the meanings given such terms in section 281 of this title.

(Pub. L. 109–482, title I, §105, Jan. 15, 2007, 120 Stat. 3694.)

## CODIFICATION

Section was enacted as part of the National Institutes of Health Reform Act of 2006, and not as part of the Public Health Service Act which comprises this chapter.

## EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

**§ 284o. Activities of the National Institutes of Health with respect to research on paralysis****(a) Coordination**

The Director of the National Institutes of Health (referred to in this section and sections 280g–9 and 284p of this title as the “Director”), pursuant to the general authority of the Director, may develop mechanisms to coordinate the paralysis research and rehabilitation activities of the Institutes and Centers of the National Institutes of Health in order to further advance such activities and avoid duplication of activities.

**(b) Christopher and Dana Reeve Paralysis Research Consortia****(1) In general**

The Director may make awards of grants to public or private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for consortia in paralysis research. The Director shall designate each consortium funded through such grants as a Christopher and Dana Reeve Paralysis Research Consortium.

**(2) Research**

Each consortium under paragraph (1)—

(A) may conduct basic, translational, and clinical paralysis research;

(B) may focus on advancing treatments and developing therapies in paralysis research;

(C) may focus on one or more forms of paralysis that result from central nervous system trauma or stroke;

(D) may facilitate and enhance the dissemination of clinical and scientific findings; and

(E) may replicate the findings of consortia members or other researchers for scientific and translational purposes.

**(3) Coordination of consortia; reports**

The Director may, as appropriate, provide for the coordination of information among

consortia under paragraph (1) and ensure regular communication among members of the consortia, and may require the periodic preparation of reports on the activities of the consortia and the submission of the reports to the Director.

**(4) Organization of consortia**

Each consortium under paragraph (1) may use the facilities of a single lead institution, or be formed from several cooperating institutions, meeting such requirements as may be prescribed by the Director.

**(c) Public input**

The Director may provide for a mechanism to educate and disseminate information on the existing and planned programs and research activities of the National Institutes of Health with respect to paralysis and through which the Director can receive comments from the public regarding such programs and activities.

(Pub. L. 111–11, title XIV, §14101, Mar. 30, 2009, 123 Stat. 1452.)

## CODIFICATION

Section was enacted as part of the Christopher and Dana Reeve Paralysis Act, and also as part of the Omnibus Public Land Management Act of 2009, and not as part of the Public Health Service Act which comprises this chapter.

**§ 284p. Activities of the National Institutes of Health with respect to research with implications for enhancing daily function for persons with paralysis****(a) In general**

The Director, pursuant to the general authority of the Director, may make awards of grants to public or private entities to pay all or part of the costs of planning, establishing, improving, and providing basic operating support to multicenter networks of clinical sites that will collaborate to design clinical rehabilitation intervention protocols and measures of outcomes on one or more forms of paralysis that result from central nervous system trauma, disorders, or stroke, or any combination of such conditions.

**(b) Research**

A multicenter network of clinical sites funded through this section may—

(1) focus on areas of key scientific concern, including—

(A) improving functional mobility;

(B) promoting behavioral adaptation to functional losses, especially to prevent secondary complications;

(C) assessing the efficacy and outcomes of medical rehabilitation therapies and practices and assisting technologies;

(D) developing improved assistive technology to improve function and independence; and

(E) understanding whole body system responses to physical impairments, disabilities, and societal and functional limitations; and

(2) replicate the findings of network members or other researchers for scientific and translation purposes.

**(c) Coordination of clinical trials networks; reports**

The Director may, as appropriate, provide for the coordination of information among networks funded through this section and ensure regular communication among members of the networks, and may require the periodic preparation of reports on the activities of the networks and submission of reports to the Director.

(Pub. L. 111-11, title XIV, §14201, Mar. 30, 2009, 123 Stat. 1453.)

## CODIFICATION

Section was enacted as part of the Christopher and Dana Reeve Paralysis Act, and also as part of the Omnibus Public Land Management Act of 2009, and not as part of the Public Health Service Act which comprises this chapter.

## DEFINITION OF “DIRECTOR”

“Director” as meaning the Director of the National Institutes of Health, see section 284o(a) of this title.

**§ 284q. Pain research****(a) Research initiatives****(1) In general**

The Director of NIH is encouraged to continue and expand, through the Pain Consortium, an aggressive program of basic and clinical research on the causes of and potential treatments for pain.

**(2) Annual recommendations**

Not less than annually, the Pain Consortium, in consultation with the Division of Program Coordination, Planning, and Strategic Initiatives, shall develop and submit to the Director of NIH recommendations on appropriate pain research initiatives that could be undertaken with funds reserved under section 282a(c)(1) of this title for the Common Fund or otherwise available for such initiatives.

**(3) Definition**

In this subsection, the term “Pain Consortium” means the Pain Consortium of the National Institutes of Health or a similar trans-National Institutes of Health coordinating entity designated by the Secretary for purposes of this subsection.

**(b) Interagency Pain Research Coordinating Committee****(1) Establishment**

The Secretary shall establish not later than 1 year after March 23, 2010, and as necessary maintain a committee, to be known as the Interagency Pain Research Coordinating Committee (in this section referred to as the “Committee”), to coordinate all efforts within the Department of Health and Human Services and other Federal agencies that relate to pain research.

**(2) Membership****(A) In general**

The Committee shall be composed of the following voting members:

- (i) Not more than 7 voting Federal representatives appoint<sup>1</sup> by the Secretary

from agencies that conduct pain care research and treatment.

- (ii) 12 additional voting members appointed under subparagraph (B).

**(B) Additional members**

The Committee shall include additional voting members appointed by the Secretary as follows:

- (i) 6 non-Federal members shall be appointed from among scientists, physicians, and other health professionals.

- (ii) 6 members shall be appointed from members of the general public, who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions.

**(C) Nonvoting members**

The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

**(3) Chairperson**

The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH.

**(4) Meetings**

The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

**(5) Duties**

The Committee shall—

- (A) develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain;

- (B) identify critical gaps in basic and clinical research on the symptoms and causes of pain;

- (C) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort;

- (D) make recommendations on how best to disseminate information on pain care; and

- (E) make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.

**(6) Review**

The Secretary shall review the necessity of the Committee at least once every 2 years.

(July 1, 1944, ch. 373, title IV, §409J, as added Pub. L. 111-148, title IV, §4305(b), Mar. 23, 2010, 124 Stat. 585.)

**§ 284q-1. NIH opioid research****(a) In general**

The Director of the National Institutes of Health (referred to in this section as the “NIH”) may intensify and coordinate fundamental, translational, and clinical research of the NIH with respect to—

- (1) the understanding of pain;

- (2) the discovery and development of therapies for chronic pain; and

<sup>1</sup> So in original. Probably should be “appointed”.

(3) the development of alternatives to opioids for effective pain treatments.

**(b) Priority and direction**

The prioritization and direction of the Federally funded portfolio of pain research studies shall consider recommendations made by the Interagency Pain Research Coordinating Committee in concert with the Pain Management Best Practices Inter-Agency Task Force, and in accordance with the National Pain Strategy, the Federal Pain Research Strategy, and the NIH-Wide Strategic Plan for Fiscal Years 2016–2020, the latter of which calls for the relative burdens of individual diseases and medical disorders to be regarded as crucial considerations in balancing the priorities of the Federal research portfolio.

(Pub. L. 114–198, title I, §108, July 22, 2016, 130 Stat. 705.)

CODIFICATION

Section was enacted as part of the Comprehensive Addiction and Recovery Act of 2016, and not as part of the Public Health Service Act which comprises this chapter.

**§ 284r. Basic research**

**(1) Developing policies**

Not later than 2 years after December 13, 2016, the Director of the National Institutes of Health (referred to in this section as the “Director of the National Institutes of Health”), taking into consideration the recommendations developed under section 2039,<sup>1</sup> shall develop policies for projects of basic research funded by National Institutes of Health to assess—

(A) relevant biological variables including sex, as appropriate; and

(B) how differences between male and female cells, tissues, or animals may be examined and analyzed.

**(2) Revising policies**

The Director of the National Institutes of Health may update or revise the policies developed under paragraph (1) as appropriate.

**(3) Consultation and outreach**

In developing, updating, or revising the policies under this section, the Director of the National Institutes of Health shall—

(A) consult with—

(i) the Office of Research on Women’s Health;

(ii) the Office of Laboratory Animal Welfare; and

(iii) appropriate members of the scientific and academic communities; and

(B) conduct outreach to solicit feedback from members of the scientific and academic communities on the influence of sex as a variable in basic research, including feedback on when it is appropriate for projects of basic research involving cells, tissues, or animals to include both male and female cells, tissues, or animals.

**(4) Additional requirements**

The Director of the National Institutes of Health shall—

(A) ensure that projects of basic research funded by the National Institutes of Health are conducted in accordance with the policies developed, updated, or revised under this section, as applicable; and

(B) encourage that the results of such research, when published or reported, be disaggregated as appropriate with respect to the analysis of any sex differences.

(Pub. L. 114–255, div. A, title II, §2038(g), Dec. 13, 2016, 130 Stat. 1066.)

REFERENCES IN TEXT

Section 2039, referred to in par. (1), is section 2039 of Pub. L. 114–255, which is set out as a note under section 282 of this title.

CODIFICATION

Section was enacted as part of the 21st Century Cures Act, and not as part of the Public Health Service Act which comprises this chapter.

**§ 284s. Tick-borne diseases**

**(a) In general**

The Secretary of Health and Human Services (referred to in this section as “the Secretary”) shall continue to conduct or support epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases.

**(b) Reports**

The Secretary shall ensure that each triennial report under section 283 of this title (as amended by section 2032) includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to tick-borne diseases.

**(c) Tick-Borne Diseases Working Group**

**(1) Establishment**

The Secretary shall establish a working group, to be known as the Tick-Borne Disease Working Group (referred to in this section as the “Working Group”), comprised of representatives of appropriate Federal agencies and other non-Federal entities, to provide expertise and to review all efforts within the Department of Health and Human Services related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities.

**(2) Responsibilities**

The working group shall—

(A) not later than 2 years after December 13, 2016, develop or update a summary of—

(i) ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention for individuals with tick-borne diseases;

(ii) advances made pursuant to such research;

(iii) Federal activities related to tick-borne diseases, including—

(I) epidemiological activities related to tick-borne diseases; and

(II) basic, clinical, and translational tick-borne disease research related to

<sup>1</sup> See References in Text note below.

the pathogenesis, prevention, diagnosis, and treatment of tick-borne diseases;

(iv) gaps in tick-borne disease research described in clause (iii)(II);

(v) the Working Group's meetings required under paragraph (4); and

(vi) the comments received by the Working Group;

(B) make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research; and

(C) solicit input from States, localities, and nongovernmental entities, including organizations representing patients, health care providers, researchers, and industry regarding scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

### (3) Membership

The members of the working group shall represent a diversity of scientific disciplines and views and shall be composed of the following members:

#### (A) Federal members

Seven Federal members, consisting of one or more representatives of each of the following:

(i) The Office of the Assistant Secretary for Health.

(ii) The Food and Drug Administration.

(iii) The Centers for Disease Control and Prevention.

(iv) The National Institutes of Health.

(v) Such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

#### (B) Non-Federal public members

Seven non-Federal public members, consisting of representatives of the following categories:

(i) Physicians and other medical providers with experience in diagnosing and treating tick-borne diseases.

(ii) Scientists or researchers with expertise.

(iii) Patients and their family members.

(iv) Nonprofit organizations that advocate for patients with respect to tick-borne diseases.

(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

### (4) Meetings

The Working Group shall meet not less than twice each year.

### (5) Reporting

Not later than 2 years after December 13, 2016, and every 2 years thereafter until termination of the Working Group pursuant to paragraph (7), the Working Group shall—

(A) submit a report on its activities under paragraph (2)(A) and any recommendations under paragraph (2)(B) to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Commit-

tee on Health, Education, Labor, and Pensions of the Senate; and

(B) make such report publicly available on the Internet website of the Department of Health and Human Services.

### (6) Applicability of FACA

The Working Group shall be treated as an advisory committee subject to the Federal Advisory Committee Act (5 U.S.C. App.).

### (7) Sunset

The Working Group under this section shall terminate 6 years after December 13, 2016.

(Pub. L. 114-255, div. A, title II, §2062, Dec. 13, 2016, 130 Stat. 1079.)

#### REFERENCES IN TEXT

Section 2032, referred to in subsec. (b), means section 2032 of Pub. L. 114-255.

The Federal Advisory Committee Act, referred to in subsec. (c)(6), is Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

#### CODIFICATION

Section was enacted as part of the 21st Century Cures Act, and not as part of the Public Health Service Act which comprises this chapter.

#### PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

##### SUBPART 1—NATIONAL CANCER INSTITUTE

### § 285. Purpose of Institute

The general purpose of the National Cancer Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

(July 1, 1944, ch. 373, title IV, §410, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 832; amended Pub. L. 100-607, title I, §121, Nov. 4, 1988, 102 Stat. 3054.)

#### AMENDMENTS

1988—Pub. L. 100-607 inserted “, rehabilitation from cancer,” after “treatment of cancer”.

##### WHITE HOUSE CANCER MOONSHOT TASK FORCE

Memorandum of President of the United States, Jan. 28, 2016, 81 F.R. 5361, provided:

Memorandum for the Heads of Executive Departments and Agencies

Cancer is a leading cause of death, and cancer incidence is expected to increase worldwide in the coming decades. But today, cancer research is on the cusp of major breakthroughs. It is of critical national importance that we accelerate progress towards prevention, treatment, and a cure—to double the rate of progress in the fight against cancer—and put ourselves on a path to achieve in just 5 years research and treatment gains that otherwise might take a decade or more. To that end, I hereby direct the following:

SECTION 1. *White House Cancer Moonshot Task Force.* There is established, within the Office of the Vice President, a White House Cancer Moonshot Task Force (Task Force), which will focus on making the most of Federal investments, targeted incentives, private sec-

tor efforts from industry and philanthropy, patient engagement initiatives, and other mechanisms to support cancer research and enable progress in treatment and care. The Vice President shall serve as Chair of the Task Force.

(a) Membership of the Task Force. In addition to the Vice President, the Task Force shall consist of the heads of the executive branch departments, agencies, and offices listed below:

- (i) the Department of Defense;
- (ii) the Department of Commerce;
- (iii) the Department of Health and Human Services;
- (iv) the Department of Energy;
- (v) the Department of Veterans Affairs;
- (vi) the Office of Management and Budget;
- (vii) the National Economic Council;
- (viii) the Domestic Policy Council;
- (ix) the Office of Science and Technology Policy;
- (x) the Food and Drug Administration;
- (xi) the National Cancer Institute (NCI);
- (xii) the National Institutes of Health (NIH);
- (xiii) the National Science Foundation; and
- (xiv) such other executive branch departments, agencies, or offices as the President may designate.

A member of the Task Force may designate, to perform the Task Force functions of the member, any person who is a part of the member's department, agency, or office, and who is a full time officer or employee of the Federal Government. At the direction of the Chair, the Task Force may establish subgroups consisting exclusively of Task Force members or their designees under this section, as appropriate.

(b) Administration of the Task Force. The NIH shall provide funding and administrative support for the Task Force to the extent permitted by law and within existing appropriations. The Vice President shall designate an officer or employee of the executive branch as the Executive Director of the Task Force, who shall coordinate the work of the Task Force.

SEC. 2. *Mission and Functions of the Task Force.* The Task Force shall work with a wide array of executive departments and agencies that have responsibility for key issues related to basic, translational, and clinical research, therapy development, regulation of medical products, and medical care related to cancer. Consistent with applicable law, the Task Force also will consult with external experts from relevant scientific sectors, including the Presidentially appointed National Cancer Advisory Board (NCAB). The NCAB shall advise the Director of NCI on its recommendations respecting the future direction and program and policy emphasis of NCI as it relates to the work of the Task Force. To assist the NCAB in providing this advice, the NCAB is strongly encouraged to establish a working group consisting of a Blue Ribbon Panel of scientific experts. The Director shall relay the advice of the NCAB to the Task Force, as appropriate. The functions of the Task Force are advisory only and shall include, but shall not be limited to, producing a detailed set of findings and recommendations to:

- (a) accelerate our understanding of cancer, and its prevention, early detection, treatment, and cure;
- (b) improve patient access and care;
- (c) support greater access to new research, data, and computational capabilities;
- (d) encourage development of cancer treatments;
- (e) identify and address any unnecessary regulatory barriers and consider ways to expedite administrative reforms;
- (f) ensure optimal investment of Federal resources; and
- (g) identify opportunities to develop public-private partnerships and increase coordination of the Federal Government's efforts with the private sector, as appropriate.

SEC. 3. *Outreach.* Consistent with the objectives set out in section 2 of this memorandum, the Task Force, in accordance with applicable law, in addition to regular meetings, shall conduct outreach with representatives of the cancer patient community, academia, busi-

ness, nonprofit organizations, State and local government agencies, the research community, and other interested persons that will assist with the Task Force's development of a detailed set of recommendations.

SEC. 4. *Transparency and Reports.* The Task Force shall facilitate the posting on the Internet of reports and engage in an open, reciprocal dialogue with the American people. The Task Force shall present to the President a report before December 31, 2016, on its findings and recommendations, which shall be made available to the public and posted on the Internet.

SEC. 5. *General Provisions.* (a) The heads of executive departments and agencies shall assist and provide information to the Task Force, consistent with applicable law, as may be necessary to carry out the functions of the Task Force. Each executive department and agency shall bear its own expense for participating in the Task Force.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:

- (i) authority granted by law to an executive department, agency, or the head thereof; or
- (ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

SEC. 6. *Publication.* The Secretary of Health and Human Services is authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

### § 285a. National Cancer Program

The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute.

(July 1, 1944, ch. 373, title IV, § 411, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 832.)

### § 285a-1. Cancer control programs

The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include—

(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting—

- (A) the detection, diagnosis, prevention, and treatment of cancer,
- (B) the continuing care of cancer patients and the families of cancer patients, and
- (C) rehabilitation and counseling respecting cancer,

to physicians and other health professionals who provide care to individuals who have cancer;

(2) the demonstration of and the education of students of the health professions and health professionals in—

(A) effective methods for the prevention and early detection of cancer and the identification of individuals with a high risk of developing cancer, and

(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

(3) the demonstration of new methods for the dissemination of information to the general public concerning the prevention, early detection, diagnosis, and treatment and control of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

(July 1, 1944, ch. 373, title IV, § 412, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 832.)

### § 285a-2. Special authorities of Director

#### (a) Information and education program

(1) The Director of the Institute shall establish an information and education program to collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to cancer patients and their families, physicians and other health professionals, and the general public, information on cancer research, diagnosis, prevention, and treatment (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer). The Director of the Institute may take such action as may be necessary to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the public and between the Institute and other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

(2) In carrying out paragraph (1), the Director of the Institute shall—

(A) provide public and patient information and education programs, providing information that will help individuals take personal steps to reduce their risk of cancer, to make them aware of early detection techniques and to motivate appropriate utilization of those techniques, to help individuals deal with cancer if it strikes, and to provide information to improve long-term survival;

(B) continue and expand programs to provide physicians and the public with state-of-the-art information on the treatment of particular forms of cancers, and to identify those clinical trials that might benefit patients while advancing knowledge of cancer treatment;

(C) assess the incorporation of state-of-the-art cancer treatments into clinical practice and the extent to which cancer patients receive such treatments and include the results of such assessments in the biennial reports required under section 284b<sup>1</sup> of this title;

(D) maintain and operate the International Cancer Research Data Bank, which shall col-

lect, catalog, store, and disseminate insofar as feasible the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country; and

(E) to the extent practicable, in disseminating the results of such cancer research and treatment, utilize information systems available to the public.

#### (b) National Cancer Program

The Director of the Institute in carrying out the National Cancer Program—

(1) shall establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for cancer research and set standards of safety and care for persons using such materials;

(2) shall, in consultation with the advisory council for the Institute, support (A) research in the cancer field outside the United States by highly qualified foreign nationals which can be expected to benefit the American people, (B) collaborative research involving American and foreign participants, and (C) the training of American scientists abroad and foreign scientists in the United States;

(3) shall, in consultation with the advisory council for the Institute, support appropriate programs of education and training (including continuing education and laboratory and clinical research training);

(4) shall encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

(5) may obtain (after consultation with the advisory council for the Institute and in accordance with section 3109 of title 5, but without regard to the limitation in such section on the period of service) the services of not more than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

(6)(A) may, in consultation with the advisory council for the Institute, acquire, construct, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to section 8141 of title 40, by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(7) may, in consultation with the advisory council for the Institute, appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments to advise the Director with respect to the Director's functions;

(8) may, subject to section 284(b)(2) of this title and without regard to section 3324 of title

<sup>1</sup> See References in Text note below.

31 and section 6101 of title 41, enter into such contracts, leases, cooperative agreements, as may be necessary in the conduct of functions of the Director, with any public agency, or with any person, firm, association, corporation, or educational institution; and

(9) shall, notwithstanding section 284(a) of this title, prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Institute's advisory council.

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (5) shall be paid or reimbursed, in accordance with title 5 for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (5) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

**(c) Pre-clinical models to evaluate promising pediatric cancer therapies**

**(1) Expansion and coordination of activities**

The Director of the National Cancer Institute shall expand, intensify, and coordinate the activities of the Institute with respect to research on the development of preclinical models to evaluate which therapies are likely to be effective for treating pediatric cancer.

**(2) Coordination with other institutes**

The Director of the Institute shall coordinate the activities under paragraph (1) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that those Institutes and agencies have responsibilities that are related to pediatric cancer.

(July 1, 1944, ch. 373, title IV, § 413, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 833; amended Pub. L. 100-607, title I, § 122, Nov. 4, 1988, 102 Stat. 3054; Pub. L. 101-93, § 5(c), Aug. 16, 1989, 103 Stat. 611; Pub. L. 103-43, title III, § 301(a)(2), June 10, 1993, 107 Stat. 150; Pub. L. 107-109, § 15(b), Jan. 4, 2002, 115 Stat. 1420.)

REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (a)(2)(C), was repealed by Pub. L. 109-482, title I, § 104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

CODIFICATION

In subsec. (b)(6)(C), "section 8141 of title 40" substituted for "the Act of March 3, 1877 (40 U.S.C. 34)" on

authority of Pub. L. 107-217, § 5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

In subsec. (b)(8), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes (41 U.S.C. 5)" on authority of Pub. L. 111-350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2002—Subsec. (c). Pub. L. 107-109 added subsec. (c).

1993—Subsec. (b)(9). Pub. L. 103-43 struck out subpar. (A) designation and subpar. (B) which permitted Director to receive from President and Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by Institute.

1989—Subsec. (a)(1). Pub. L. 101-93 substituted "Institute and" for "Institute and and".

1988—Subsec. (a). Pub. L. 100-607, § 122(1), designated existing provisions as par. (1), substituted "education program" for "education center", inserted "and the public and between the Institute and" after "between the Institute", and added par. (2).

Subsec. (b)(5). Pub. L. 100-607, § 122(2)(A), substituted "after consultation with" for "with the approval of".

Subsec. (b)(8) to (10). Pub. L. 100-607, § 122(2)(B), inserted "and" after "or educational institution;" in par. (8), redesignated par. (10) as (9), and struck out former par. (9) which related to International Cancer Research Data Bank.

**§ 285a-3. National cancer research and demonstration centers**

**(a) Cooperative agreements and grants for establishing and supporting**

(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, control, and treatment methods for cancer.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

**(b) Uses for Federal payments under cooperative agreements or grants**

Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) construction (notwithstanding any limitation under section 289e of this title);

(2) staffing and other basic operating costs, including such patient care costs as are required for research;

(3) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer; and

(4) demonstration purposes.

As used in this paragraph, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which Ruth L. Kirschstein National Research Service Awards may be provided under section 288 of this title.

**(c) Period of support; additional periods**

Support of a center under subsection (a) may be for a period of not to exceed five years. Such

period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

**(d) Construction**

Research centers under this section may not be considered centers of excellence for purposes of section 282(b)(10) of this title.

(July 1, 1944, ch. 373, title IV, § 414, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 835; amended Pub. L. 100-607, title I, § 123, Nov. 4, 1988, 102 Stat. 3055; Pub. L. 107-206, title I, § 804(c), Aug. 2, 2002, 116 Stat. 874; Pub. L. 109-482, title I, § 108(b), Jan. 15, 2007, 120 Stat. 3697.)

AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482 added subsec. (d).  
 2002—Subsec. (b). Pub. L. 107-206 substituted “Ruth L. Kirschstein National Research Service Awards” for “National Research Service Awards” in concluding provisions.  
 1988—Subsec. (a)(1). Pub. L. 100-607 inserted “control,” after “prevention.”

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 285a-4. President’s Cancer Panel; establishment, membership, etc., functions**

(a)(1) The President’s Cancer Panel (hereafter in this section referred to as the “Panel”) shall be composed of three persons appointed by the President who by virtue of their training, experience, and background are exceptionally qualified to appraise the National Cancer Program. At least two members of the Panel shall be distinguished scientists or physicians.

(2)(A) Members of the Panel shall be appointed for three-year terms, except that (i) any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member’s predecessor was appointed shall be appointed only for the remainder of such term, and (ii) a member may serve until the member’s successor has taken office. If a vacancy occurs in the Panel, the President shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

(B) The President shall designate one of the members to serve as the chairman of the Panel for a term of one year.

(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties as members of the Panel and shall be paid or reimbursed, in accordance with title 5, for their travel to and from their place of service and for other expenses associated with their assignment.

(3) The Panel shall meet at the call of the chairman, but not less often than four times a year. A transcript shall be kept of the proceed-

ings of each meeting of the Panel, and the chairman shall make such transcript available to the public.

(b) The Panel shall monitor the development and execution of the activities of the National Cancer Program, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the National Cancer Program and shall submit to the President, the Secretary, and the Congress an annual evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct.

(July 1, 1944, ch. 373, title IV, § 415, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 835.)

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions in subsec. (b) of this section relating to the requirement that the Panel submit to Congress an annual evaluation of the efficacy of the Program and suggestions for improvements, see section 3003 of Pub. L. 104-66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 189 of House Document No. 103-7.

TERMINATION OF ADVISORY PANELS

Advisory panels established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a panel established by the President or an officer of the Federal Government, such panel is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a panel established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

**§ 285a-5. Associate Director for Prevention; appointment; function**

(a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of cancer. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b<sup>1</sup> of this title a description of the prevention activities of the Institute,

<sup>1</sup> See References in Text note below.

including a description of the staff and resources allocated to those activities.

(July 1, 1944, ch. 373, title IV, § 416, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 836.)

#### REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (b), was repealed by Pub. L. 109-482, title I, § 104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

### § 285a-6. Breast and gynecological cancers

#### (a) Expansion and coordination of activities

The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on breast cancer, ovarian cancer, and other cancers of the reproductive system of women.

#### (b) Coordination with other institutes

The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes<sup>1</sup> and agencies have responsibilities that are related to breast cancer and other cancers of the reproductive system of women.

#### (c) Programs for breast cancer

##### (1) In general

In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, breast cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

(A) basic research concerning the etiology and causes of breast cancer;

(B) clinical research and related activities concerning the causes, prevention, detection and treatment of breast cancer;

(C) control programs with respect to breast cancer in accordance with section 285a-1 of this title, including community-based programs designed to assist women who are members of medically underserved populations, low-income populations, or minority groups;

(D) information and education programs with respect to breast cancer in accordance with section 285a-2 of this title; and

(E) research and demonstration centers with respect to breast cancer in accordance with section 285a-3 of this title, including the development and operation of centers for breast cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and treatment research and related activities on breast cancer.

Not less than six centers shall be operated under subparagraph (E). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give prior-

ity to expediting the transfer of research advances to clinical applications.

#### (2) Implementation of plan for programs

(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 285a-2(9)<sup>2</sup> of this title. The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

(B) Not later than October 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary and the Director of NIH.

(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

#### (d) Other cancers

In carrying out subsection (a), the Director of the Institute shall conduct or support research on ovarian cancer and other cancers of the reproductive system of women. Activities under such subsection shall provide for the conduct and support of—

(1) basic research concerning the etiology and causes of ovarian cancer and other cancers of the reproductive system of women;

(2) clinical research and related activities into the causes, prevention, detection and treatment of ovarian cancer and other cancers of the reproductive system of women;

(3) control programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 285a-1 of this title;

(4) information and education programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 285a-2 of this title; and

(5) research and demonstration centers with respect to ovarian cancer and cancers of the reproductive system in accordance with section 285a-3 of this title.

#### (e) Report

The Director of the Institute shall prepare, for inclusion in the biennial report submitted under section 284b<sup>3</sup> of this title, a report that describes the activities of the National Cancer Institute under the research programs referred to in subsection (a), that shall include—

(1) a description of the research plan with respect to breast cancer prepared under subsection (c);

<sup>1</sup> So in original. Probably should not be capitalized.

<sup>2</sup> So in original. Probably should be section "285a-2(b)(9)".

<sup>3</sup> See References in Text note below.

(2) an assessment of the development, revision, and implementation of such plan;

(3) a description and evaluation of the progress made, during the period for which such report is prepared, in the research programs on breast cancer and cancers of the reproductive system of women;

(4) a summary and analysis of expenditures made, during the period for which such report is made, for activities with respect to breast cancer and cancers of the reproductive system of women conducted and supported by the National Institutes of Health; and

(5) such comments and recommendations as the Director considers appropriate.

(July 1, 1944, ch. 373, title IV, § 417, as added Pub. L. 103-43, title IV, § 401, June 10, 1993, 107 Stat. 153.)

#### REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (e), was repealed by Pub. L. 109-482, title I, § 104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

#### CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104-14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

### § 285a-7. Prostate cancer

#### (a) Expansion and coordination of activities

The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on prostate cancer.

#### (b) Coordination with other institutes

The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes<sup>1</sup> and agencies have responsibilities that are related to prostate cancer.

#### (c) Programs

##### (1) In general

In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, prostate cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

(A) basic research concerning the etiology and causes of prostate cancer;

(B) clinical research and related activities concerning the causes, prevention, detection and treatment of prostate cancer;

(C) prevention and control and early detection programs with respect to prostate cancer in accordance with section 285a-1 of this title, particularly as it relates to intensifying research on the role of prostate specific antigen for the screening and early detection of prostate cancer;

(D) an Inter-Institute Task Force, under the direction of the Director of the Institute, to provide coordination between relevant National Institutes of Health components of research efforts on prostate cancer;

(E) control programs with respect to prostate cancer in accordance with section 285a-1 of this title;

(F) information and education programs with respect to prostate cancer in accordance with section 285a-2 of this title; and

(G) research and demonstration centers with respect to prostate cancer in accordance with section 285a-3 of this title, including the development and operation of centers for prostate cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and control, treatment, research, and related activities on prostate cancer.

Not less than six centers shall be operated under subparagraph (G). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

#### (2) Implementation of plan for programs

(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 285a-2(9)<sup>2</sup> of this title. The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

(B) Not later than October 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

<sup>1</sup> So in original. Probably should not be capitalized.

<sup>2</sup> So in original. Probably should be section "285a-2(b)(9)".

(July 1, 1944, ch. 373, title IV, §417A, as added Pub. L. 103-43, title IV, §402, June 10, 1993, 107 Stat. 155.)

#### CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104-14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

#### § 285a-8. Repealed. Pub. L. 109-482, title I, § 103(b)(15), Jan. 15, 2007, 120 Stat. 3687

Section, act July 1, 1944, ch. 373, title IV, §417B, as added Pub. L. 103-43, title IV, §403(a), June 10, 1993, 107 Stat. 157; amended Pub. L. 105-340, title I, §103, Oct. 31, 1998, 112 Stat. 3192; Pub. L. 106-505, title VI, §602(b), Nov. 13, 2000, 114 Stat. 2346, related to authorization of appropriations.

#### EFFECTIVE DATE OF REPEAL

Repeal applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

#### § 285a-9. Grants for education, prevention, and early detection of radiogenic cancers and diseases

##### (a) Definition

In this section the term “entity” means any—

- (1) National Cancer Institute-designated cancer center;
- (2) Department of Veterans Affairs hospital or medical center;
- (3) Federally Qualified Health Center, community health center, or hospital;
- (4) agency of any State or local government, including any State department of health; or
- (5) nonprofit organization.

##### (b) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration in consultation with the Director of the National Institutes of Health and the Director of the Indian Health Service, may make competitive grants to any entity for the purpose of carrying out programs to—

- (1) screen individuals described under section 4(a)(1)(A)(i) or 5(a)(1)(A) of the Radiation Exposure Compensation Act (42 U.S.C. 2210 note) for cancer as a preventative health measure;
- (2) provide appropriate referrals for medical treatment of individuals screened under paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services;
- (3) develop and disseminate public information and education programs for the detection,

prevention, and treatment of radiogenic cancers and diseases; and

- (4) facilitate putative applicants in the documentation of claims as described in section 5(a) of the Radiation Exposure Compensation Act (42 U.S.C. 2210 note).

##### (c) Indian Health Service

The programs under subsection (a) shall include programs provided through the Indian Health Service or through tribal contracts, compacts, grants, or cooperative agreements with the Indian Health Service and which are determined appropriate to raising the health status of Indians.

##### (d) Grant and contract authority

Entities receiving a grant under subsection (b) may expend the grant to carry out the purpose described in such subsection.

##### (e) Health coverage unaffected

Nothing in this section shall be construed to affect any coverage obligation of a governmental or private health plan or program relating to an individual referred to under subsection (b)(1).

(July 1, 1944, ch. 373, title IV, §417C, as added Pub. L. 106-245, §4, July 10, 2000, 114 Stat. 508; amended Pub. L. 109-482, title I, §§103(b)(16), 104(b)(1)(F), Jan. 15, 2007, 120 Stat. 3687, 3693.)

#### REFERENCES IN TEXT

Sections 4 and 5 of the Radiation Exposure Compensation Act, referred to in subsec. (b)(1) and (4), are sections 4 and 5 of Pub. L. 101-426, which are set out as a note under section 2210 of this title.

#### AMENDMENTS

2007—Subsec. (f). Pub. L. 109-482, §104(b)(1)(F), struck out heading and text of subsec. (f). Text read as follows: “Beginning on October 1 of the year following the date on which amounts are first appropriated to carry out this section and annually on each October 1 thereafter, the Secretary shall submit a report to the Committee on the Judiciary and the Committee on Health, Education, Labor, and Pensions of the Senate and to the Committee on the Judiciary and the Committee on Commerce of the House of Representatives. Each report shall summarize the expenditures and programs funded under this section as the Secretary determines to be appropriate.”

Subsec. (g). Pub. L. 109-482, §103(b)(16), struck out heading and text of subsec. (g). Text read as follows: “There are authorized to be appropriated for the purpose of carrying out this section \$20,000,000 for fiscal year 1999 and such sums as may be necessary for each of the fiscal years 2000 through 2009.”

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### § 285a-10. Research, information, and education with respect to blood cancer

##### (a) Joe Moakley Research Excellence Program

###### (1) In general

The Director of NIH shall expand, intensify, and coordinate programs for the conduct and support of research with respect to blood cancer, and particularly with respect to leukemia, lymphoma, and multiple myeloma.

**(2) Administration**

The Director of NIH shall carry out this subsection through the Director of the National Cancer Institute and in collaboration with any other agencies that the Director determines to be appropriate.

**(b) Geraldine Ferraro Cancer Education Program****(1) In general**

The Secretary shall direct the appropriate agency within the Department of Health and Human Services, in collaboration with the Director of NIH, to establish and carry out a program to provide information and education for patients and the general public with respect to blood cancer, and particularly with respect to the treatment of leukemia, lymphoma, and multiple myeloma.

**(2) Administration**

The Agency determined by the Secretary under paragraph (1) shall carry out this subsection in collaboration with private health organizations that have national education and patient assistance programs on blood-related cancers.

(July 1, 1944, ch. 373, title IV, §417D, as added Pub. L. 107-172, §3, May 14, 2002, 116 Stat. 541; amended Pub. L. 109-482, title I, §103(b)(17), Jan. 15, 2007, 120 Stat. 3688.)

## CODIFICATION

Section 3 of Pub. L. 107-172, which directed that section 417D (this section) be inserted after section 419C of part C of title IV of the Public Health Service Act, was executed by adding section 417D to part C of title IV of the Public Health Service Act, to reflect the probable intent of Congress, notwithstanding that part C does not contain a section 419C.

## AMENDMENTS

2007—Subsec. (a)(3). Pub. L. 109-482, §103(b)(17)(A), struck out heading and text of par. (3). Text read as follows: “For the purpose of carrying out this subsection, there is authorized to be appropriated such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year. Such authorizations of appropriations are in addition to other authorizations of appropriations that are available for such purpose.”

Subsec. (b)(3). Pub. L. 109-482, §103(b)(17)(B), struck out heading and text of par. (3). Text read as follows: “For the purpose of carrying out this subsection, there is authorized to be appropriated such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year. Such authorizations of appropriations are in addition to other authorizations of appropriations that are available for such purpose.”

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

## CONGRESSIONAL FINDINGS

Pub. L. 107-172, §2, May 14, 2002, 116 Stat. 541, provided that: “Congress finds that:

“(1) An estimated 109,500 people in the United States will be diagnosed with leukemia, lymphoma, and multiple myeloma in 2001.

“(2) New cases of the blood cancers described in paragraph (1) account for 8.6 percent of new cancer cases.

“(3) Those devastating blood cancers will cause the deaths of an estimated 60,300 persons in the United States in 2001. Every 9 minutes, a person in the United States dies from leukemia, lymphoma, or multiple myeloma.

“(4) While less than 5 percent of Federal funds for cancer research are spent on those blood cancers, those blood cancers cause 11 percent of all cancer deaths in the United States.

“(5) Increased Federal support of research into leukemia, lymphoma, and multiple myeloma has resulted and will continue to result in significant advances in the treatment, and ultimately the cure, of those blood cancers as well as other cancers.”

**§ 285a-11. Pediatric cancer research and awareness****(a) Pediatric cancer research****(1) Programs of research excellence in pediatric cancer**

The Secretary, in collaboration with the Director of NIH and other Federal agencies with interest in prevention and treatment of pediatric cancer, shall continue to enhance, expand, and intensify pediatric cancer research and other activities related to pediatric cancer, including therapeutically applicable research to generate effective treatments, pediatric preclinical testing, and pediatric clinical trials through National Cancer Institute-supported pediatric cancer clinical trial groups and their member institutions. In enhancing, expanding, and intensifying such research and other activities, the Secretary is encouraged to take into consideration the application of such research and other activities for minority, health disparity, and medically underserved communities. For purposes of this section, the term “pediatric cancer research” means research on the causes, prevention, diagnosis, recognition, treatment, and long-term effects of pediatric cancer.

**(2) Peer review requirements**

All grants awarded under this subsection shall be awarded in accordance with section 289a of this title.

**(b) Public awareness of pediatric cancers and available treatments and research****(1) In general**

The Secretary may award grants to childhood cancer professional and direct service organizations for the expansion and widespread implementation of—

(A) activities that provide available information on treatment protocols to ensure early access to the best available therapies and clinical trials for pediatric cancers;

(B) activities that provide available information on the late effects of pediatric cancer treatment to ensure access to necessary long-term medical and psychological care; and

(C) direct resource services such as educational outreach for parents, peer-to-peer and parent-to-parent support networks, information on school re-entry and post-secondary education, and resource directories or referral services for financial assistance, psychological counseling, and other support services.

In awarding grants under this paragraph, the Secretary is encouraged to take into consideration the extent to which an entity would use such grant for purposes of making activities and services described in this paragraph available to minority, health disparity, and medically underserved communities.

**(2) Performance measurement, transparency, and accountability**

For each grant awarded under this subsection, the Secretary shall develop and implement metrics-based performance measures to assess the effectiveness of activities funded under such grant.

**(3) Informational requirements**

Any information made available pursuant to a grant awarded under paragraph (1) shall be—

- (A) culturally and linguistically appropriate as needed by patients and families affected by childhood cancer; and
- (B) approved by the Secretary.

**(c) Rule of construction**

Nothing in this section shall be construed as being inconsistent with the goals and purposes of the Minority Health and Health Disparities Research and Education Act of 2000 (42 U.S.C. 202 note).<sup>1</sup>

**(d) Authorization of appropriations**

For purposes of carrying out this section and section 280e-3a of this title, there are authorized to be appropriated \$30,000,000 for each of fiscal years 2009 through 2013. Such authorization of appropriations is in addition to the authorization of appropriations established in section 282a of this title with respect to such purpose. Funds appropriated under this subsection shall remain available until expended.

(July 1, 1944, ch. 373, title IV, §417E, as added Pub. L. 110-285, §4(a), July 29, 2008, 122 Stat. 2629.)

REFERENCES IN TEXT

The Minority Health and Health Disparities Research and Education Act of 2000, referred to in subsec. (c), is Pub. L. 106-525, Nov. 22, 2000, 114 Stat. 2495. For complete classification of this Act to the Code, see Short Title of 2000 Amendments note set out under section 201 of this title and Tables.

**§ 285a-12. Interagency Breast Cancer and Environmental Research Coordinating Committee**

**(a) Interagency Breast Cancer and Environmental Research Coordinating Committee**

**(1) Establishment**

Not later than 6 months after October 8, 2008, the Secretary shall establish a committee, to be known as the Interagency Breast Cancer and Environmental Research Coordinating Committee (in this section referred to as the “Committee”).

**(2) Duties**

The Committee shall—

- (A) share and coordinate information on existing research activities, and make recommendations to the National Institutes of

Health and other Federal agencies regarding how to improve existing research programs, that are related to breast cancer research;

(B) develop a comprehensive strategy and advise the National Institutes of Health and other Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research, including proposals to evaluate environmental and genomic factors that may be related to the etiology of breast cancer that would—

(i) result in innovative approaches to study emerging scientific opportunities or eliminate knowledge gaps in research to improve the research portfolio;

(ii) outline key research questions, methodologies, and knowledge gaps;

(iii) expand the number of research proposals that involve collaboration between 2 or more national research institutes or national centers, including proposals for Common Fund research described in section 282(b)(7) of this title to improve the research portfolio; and

(iv) expand the number of collaborative, multidisciplinary, and multi-institutional research grants;

(C) develop a summary of advances in breast cancer research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and treatment of cancer and other diseases and disorders; and

(D) not later than 2 years after the date of the establishment of the Committee, make recommendations to the Secretary—

(i) regarding any appropriate changes to research activities, including recommendations to improve the research portfolio of the National Institutes of Health to ensure that scientifically-based strategic planning is implemented in support of research priorities that impact breast cancer research activities;

(ii) to ensure that the activities of the National Institutes of Health and other Federal agencies, including the Department of Defense, are free of unnecessary duplication of effort;

(iii) regarding public participation in decisions relating to breast cancer research to increase the involvement of patient advocacy and community organizations representing a broad geographical area;

(iv) on how best to disseminate information on breast cancer research progress; and

(v) on how to expand partnerships between public entities, including Federal agencies, and private entities to expand collaborative, cross-cutting research.

**(3) Rule of construction**

For the purposes of the Committee, when focusing on research to evaluate environmental and genomic factors that may be related to the etiology of breast cancer, nothing in this section shall be construed to restrict the Secretary from including other forms of cancer, as appropriate, when doing so may advance research in breast cancer or advance research in other forms of cancer.

<sup>1</sup> So in original. See References in Text note below.

**(4) Membership****(A) In general**

The Committee shall be composed of the following voting members:

(i) Not more than 7 voting Federal representatives as follows:

(I) The Director of the Centers for Disease Control and Prevention.

(II) The Director of the National Institutes of Health and the directors of such national research institutes and national centers (which may include the National Institute of Environmental Health Sciences) as the Secretary determines appropriate.

(III) One representative from the National Cancer Institute Board of Scientific Advisors, appointed by the Director of the National Cancer Institute.

(IV) The heads of such other agencies of the Department of Health and Human Services as the Secretary determines appropriate.

(V) Representatives of other Federal agencies that conduct or support cancer research, including the Department of Defense.

(ii) 12 additional voting members appointed under subparagraph (B).

**(B) Additional members**

The Committee shall include additional voting members appointed by the Secretary as follows:

(i) 6 members shall be appointed from among scientists, physicians, and other health professionals, who—

(I) are not officers or employees of the United States;

(II) represent multiple disciplines, including clinical, basic, and public health sciences;

(III) represent different geographical regions of the United States;

(IV) are from practice settings, academia, or other research settings; and

(V) are experienced in scientific peer review process.

(ii) 6 members shall be appointed from members of the general public, who represent individuals with breast cancer.

**(C) Nonvoting members**

The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

**(5) Chairperson**

The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH.

**(6) Meetings**

The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

**(b) Review**

The Secretary shall review the necessity of the Committee in calendar year 2011 and, thereafter, at least once every 2 years.

(July 1, 1944, ch. 373, title IV, §417F, as added Pub. L. 110-354, §2(a), Oct. 8, 2008, 122 Stat. 3984.)

**§ 285a-13. Scientific framework for recalcitrant cancers****(a) Development of scientific framework****(1) In general**

For each recalcitrant cancer identified under subsection (b), the Director of the Institute shall develop (in accordance with subsection (c)) a scientific framework for the conduct or support of research on such cancer.

**(2) Contents**

The scientific framework with respect to a recalcitrant cancer shall include the following:

**(A) Current status****(i) Review of literature**

A summary of findings from the current literature in the areas of—

(I) the prevention, diagnosis, and treatment of such cancer;

(II) the fundamental biologic processes that regulate such cancer (including similarities and differences of such processes from the biological processes that regulate other cancers); and

(III) the epidemiology of such cancer.

**(ii) Scientific advances**

The identification of relevant emerging scientific areas and promising scientific advances in basic, translational, and clinical science relating to the areas described in subclauses (I) and (II) of clause (i).

**(iii) Researchers**

A description of the availability of qualified individuals to conduct scientific research in the areas described in clause (i).

**(iv) Coordinated research initiatives**

The identification of the types of initiatives and partnerships for the coordination of intramural and extramural research of the Institute in the areas described in clause (i) with research of the relevant national research institutes, Federal agencies, and non-Federal public and private entities in such areas.

**(v) Research resources**

The identification of public and private resources, such as patient registries and tissue banks, that are available to facilitate research relating to each of the areas described in clause (i).

**(B) Identification of research questions**

The identification of research questions relating to basic, translational, and clinical science in the areas described in subclauses (I) and (II) of subparagraph (A)(i) that have not been adequately addressed with respect to such recalcitrant cancer.

**(C) Recommendations**

Recommendations for appropriate actions that should be taken to advance research in the areas described in subparagraph (A)(i)

and to address the research questions identified in subparagraph (B), as well as for appropriate benchmarks to measure progress on achieving such actions, including the following:

**(i) Researchers**

Ensuring adequate availability of qualified individuals described in subparagraph (A)(iii).

**(ii) Coordinated research initiatives**

Promoting and developing initiatives and partnerships described in subparagraph (A)(iv).

**(iii) Research resources**

Developing additional public and private resources described in subparagraph (A)(v) and strengthening existing resources.

**(3) Timing**

**(A) Initial development and subsequent update**

For each recalcitrant cancer identified under subsection (b)(1), the Director of the Institute shall—

- (i) develop a scientific framework under this subsection not later than 18 months after January 2, 2013; and
- (ii) review and update the scientific framework not later than 5 years after its initial development.

**(B) Other updates**

The Director of the Institute may review and update each scientific framework developed under this subsection as necessary.

**(4) Public notice**

With respect to each scientific framework developed under subsection (a), not later than 30 days after the date of completion of the framework, the Director of the Institute shall—

- (A) submit such framework to the Committee on Energy and Commerce and Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and Committee on Appropriations of the Senate; and
- (B) make such framework publically<sup>1</sup> available on the Internet website of the Department of Health and Human Services.

**(b) Identification of recalcitrant cancer**

**(1) In general**

Not later than 6 months after January 2, 2013, the Director of the Institute shall identify two or more recalcitrant cancers that each—

- (A) have a 5-year relative survival rate of less than 20 percent; and
- (B) are estimated to cause the death of at least 30,000 individuals in the United States per year.

**(2) Additional cancers**

The Director of the Institute may, at any time, identify other recalcitrant cancers for

purposes of this section. In identifying a recalcitrant cancer pursuant to the previous sentence, the Director may consider additional metrics of progress (such as incidence and mortality rates) against such type of cancer.

**(c) Working groups**

For each recalcitrant cancer identified under subsection (b), the Director of the Institute shall convene a working group comprised of representatives of appropriate Federal agencies and other non-Federal entities to provide expertise on, and assist in developing, a scientific framework under subsection (a). The Director of the Institute (or the Director's designee) shall participate in the meetings of each such working group.

**(d) Reporting**

**(1) Biennial reports**

The Director of NIH shall ensure that each biennial report under section 283 of this title includes information on actions undertaken to carry out each scientific framework developed under subsection (a) with respect to a recalcitrant cancer, including the following:

- (A) Information on research grants awarded by the National Institutes of Health for research relating to such cancer.
- (B) An assessment of the progress made in improving outcomes (including relative survival rates) for individuals diagnosed with such cancer.
- (C) An update on activities pertaining to such cancer under the authority of section 285a-2(b)(7) of this title.

**(2) Additional one-time report for certain frameworks**

For each recalcitrant cancer identified under subsection (b)(1), the Director of the Institute shall, not later than 6 years after the initial development of a scientific framework under subsection (a), submit a report to the Congress on the effectiveness of the framework (including the update required by subsection (a)(3)(A)(ii)) in improving the prevention, detection, diagnosis, and treatment of such cancer.

**(e) Recommendations for exception funding**

The Director of the Institute shall consider each relevant scientific framework developed under subsection (a) when making recommendations for exception funding for grant applications.

**(f) Definition**

In this section, the term “recalcitrant cancer” means a cancer for which the five-year relative survival rate is below 50 percent.

(July 1, 1944, ch. 373, title IV, §417G, as added Pub. L. 112-239, div. A, title X, §1083, Jan. 2, 2013, 126 Stat. 1960.)

SUBPART 2—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

**§ 285b. Purpose of Institute**

The general purpose of the National Heart, Lung, and Blood Institute (hereafter in this subpart referred to as the “Institute”) is the con-

<sup>1</sup> So in original. Probably should be “publicly”.

duct and support of research, training, health information dissemination, and other programs with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood products and the management of blood resources.

(July 1, 1944, ch. 373, title IV, § 418, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 836.)

**§ 285b-1. Heart, blood vessel, lung, and blood disease prevention and control programs**

(a) The Director of the Institute shall conduct and support programs for the prevention and control of heart, blood vessel, lung, and blood diseases. Such programs shall include community-based and population-based programs carried out in cooperation with other Federal agencies, with public health agencies of State or local governments, with nonprofit private entities that are community-based health agencies, or with other appropriate public or nonprofit private entities.

(b) In carrying out programs under subsection (a), the Director of the Institute shall give special consideration to the prevention and control of heart, blood vessel, lung, and blood diseases in children, and in populations that are at increased risk with respect to such diseases.

(July 1, 1944, ch. 373, title IV, § 419, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 836; amended Pub. L. 103-43, title V, § 505, June 10, 1993, 107 Stat. 160.)

AMENDMENTS

1993—Pub. L. 103-43 substituted subsecs. (a) and (b) for former section which read as follows: “The Director of the Institute, under policies established by the Director of NIH and after consultation with the advisory council for the Institute, shall establish programs as necessary for cooperation with other Federal health agencies, State, local, and regional public health agencies, and nonprofit private health agencies in the diagnosis, prevention, and treatment (including the provision of emergency medical services) of heart, blood vessel, lung, and blood diseases, appropriately emphasizing the prevention, diagnosis, and treatment of such diseases of children.”

**§ 285b-2. Information and education**

The Director of the Institute shall collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to patients, families of patients, physicians and other health professionals, and the general public, information on research, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases, the maintenance of health to reduce the incidence of such diseases, and on the use of blood and blood products and the management of blood resources. In carrying out this section, the Director of the Institute shall place special emphasis upon the utilization of collaborative efforts with both the public and private sectors to—

(1) increase the awareness and knowledge of health care professionals and the public regarding the prevention of heart and blood vessel, lung, and blood diseases and the utilization of blood resources; and

(2) develop and disseminate to health professionals, patients and patient families, and the

public information designed to encourage adults and children to adopt healthful practices concerning the prevention of such diseases.

(July 1, 1944, ch. 373, title IV, § 420, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 837; amended Pub. L. 100-607, title I, § 126, Nov. 4, 1988, 102 Stat. 3055.)

AMENDMENTS

1988—Pub. L. 100-607 amended second sentence generally. Prior to amendment, second sentence read as follows: “In carrying out this section the Director of the Institute shall place special emphasis upon—

“(1) the dissemination of information regarding diet and nutrition, environmental pollutants, exercise, stress, hypertension, cigarette smoking, weight control, and other factors affecting the prevention of arteriosclerosis and other cardiovascular diseases and of pulmonary and blood diseases; and

“(2) the dissemination of information designed to encourage children to adopt healthful habits respecting the risk factors related to the prevention of such diseases.”

**§ 285b-3. National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program; administrative provisions**

(a)(1) The National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this subpart referred to as the “Program”) may provide for—

(A) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;

(B) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

(C) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including the provision of emergency medical services), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

(D) establishment of programs that will focus and apply scientific and technological efforts involving the biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on the refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of and rehabilitation from such diseases;

(E) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;

(F) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the manage-

ment of blood resources in the United States, including the collection, preservation, fractionation, and distribution of blood and blood products;

(G) the education (including continuing education) and training of scientists, clinical investigators, and educators, in fields and specialties (including computer sciences) requisite to the conduct of clinical programs respecting heart, blood vessel, lung, and blood diseases and blood resources;

(H) public and professional education relating to all aspects of such diseases, including the prevention of such diseases, and the use of blood and blood products and the management of blood resources;

(I) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, hemolytic diseases such as sickle cell anemia and Cooley's anemia, and hemophilic diseases) and for the development and demonstration of diagnostic, treatment, and preventive approaches to such diseases; and

(J) establishment of programs for study, research, development, demonstrations and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, or blood diseases.

(2) The Program shall be coordinated with other national research institutes to the extent that they have responsibilities respecting such diseases and shall give special emphasis to the continued development in the Institute of programs related to the causes of stroke and to effective coordination of such programs with related stroke programs in the National Institute of Neurological and Communicative Disorders and Stroke. The Director of the Institute, with the advice of the advisory council for the Institute, shall revise annually the plan for the Program and shall carry out the Program in accordance with such plan.

(b) In carrying out the Program, the Director of the Institute, under policies established by the Director of NIH—

(1) may, after consultation with the advisory council for the Institute, obtain (in accordance with section 3109 of title 5, but without regard to the limitation in such section on the period of such service) the services of not more than one hundred experts or consultants who have scientific or professional qualifications;

(2)(A) may, in consultation with the advisory council for the Institute, acquire and construct, improve, repair, operate, alter, renovate, and maintain, heart, blood vessel, lung, and blood disease and blood resource laboratories, research, training, and other facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to section 8141 of title 40, by lease or otherwise, through the Administrator of Gen-

eral Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(3) subject to section 284(b)(2) of this title and without regard to section 3324 of title 31 and section 6101 of title 41, may enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary in the conduct of the Director's functions, with any public agency, or with any person, firm, association, corporation, or educational institutions;

(4) may make grants to public and nonprofit private entities to assist in meeting the cost of the care of patients in hospitals, clinics, and related facilities who are participating in research projects; and

(5) shall, in consultation with the advisory council for the Institute, conduct appropriate intramural training and education programs, including continuing education and laboratory and clinical research training programs.

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

(July 1, 1944, ch. 373, title IV, § 421, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 837; amended Pub. L. 100-607, title I, § 127, Nov. 4, 1988, 102 Stat. 3055; Pub. L. 103-43, title V, § 501, title XX, § 2008(b)(3), June 10, 1993, 107 Stat. 158, 211.)

#### CODIFICATION

In subsec. (b)(2)(C), "section 8141 of title 40" substituted for "the Act of March 3, 1877 (40 U.S.C. 34)" on authority of Pub. L. 107-217, § 5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

In subsec. (b)(3), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes (41 U.S.C. 5)" on authority of Pub. L. 111-350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

#### AMENDMENTS

1993—Subsec. (b)(1). Pub. L. 103-43, § 2008(b)(3), inserted comma after "may".

Subsec. (b)(5). Pub. L. 103-43, § 501, added par. (5).

1988—Subsec. (a)(1)(D). Pub. L. 100-607, § 127(1), inserted "and rehabilitation from" after "and treatment of".

Subsec. (b)(1). Pub. L. 100-607, § 127(2), substituted "after consultation with" for "after approval of".

**§ 285b-4. National research and demonstration centers**

**(a) Heart, blood vessel, lung, blood diseases, and blood resources; utilization of centers for prevention programs**

(1) The Director of the Institute may provide, in accordance with subsection (c), for the development of—

(A) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment and rehabilitation methods (including methods of providing emergency medical services) for heart and blood vessel diseases;

(B) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment and rehabilitation methods (including methods of providing emergency medical services) for lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children);

(C) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood diseases and research into blood, in the use of blood products and in the management of blood resources; and

(D) three centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment (including genetic studies, intrauterine environment studies, postnatal studies, heart arrhythmias, and acquired heart disease and preventive cardiology) for cardiovascular diseases in children.

(2) The centers developed under paragraph (1) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, pulmonary, and blood diseases:

(A) Programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular, pulmonary, and blood diseases.

(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such diseases.

(C) Programs to develop health professions and allied health professions personnel highly skilled in the prevention of such diseases.

(D) Programs to develop improved methods of providing emergency medical services for persons with such diseases.

(E) Programs of continuing education for health and allied health professionals in the diagnosis, prevention, and treatment of such diseases and the maintenance of health to reduce the incidence of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases and the maintenance of health.

(3) The research, training, and demonstration activities carried out through any such center may relate to any one or more of the diseases referred to in paragraph (1) of this subsection.

**(b) Sickle cell anemia**

The Director of the Institute shall provide, in accordance with subsection (c), for the development of ten centers for basic and clinical research into the diagnosis, treatment, and control of sickle cell anemia.

**(c) Cooperative agreements and grants for establishing and supporting; uses for Federal payments; period of support, additional periods**

(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(3) Federal payments made under a cooperative agreement or grant under paragraph (1) may be used for—

(A) construction (notwithstanding any limitation under section 289e of this title);

(B) staffing and other basic operating costs, including such patient care costs as are required for research;

(C) training, including training for allied health professionals; and

(D) demonstration purposes.

As used in this subsection, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which Ruth L. Kirschstein National Research Service Awards may be provided under section 288 of this title.

(4) Support of a center under paragraph (1) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, §422, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 839; amended Pub. L. 100-607, title I, §128, Nov. 4, 1988, 102 Stat. 3055; Pub. L. 103-43, title V, §502, June 10, 1993, 107 Stat. 158; Pub. L. 107-206, title I, §804(c), Aug. 2, 2002, 116 Stat. 874.)

AMENDMENTS

2002—Subsec. (c)(3). Pub. L. 107-206 substituted "Ruth L. Kirschstein National Research Service Awards" for "National Research Service Awards" in concluding provisions.

1993—Subsec. (a)(1)(D). Pub. L. 103-43 added subpar. (D).

1988—Subsec. (a)(1)(A), (B). Pub. L. 100-607 inserted "and rehabilitation" after "prevention, and treatment".

**§ 285b-5. Repealed. Pub. L. 100-607, title I, § 129, Nov. 4, 1988, 102 Stat. 3055**

Section, act July 1, 1944, ch. 373, title IV, § 423, as added Nov. 20, 1985, Pub. L. 99-158, § 2, 99 Stat. 841, directed Secretary to establish an Interagency Technical Committee on Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources.

**§ 285b-6. Associate Director for Prevention; appointment; function**

(a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of heart, blood vessel, lung, and blood diseases. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b<sup>1</sup> of this title a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

(July 1, 1944, ch. 373, title IV, § 423, formerly § 424, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 841; renumbered § 423, Pub. L. 100-607, title I, § 129, Nov. 4, 1988, 102 Stat. 3055.)

REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (b), was repealed by Pub. L. 109-482, title I, § 104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

PRIOR PROVISIONS

A prior section 423 of act July 1, 1944, was classified to section 285b-5 of this title prior to repeal by Pub. L. 100-607.

**§ 285b-7. National Center on Sleep Disorders Research**

**(a) Establishment**

Not later than 1 year after June 10, 1993, the Director of the Institute shall establish the National Center on Sleep Disorders Research (in this section referred to as the "Center"). The Center shall be headed by a director, who shall be appointed by the Director of the Institute.

**(b) Purpose**

The general purpose of the Center is—

(1) the conduct and support of research, training, health information dissemination, and other activities with respect to sleep disorders, including biological and circadian rhythm research, basic understanding of sleep, chronobiological and other sleep related research; and

(2) to coordinate the activities of the Center with similar activities of other Federal agencies, including the other agencies of the National Institutes of Health, and similar activities of other public entities and nonprofit entities.

**(c) Sleep Disorders Research Advisory Board**

(1) The Director of the National Institutes of Health shall establish a board to be known as

the Sleep Disorders Research Advisory Board (in this section referred to as the "Advisory Board").

(2) The Advisory Board shall advise, assist, consult with, and make recommendations to the Director of the National Institutes of Health, through the Director of the Institute, and the Director of the Center concerning matters relating to the scientific activities carried out by and through the Center and the policies respecting such activities, including recommendations with respect to the plan required in subsection (c).<sup>1</sup>

(3)(A) The Director of the National Institutes of Health shall appoint to the Advisory Board 12 appropriately qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, eight shall be representatives of health and scientific disciplines with respect to sleep disorders and four shall be individuals representing the interests of individuals with or undergoing treatment for sleep disorders.

(B) The following officials shall serve as ex officio members of the Advisory Board:

(i) The Director of the National Institutes of Health.

(ii) The Director of the Center.

(iii) The Director of the National Heart, Lung and Blood Institute.

(iv) The Director of the National Institute of Mental Health.

(v) The Director of the National Institute on Aging.

(vi) The Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

(vii) The Director of the National Institute of Neurological Disorders and Stroke.

(viii) The Assistant Secretary for Health.

(ix) The Assistant Secretary of Defense (Health Affairs).

(x) The Chief Medical Director of the Veterans' Administration.

(4) The members of the Advisory Board shall, from among the members of the Advisory Board, designate an individual to serve as the chair of the Advisory Board.

(5) Except as inconsistent with, or inapplicable to, this section, the provisions of section 284a of this title shall apply to the advisory board<sup>2</sup> established under this section in the same manner as such provisions apply to any advisory council established under such section.

**(d) Development of comprehensive research plan; revision**

(1) After consultation with the Director of the Center and the advisory board<sup>2</sup> established under subsection (c), the Director of the National Institutes of Health shall develop a comprehensive plan for the conduct and support of sleep disorders research.

(2) The plan developed under paragraph (1) shall identify priorities with respect to such research and shall provide for the coordination of such research conducted or supported by the agencies of the National Institutes of Health.

(3) The Director of the National Institutes of Health (after consultation with the Director of

<sup>1</sup> So in original. Probably should be subsection "(d)".

<sup>2</sup> So in original. Probably should be capitalized.

<sup>1</sup> See References in Text note below.

the Center and the advisory board<sup>2</sup> established under subsection (c)) shall revise the plan developed under paragraph (1) as appropriate.

**(e) Collection and dissemination of information**

The Director of the Center, in cooperation with the Centers for Disease Control and Prevention, is authorized to coordinate activities with the Department of Transportation, the Department of Defense, the Department of Education, the Department of Labor, and the Department of Commerce to collect data, conduct studies, and disseminate public information concerning the impact of sleep disorders and sleep deprivation.

(July 1, 1944, ch. 373, title IV, § 424, as added Pub. L. 103-43, title V, § 503, June 10, 1993, 107 Stat. 159; amended Pub. L. 110-154, § 1(b)(5), Dec. 21, 2007, 121 Stat. 1827.)

AMENDMENTS

2007—Subsec. (c)(3)(B)(vi). Pub. L. 110-154 substituted “Eunice Kennedy Shriver National Institute of Child Health and Human Development” for “National Institute of Child Health and Human Development”.

CHANGE OF NAME

Reference to Chief Medical Director of Department of Veterans Affairs deemed to refer to Under Secretary for Health of Department of Veterans Affairs pursuant to section 302(e) of Pub. L. 102-405, set out as a note under section 305 of Title 38, Veterans' Benefits.

Reference to Chief Medical Director of Veterans' Administration deemed to refer to Chief Medical Director of Department of Veterans Affairs pursuant to section 10 of Pub. L. 100-527, set out as a Department of Veterans Affairs Act note under section 201 of Title 38.

TERMINATION OF ADVISORY BOARDS

Advisory boards established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a board established by the President or an officer of the Federal Government, such board is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a board established by Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

**§ 285b-7a. Heart attack, stroke, and other cardiovascular diseases in women**

**(a) In general**

The Director of the Institute shall expand, intensify, and coordinate research and related activities of the Institute with respect to heart attack, stroke, and other cardiovascular diseases in women.

**(b) Coordination with other institutes**

The Director of the Institute shall coordinate activities under subsection (a) with similar activities conducted by the other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to heart attack, stroke, and other cardiovascular diseases in women.

**(c) Certain programs**

In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the causes of, and to develop methods for preventing, cardiovascular diseases in women. Activities under such subsection shall include conducting and supporting the following:

(1) Research to determine the reasons underlying the prevalence of heart attack, stroke, and other cardiovascular diseases in women, including African-American women and other women who are members of racial or ethnic minority groups.

(2) Basic research concerning the etiology and causes of cardiovascular diseases in women.

(3) Epidemiological studies to address the frequency and natural history of such diseases and the differences among men and women, and among racial and ethnic groups, with respect to such diseases.

(4) The development of safe, efficient, and cost-effective diagnostic approaches to evaluating women with suspected ischemic heart disease.

(5) Clinical research for the development and evaluation of new treatments for women, including rehabilitation.

(6) Studies to gain a better understanding of methods of preventing cardiovascular diseases in women, including applications of effective methods for the control of blood pressure, lipids, and obesity.

(7) Information and education programs for patients and health care providers on risk factors associated with heart attack, stroke, and other cardiovascular diseases in women, and on the importance of the prevention or control of such risk factors and timely referral with appropriate diagnosis and treatment. Such programs shall include information and education on health-related behaviors that can improve such important risk factors as smoking, obesity, high blood cholesterol, and lack of exercise.

(July 1, 1944, ch. 373, title IV, § 424A, as added Pub. L. 105-340, title I, § 104, Oct. 31, 1998, 112 Stat. 3192; amended Pub. L. 109-482, title I, § 103(b)(18), Jan. 15, 2007, 120 Stat. 3688.)

AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482 struck out heading and text of subsec. (d). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriation that is available for such purpose.”

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 285b-7b. Coordination of Federal asthma activities**

**(a) In general**

The Director of<sup>1</sup> Institute shall, through the National Asthma Education Prevention Program Coordinating Committee—

- (1) identify all Federal programs that carry out asthma-related activities; and
- (2) develop, in consultation with appropriate Federal agencies and professional and voluntary health organizations, a Federal plan for responding to asthma.

**(b) Representation of the Department of Housing and Urban Development**

A representative of the Department of Housing and Urban Development shall be included on the National Asthma Education Prevention Program Coordinating Committee for the purpose of performing the tasks described in subsection (a).

(July 1, 1944, ch. 373, title IV, § 424B, as added Pub. L. 106-310, div. A, title V, § 521, Oct. 17, 2000, 114 Stat. 1116; amended Pub. L. 109-482, title I, §§ 103(b)(19), 104(b)(1)(G), Jan. 15, 2007, 120 Stat. 3688, 3693.)

AMENDMENTS

2007—Subsec. (a). Pub. L. 109-482, § 104(b)(1)(G), inserted “and” at end of par. (1), substituted a period for “; and” at end of par. (2), and struck out par. (3) which read as follows: “not later than 12 months after October 17, 2000, submit recommendations to the appropriate committees of the Congress on ways to strengthen and improve the coordination of asthma-related activities of the Federal Government.”

Subsec. (c). Pub. L. 109-482, § 103(b)(19), struck out heading and text of subsec. (c). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.”

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 285b-7c. Tuberculosis**

**(a) In general**

The Director of the National Institutes of Health may expand, intensify, and coordinate research and development and related activities of the Institutes with respect to tuberculosis including activities toward the goal of eliminating such disease.

**(b) Certain activities**

Activities under subsection (a) may include—

- (1) enhancing basic and clinical research on tuberculosis, including drug resistant tuberculosis;
- (2) expanding research on the relationship between such disease and the human immunodeficiency virus; and
- (3) developing new tools for the elimination of tuberculosis, including public health interventions and methods to enhance detection and response to outbreaks of tuberculosis, including multidrug resistant tuberculosis.

<sup>1</sup> So in original. Probably should be followed by “the”.

(July 1, 1944, ch. 373, title IV, § 424C, as added Pub. L. 110-392, title II, § 201, Oct. 13, 2008, 122 Stat. 4201.)

**§ 285b-8. Congenital heart disease**

**(a) In general**

The Director of the Institute may expand, intensify, and coordinate research and related activities of the Institute with respect to congenital heart disease, which may include congenital heart disease research with respect to—

- (1) causation of congenital heart disease, including genetic causes;
- (2) long-term outcomes in individuals with congenital heart disease, including infants, children, teenagers, adults, and elderly individuals;
- (3) diagnosis, treatment, and prevention;
- (4) studies using longitudinal data and retrospective analysis to identify effective treatments and outcomes for individuals with congenital heart disease; and
- (5) identifying barriers to life-long care for individuals with congenital heart disease.

**(b) Coordination of research activities**

The Director of the Institute may coordinate research efforts related to congenital heart disease among multiple research institutions and may develop research networks.

**(c) Minority and medically underserved communities**

In carrying out the activities described in this section, the Director of the Institute shall consider the application of such research and other activities to minority and medically underserved communities.

(July 1, 1944, ch. 373, title IV, § 425, as added Pub. L. 111-148, title X, § 10411(b)(2), Mar. 23, 2010, 124 Stat. 989.)

PRIOR PROVISIONS

A prior section 285b-8, act July 1, 1944, ch. 373, title IV, § 425, as added Pub. L. 103-43, title V, § 504, June 10, 1993, 107 Stat. 160, authorized appropriations to carry out this subpart, prior to repeal by Pub. L. 109-482, title I, §§ 103(b)(20), 109, Jan. 15, 2007, 120 Stat. 3688, 3697, applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years.

SUBPART 3—NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

**§ 285c. Purpose of Institute**

The general purpose of the National Institute of Diabetes and Digestive and Kidney Diseases (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases.

(July 1, 1944, ch. 373, title IV, § 426, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 841.)

STUDY ON METABOLIC DISORDERS

Pub. L. 106-310, div. A, title XXVIII, § 2802, Oct. 17, 2000, 114 Stat. 1167, provided that:

“(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ‘Sec-

retary) shall, in consultation with relevant experts or through the Institute of Medicine, study issues related to treatment of PKU and other metabolic disorders for children, adolescents, and adults, and mechanisms to assure access to effective treatment, including special diets, for children and others with PKU and other metabolic disorders. Such mechanisms shall be evidence-based and reflect the best scientific knowledge regarding effective treatment and prevention of disease progression.

“(b) DISSEMINATION OF RESULTS.—Upon completion of the study referred to in subsection (a), the Secretary shall disseminate and otherwise make available the results of the study to interested groups and organizations, including insurance commissioners, employers, private insurers, health care professionals, State and local public health agencies, and State agencies that carry out the Medicaid program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] or the State children’s health insurance program under title XXI of such Act [42 U.S.C. 1397aa et seq.].

“(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2003.”

REVIEW OF DISEASE RESEARCH PROGRAMS OF THE NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Pub. L. 99-158, § 10, Nov. 20, 1985, 99 Stat. 883, provided that: “The Secretary of Health and Human Services shall conduct an administrative review of the disease research programs of the National Institute of Diabetes and Digestive and Kidney Diseases to determine if any of such programs could be more effectively and efficiently managed by other national research institutes. The Secretary shall complete such review within the one-year period beginning on the date of enactment of this Act [Nov. 20, 1985].”

**§ 285c-1. Data systems and information clearinghouses**

**(a) National Diabetes Data System and National Diabetes Clearinghouse**

The Director of the Institute shall (1) establish the National Diabetes Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with diabetes, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing diabetes, and (2) establish the National Diabetes Information Clearinghouse to facilitate and enhance knowledge and understanding of diabetes on the part of health professionals, patients, and the public through the effective dissemination of information.

**(b) National Digestive Diseases Data System and National Digestive Diseases Information Clearinghouse**

The Director of the Institute shall (1) establish the National Digestive Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with digestive diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing digestive diseases, and (2) establish the National Digestive Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of digestive diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

**(c) National Kidney and Urologic Diseases Data System and National Kidney and Urologic Diseases Information Clearinghouse**

The Director of the Institute shall (1) establish the National Kidney and Urologic Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with kidney and urologic diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing kidney and urologic diseases, and (2) establish the National Kidney and Urologic Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of kidney and urologic diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

(July 1, 1944, ch. 373, title IV, § 427, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 841.)

**§ 285c-2. Division Directors for Diabetes, Endocrinology, and Metabolic Diseases, Digestive Diseases and Nutrition, and Kidney, Urologic, and Hematologic Diseases; functions**

(a)(1) In the Institute there shall be a Division Director for Diabetes, Endocrinology, and Metabolic Diseases, a Division Director for Digestive Diseases and Nutrition, and a Division Director for Kidney, Urologic, and Hematologic Diseases. Such Division Directors, under the supervision of the Director of the Institute, shall be responsible for—

(A) developing a coordinated plan (including recommendations for expenditures) for each of the national research institutes within the National Institutes of Health with respect to research and training concerning diabetes, endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases;

(B) assessing the adequacy of management approaches for the activities within such institutes concerning such diseases and nutrition and developing improved approaches if needed;

(C) monitoring and reviewing expenditures by such institutes concerning such diseases and nutrition; and

(D) identifying research opportunities concerning such diseases and nutrition and recommending ways to utilize such opportunities.

(2) The Director of the Institute shall transmit to the Director of NIH the plans, recommendations, and reviews of the Division Directors under subparagraphs (A) through (D) of paragraph (1) together with such comments and recommendations as the Director of the Institute determines appropriate.

(b) The Director of the Institute, acting through the Division Director for Diabetes, Endocrinology, and Metabolic Diseases, the Division Director for Digestive Diseases and Nutrition, and the Division Director for Kidney, Urologic, and Hematologic Diseases, shall—

(1) carry out programs of support for research and training (other than training for which Ruth L. Kirschstein National Research Service Awards may be made under section 288 of this title) in the diagnosis, prevention, and

treatment of diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

(July 1, 1944, ch. 373, title IV, § 428, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 842; amended Pub. L. 103-43, title XX, § 2008(b)(4), June 10, 1993, 107 Stat. 211; Pub. L. 107-206, title I, § 804(c), Aug. 2, 2002, 116 Stat. 874.)

#### AMENDMENTS

2002—Subsec. (b)(1). Pub. L. 107-206 substituted “Ruth L. Kirschstein National Research Service Awards” for “National Research Service Awards”.

1993—Subsec. (b). Pub. L. 103-43 substituted “the” for “the the” before “Division Director for Diabetes” in introductory provisions.

### § 285c-3. Interagency coordinating committees

#### (a) Establishment and purpose

For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to diabetes mellitus, digestive diseases, and kidney, urologic, and hematologic diseases; and

(2) coordinating those aspects of all Federal health programs and activities relating to such diseases to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities;

the Secretary shall establish a Diabetes Mellitus Interagency Coordinating Committee, a Digestive Diseases Interagency Coordinating Committee, and a Kidney, Urologic, and Hematologic Diseases Coordinating Committee (hereafter in this section individually referred to as a “Committee”).

#### (b) Membership; chairman; meetings

Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research with respect to the diseases for which the Committee is established, the Division Director of the Institute for the diseases for which the Committee is established, the Under Secretary for Health of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers) and shall include representation from all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

(July 1, 1944, ch. 373, title IV, § 429, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 843; amended

Pub. L. 100-527, § 10(4), Oct. 25, 1988, 102 Stat. 2641; Pub. L. 102-405, title III, § 302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 108-362, § 3, Oct. 25, 2004, 118 Stat. 1703; Pub. L. 109-482, title I, § 104(b)(1)(H), Jan. 15, 2007, 120 Stat. 3693.)

#### AMENDMENTS

2007—Subsecs. (c), (d). Pub. L. 109-482 struck out subsecs. (c) and (d) which required an annual report detailing the work of the Committee in carrying out subsec. (a) and an annual assessment on Federal pancreatic islet cell transplantation, respectively.

2004—Subsec. (d). Pub. L. 108-362 added subsec. (d).

1992—Subsec. (b). Pub. L. 102-405 substituted “Under Secretary for Health of the Department of Veterans Affairs” for “Chief Medical Director of the Department of Veterans Affairs”.

1988—Subsec. (b). Pub. L. 100-527 substituted “Chief Medical Director of the Department of Veterans Affairs” for “Chief Medical Director of the Veterans’ Administration”.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-527 effective Mar. 15, 1989, see section 18(a) of Pub. L. 100-527, set out as a Department of Veterans Affairs Act note under section 301 of Title 38, Veterans’ Benefits.

### § 285c-4. Advisory boards

#### (a) Establishment

The Secretary shall establish in the Institute the National Diabetes Advisory Board, the National Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases Advisory Board (hereafter in this section individually referred to as an “Advisory Board”).

#### (b) Membership; ex officio members

Each Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to the diseases with respect to which the Advisory Board is established; and

(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in the fields of health education, nursing, data systems, public information, and community program development.

(2)(A) The following shall be ex officio members of each Advisory Board:

(i) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, the Director of the Centers for Disease Control and Prevention, the Under

Secretary for Health of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs, and the Division Director of the National Institute of Diabetes and Digestive and Kidney Diseases for the diseases for which the Board is established (or the designees of such officers).

(ii) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(B) In the case of the National Diabetes Advisory Board, the following shall also be ex officio members: The Director of the National Heart, Lung, and Blood Institute, the Director of the National Eye Institute, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the Administrator of the Health Resources and Services Administration (or the designees of such officers).

**(c) Compensation**

Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

**(d) Term of office; vacancy**

The term of office of an appointed member of an Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in an Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

**(e) Chairman**

The members of each Advisory Board shall select a chairman from among the appointed members.

**(f) Executive director; professional and clerical staff; administrative support services and facilities**

The Secretary shall, after consultation with and consideration of the recommendations of an Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

**(g) Meetings**

Each Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

**(h) Functions of National Diabetes Advisory Board and National Digestive Diseases Advisory Board**

The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board shall—

(1) review and evaluate the implementation of the plan (referred to in section 285c-7 of this title) respecting the diseases with respect to which the Advisory Board was established and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting such diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan, the coordinating committee for such diseases, and with key non-Federal entities involved in activities affecting the control of such diseases.

**(i) Subcommittees; establishment and membership**

In carrying out its functions, each Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

**(j) Termination of predecessor boards; time within which to appoint members**

The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board in existence on November 20, 1985, shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Boards established under subsection (a) before the expiration of 90 days after November 20, 1985. The members of the Boards in existence on November 20, 1985, may be appointed, in accordance with subsections (b) and (d), to the Boards established under subsection (a) for diabetes and digestive diseases, except that at least one-half of the members of the National Diabetes Advisory Board in existence on November 20, 1985, shall be appointed to the National Diabetes Advisory Board first established under subsection (a).

(July 1, 1944, ch. 373, title IV, §430, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 844; amended Pub. L. 100-607, title I, §131, Nov. 4, 1988, 102 Stat. 3056; Pub. L. 102-405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 102-531, title III, §312(d)(6), Oct. 27, 1992, 106 Stat. 3504; Pub. L. 103-43, title XX, §2008(b)(5), June 10, 1993, 107

Stat. 211; Pub. L. 105-362, title VI, §601(a)(1)(C), Nov. 10, 1998, 112 Stat. 3285; Pub. L. 110-154, §1(b)(6), Dec. 21, 2007, 121 Stat. 1827.)

#### AMENDMENTS

2007—Subsec. (b)(2)(B). Pub. L. 110-154 substituted “Eunice Kennedy Shriver National Institute of Child Health and Human Development” for “National Institute of Child Health and Human Development”.

1998—Subsecs. (j), (k). Pub. L. 105-362 redesignated subsec. (k) as (j) and struck out former subsec. (j) which read as follows: “Each Advisory Board shall prepare an annual report for the Secretary which—

“(1) describes the Advisory Board’s activities in the fiscal year for which the report is made;

“(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the diseases with respect to which the Advisory Board was established;

“(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year; and

“(4) contains the Advisory Board’s recommendations (if any) for changes in the plan referred to in section 285c-7 of this title.”

1993—Subsec. (b)(2)(A)(i). Pub. L. 103-43 substituted “Department of Veterans Affairs” for “Veterans’ Administration”.

1992—Subsec. (b)(2)(A)(i). Pub. L. 102-531 substituted “Centers for Disease Control and Prevention” for “Centers for Disease Control”.

Pub. L. 102-405 substituted “Under Secretary for Health” for “Chief Medical Director”.

1988—Subsecs. (k), (l). Pub. L. 100-607 redesignated subsec. (l) as (k) and struck out former subsec. (k) which read as follows: “Each Advisory Board shall expire on September 30, 1988.”

#### TERMINATION OF ADVISORY BOARDS

Advisory boards established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a board established by the President or an officer of the Federal Government, such board is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a board established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

#### REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

### § 285c-5. Research and training centers; development or expansion

#### (a) Diabetes mellitus and related endocrine and metabolic diseases

(1) Consistent with applicable recommendations of the National Commission on Diabetes, the Director of the Institute shall provide for the development or substantial expansion of centers for research and training in diabetes mellitus and related endocrine and metabolic

diseases. Each center developed or expanded under this subsection shall—

(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Secretary; and

(B) conduct—

(i) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic diseases and the complications resulting from such diseases;

(ii) training programs for physicians and allied health personnel in current methods of diagnosis and treatment of such diseases and complications, and in research in diabetes; and

(iii) information programs for physicians and allied health personnel who provide primary care for patients with such diseases or complications.

(2) A center may use funds provided under paragraph (1) to provide stipends for nurses and allied health professionals enrolled in research training programs described in paragraph (1)(B)(ii).

#### (b) Digestive diseases and related functional, congenital, metabolic disorders, and normal development of digestive tract

Consistent with applicable recommendations of the National Digestive Diseases Advisory Board, the Director shall provide for the development or substantial expansion of centers for research in digestive diseases and related functional, congenital, metabolic disorders, and normal development of the digestive tract. Each center developed or expanded under this subsection—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of digestive diseases and nutritional disorders and related functional, congenital, or metabolic complications resulting from such diseases or disorders;

(3) shall encourage research into and programs for—

(A) providing information for patients with such diseases and the families of such patients, physicians and others who care for such patients, and the general public;

(B) model programs for cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases, disorders, and complications; and

(4) may perform research and participate in epidemiological studies and data collection relevant to digestive diseases and disorders and disseminate such research, studies, and data to the health care profession and to the public.

#### (c) Kidney and urologic diseases

The Director shall provide for the development or substantial expansion of centers for re-

search in kidney and urologic diseases. Each center developed or expanded under this subsection—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of kidney and urologic diseases;

(3) shall encourage research into and programs for—

(A) providing information for patients with such diseases, disorders, and complications and the families of such patients, physicians and others who care for such patients, and the general public;

(B) model programs for cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases; and

(4) may perform research and participate in epidemiological studies and data collection relevant to kidney and urologic diseases in order to disseminate such research, studies, and data to the health care profession and to the public.

**(d) Nutritional disorders**

(1) The Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the development or substantial expansion of centers for research and training regarding nutritional disorders, including obesity.

(2) The Director of the Institute shall carry out paragraph (1) in collaboration with the Director of the National Cancer Institute and with the Directors of such other agencies of the National Institutes of Health as the Director of NIH determines to be appropriate.

(3) Each center developed or expanded under paragraph (1) shall—

(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director;

(B) conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of nutritional disorders, including obesity and the impact of nutrition and diet on child development;

(C) conduct training programs for physicians and allied health professionals in current methods of diagnosis and treatment of such diseases and complications, and in research in such disorders; and

(D) conduct information programs for physicians and allied health professionals who provide primary care for patients with such disorders or complications.

**(e) Geographic distribution; period of support, additional periods**

Insofar as practicable, centers developed or expanded under this section should be geographically dispersed throughout the United States and in environments with proven research capa-

bilities. Support of a center under this section may be for a period of not to exceed five years and such period may be extended by the Director of the Institute for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, §431, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 846; amended Pub. L. 103-43, title VI, §601(b), June 10, 1993, 107 Stat. 161.)

AMENDMENTS

1993—Subsecs. (d), (e). Pub. L. 103-43 added subsec. (d) and redesignated former subsec. (d) as (e).

**§ 285c-6. Advisory council subcommittees**

There are established within the advisory council for the Institute appointed under section 284a of this title a subcommittee on diabetes and endocrine and metabolic diseases, a subcommittee on digestive diseases and nutrition, and a subcommittee on kidney, urologic, and hematologic diseases. The subcommittees shall be composed of members of the advisory council who are outstanding in the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and members of the advisory council who are leaders in the fields of education and public affairs. The subcommittees are authorized to review applications made to the Director of the Institute for grants for research and training projects relating to the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and shall recommend to the advisory council those applications and contracts that the subcommittees determine will best carry out the purposes of the Institute. The subcommittees shall also review and evaluate the diabetes and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases programs of the Institute and recommend to the advisory council such changes in the administration of such programs as the subcommittees determine are necessary.

(July 1, 1944, ch. 373, title IV, §432, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 847.)

**§ 285c-7. Biennial report**

The Director of the Institute shall prepare for inclusion in the biennial report made under section 284b<sup>1</sup> of this title a description of the Institute's activities—

(1) under the current diabetes plan under the National Diabetes Mellitus Research and Education Act; and

(2) under the current digestive diseases plan formulated under the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976.

The description submitted by the Director shall include an evaluation of the activities of the centers supported under section 285c-5 of this title.

<sup>1</sup> See References in Text note below.

(July 1, 1944, ch. 373, title IV, § 433, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 848.)

## REFERENCES IN TEXT

Section 284b of this title, referred to in text, was repealed by Pub. L. 109-482, title I, § 104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

The National Diabetes Mellitus Research and Education Act, referred to in par. (1), is Pub. L. 93-354, July 23, 1974, 88 Stat. 373, as amended, which enacted former sections 289c-1a, 289c-2, and 289c-3 of this title, amended section 247b and former section 289c-1 of this title, and enacted provisions formerly set out as notes under section 289c-2 of this title. For complete classification of this Act to the Code, see Short Title of 1974 Amendments note set out under section 201 of this title and Tables.

The Arthritis, Diabetes, and Digestive Diseases Amendments of 1976, referred to in par. (2), is Pub. L. 94-562, Oct. 19, 1976, 90 Stat. 2645, as amended, which enacted former sections 289c-3a, 289c-7, and 289c-8 of this title, amended former sections 289c-2, 289c-5, and 289c-6 of this title, and enacted provisions formerly set out as notes under sections 289a, 289c-3a, and 289c-7 of this title. For complete classification of this Act to the Code, see Short Title of 1976 Amendments note set out under section 201 of this title and Tables.

### § 285c-8. Nutritional disorders program

#### (a) Establishment

The Director of the Institute, in consultation with the Director of NIH, shall establish a program of conducting and supporting research, training, health information dissemination, and other activities with respect to nutritional disorders, including obesity.

#### (b) Support of activities

In carrying out the program established under subsection (a), the Director of the Institute shall conduct and support each of the activities described in such subsection.

#### (c) Dissemination of information

In carrying out the program established under subsection (a), the Director of the Institute shall carry out activities to facilitate and enhance knowledge and understanding of nutritional disorders, including obesity, on the part of health professionals, patients, and the public through the effective dissemination of information.

(July 1, 1944, ch. 373, title IV, § 434, as added Pub. L. 103-43, title VI, § 601(a), June 10, 1993, 107 Stat. 161.)

### § 285c-9. Juvenile diabetes

#### (a) Long-term epidemiology studies

The Director of the Institute shall conduct or support long-term epidemiology studies in which individuals with or at risk for type 1, or juvenile, diabetes are followed for 10 years or more. Such studies shall investigate the causes and characteristics of the disease and its complications.

#### (b) Clinical trial infrastructure/innovative treatments for juvenile diabetes

The Secretary, acting through the Director of the National Institutes of Health, shall support regional clinical research centers for the prevention, detection, treatment, and cure of juvenile diabetes.

### (c) Prevention of type 1 diabetes

The Secretary, acting through the appropriate agencies, shall provide for a national effort to prevent type 1 diabetes. Such effort shall provide for a combination of increased efforts in research and development of prevention strategies, including consideration of vaccine development, coupled with appropriate ability to test the effectiveness of such strategies in large clinical trials of children and young adults.

(July 1, 1944, ch. 373, title IV, § 434A, as added Pub. L. 106-310, div. A, title IV, § 402, Oct. 17, 2000, 114 Stat. 1112; amended Pub. L. 109-482, title I, § 103(b)(21), Jan. 15, 2007, 120 Stat. 3688.)

## AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482 struck out heading and text of subsec. (d). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.”

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

## SUBPART 4—NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

### § 285d. Purpose of Institute

The general purpose of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research and training, the dissemination of health information, and other programs with respect to arthritis and musculoskeletal and skin diseases (including sports-related disorders), with particular attention to the effect of these diseases on children.

(July 1, 1944, ch. 373, title IV, § 435, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 848; amended Pub. L. 103-43, title VII, § 701(a), June 10, 1993, 107 Stat. 162.)

## AMENDMENTS

1993—Pub. L. 103-43 substituted “(including sports-related disorders), with particular attention to the effect of these diseases on children” for “, including sports-related disorders”.

### § 285d-1. National arthritis and musculoskeletal and skin diseases program

#### (a) Plan to expand, intensify, and coordinate activities; submission; periodic review and revision

The Director of the Institute, with the advice of the Institute’s advisory council, shall prepare and transmit to the Director of NIH a plan for a national arthritis and musculoskeletal and skin diseases program to expand, intensify, and coordinate the activities of the Institute respecting arthritis and musculoskeletal and skin diseases. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The plan shall place particular emphasis upon expanding research into better understanding the causes and

the development of effective treatments for arthritis affecting children. The Director of the Institute shall periodically review and revise such plan and shall transmit any revisions of such plan to the Director of NIH.

**(b) Coordination of activities with other national research institutes; minimum activities under program**

Activities under the national arthritis and musculoskeletal and skin diseases program shall be coordinated with the other national research institutes to the extent that such institutes have responsibilities respecting arthritis and musculoskeletal and skin diseases, and shall, at least, provide for—

(1) investigation into the epidemiology, etiology, and prevention of all forms of arthritis and musculoskeletal and skin diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important knowledge to the treatment and understanding of arthritis and musculoskeletal and skin diseases;

(2) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treatment, including medical rehabilitation, and prevention of arthritis and musculoskeletal and skin diseases;

(3) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute for damaged bone, muscle, and joints and other supporting structures;

(4) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields; and

(5) research into the causes of arthritis affecting children and the development, trial, and evaluation of techniques, drugs and devices used in the diagnosis, treatment (including medical rehabilitation), and prevention of arthritis in children.

**(c) Program to be carried out in accordance with plan**

The Director of the Institute shall carry out the national arthritis and musculoskeletal and skin diseases program in accordance with the plan prepared under subsection (a) and any revisions of such plan made under such subsection.

(July 1, 1944, ch. 373, title IV, § 436, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 848; amended Pub. L. 100-607, title I, § 136, Nov. 4, 1988, 102 Stat. 3056; Pub. L. 103-43, title VII, § 701(b), June 10, 1993, 107 Stat. 162.)

AMENDMENTS

1993—Subsec. (a). Pub. L. 103-43, § 701(b)(1), inserted after second sentence “The plan shall place particular emphasis upon expanding research into better understanding the causes and the development of effective treatments for arthritis affecting children.”

Subsec. (b)(5). Pub. L. 103-43, § 701(b)(2), added par. (5).  
1988—Pub. L. 100-607 inserted “and skin” after “musculoskeletal” in section catchline and wherever appearing in text.

**§ 285d-2. Research and training**

The Director of the Institute shall—

(1) carry out programs of support for research and training (other than training for which Ruth L. Kirschstein National Research Service Awards may be made under section 288 of this title) in the diagnosis, prevention, and treatment of arthritis and musculoskeletal and skin diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

(July 1, 1944, ch. 373, title IV, § 437, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 849; amended Pub. L. 107-206, title I, § 804(c), Aug. 2, 2002, 116 Stat. 874.)

AMENDMENTS

2002—Par. (1). Pub. L. 107-206 substituted “Ruth L. Kirschstein National Research Service Awards” for “National Research Service Awards”.

**§ 285d-3. Data system and information clearinghouse**

(a) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with arthritis and musculoskeletal and skin diseases, including where possible, data involving general populations for the purpose of detection of individuals with a risk of developing arthritis and musculoskeletal and skin diseases.

(b) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of arthritis and musculoskeletal and skin diseases, including juvenile arthritis and related conditions, by health professionals, patients, and the public.

(July 1, 1944, ch. 373, title IV, § 438, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 849; amended Pub. L. 106-310, div. A, title III, § 302, Oct. 17, 2000, 114 Stat. 1111.)

AMENDMENTS

2000—Subsec. (b). Pub. L. 106-310 inserted “, including juvenile arthritis and related conditions,” after “skin diseases”.

**§ 285d-4. Interagency coordinating committees**

**(a) Establishment and purpose**

For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to arthritis, musculoskeletal diseases, and skin diseases, including sports-related disorders; and

(2) coordinating the aspects of all Federal health programs and activities relating to arthritis, musculoskeletal diseases, and skin diseases in order to assure the adequacy and technical soundness of such programs and activities and in order to provide for the full communication and exchange of information

necessary to maintain adequate coordination of such programs and activities,

the Secretary shall establish an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and a Skin Diseases Interagency Coordinating Committee (hereafter in this section individually referred to as a “Committee”).

**(b) Membership; chairman; meetings**

Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the Under Secretary for Health of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and representatives of all other Federal departments and agencies (as determined by the Secretary) whose programs involve health functions or responsibilities relevant to arthritis and musculoskeletal diseases or skin diseases, as the case may be. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

(July 1, 1944, ch. 373, title IV, § 439, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 849; amended Pub. L. 102-405, title III, § 302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 103-43, title XX, § 2008(b)(6), June 10, 1993, 107 Stat. 211; Pub. L. 105-362, title VI, § 601(a)(1)(D), Nov. 10, 1998, 112 Stat. 3285.)

AMENDMENTS

1998—Subsec. (c). Pub. L. 105-362 struck out subsec. (c) which read as follows: “Not later than 120 days after the end of each fiscal year, each Committee shall prepare and transmit to the Secretary, the Director of NIH, the Director of the Institute, and the advisory council for the Institute a report detailing the activities of the Committee in such fiscal year in carrying out paragraphs (1) and (2) of subsection (a) of this section.”

1993—Subsec. (b). Pub. L. 103-43 substituted “Department of Veterans Affairs” for “Veterans’ Administration”.

1992—Subsec. (b). Pub. L. 102-405 substituted “Under Secretary for Health” for “Chief Medical Director”.

**§ 285d-5. Arthritis and musculoskeletal diseases demonstration projects**

**(a) Grants for establishment and support**

The Director of the Institute may make grants to public and private nonprofit entities to establish and support projects for the development and demonstration of methods for screening, detection, and referral for treatment of arthritis and musculoskeletal diseases and for the dissemination of information on such methods to the health and allied health professions. Activities under such projects shall be coordinated with Federal, State, local, and regional health agencies, centers assisted under section 285d-6 of this title, and the data system established under subsection (c).

**(b) Programs included**

Projects supported under this section shall include—

(1) programs which emphasize the development and demonstration of new and improved methods of screening and early detection, referral for treatment, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) programs which emphasize the development and demonstration of new and improved methods for patient referral from local hospitals and physicians to appropriate centers for early diagnosis and treatment;

(3) programs which emphasize the development and demonstration of new and improved means of standardizing patient data and recordkeeping;

(4) programs which emphasize the development and demonstration of new and improved methods of dissemination of knowledge about the programs, methods, and means referred to in paragraphs (1), (2), and (3) of this subsection to health and allied health professionals;

(5) programs which emphasize the development and demonstration of new and improved methods for the dissemination to the general public of information—

(A) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(B) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive treatment, and control methods for arthritis and unapproved and ineffective drugs and devices for arthritis and musculoskeletal diseases; and

(6) projects for investigation into the epidemiology of all forms and aspects of arthritis and musculoskeletal diseases, including investigations into the social, environmental, behavioral, nutritional, and genetic determinants and influences involved in the epidemiology of arthritis and musculoskeletal diseases.

**(c) Standardization of patient data and recordkeeping**

The Director shall provide for the standardization of patient data and recordkeeping for the collection, storage, analysis, retrieval, and dissemination of such data in cooperation with projects assisted under this section, centers assisted under section 285d-6 of this title, and other persons engaged in arthritis and musculoskeletal disease programs.

(July 1, 1944, ch. 373, title IV, § 440, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 850.)

**§ 285d-6. Multipurpose arthritis and musculoskeletal diseases centers**

**(a) Development, modernization, and operation**

The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including staffing and other operating costs such as the costs of patient care required for research) of new and existing centers for arthritis and musculoskeletal diseases. For purposes of this section, the term “modernization” means the alteration, remodeling, improvement, expansion, and repair of existing

buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

**(b) Duties and functions**

Each center assisted under this section shall—

(1)(A) use the facilities of a single institution or a consortium of cooperating institutions, and (B) meet such qualifications as may be prescribed by the Secretary; and

(2) conduct—

(A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of and rehabilitation from arthritis and musculoskeletal diseases and complications resulting from arthritis and musculoskeletal diseases, including research into implantable biomaterials and biomechanical and other orthopedic procedures;

(B) training programs for physicians, scientists, and other health and allied health professionals;

(C) information and continuing education programs for physicians and other health and allied health professionals who provide care for patients with arthritis and musculoskeletal diseases; and

(D) programs for the dissemination to the general public of information—

(i) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(ii) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods and unapproved and ineffective drugs and devices.

A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in paragraph (2)(B).

**(c) Optional programs**

Each center assisted under this section may conduct programs to—

(1) establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping; and

(3) develop community consultative services to facilitate the referral of patients to centers for treatment.

**(d) Geographical distribution**

The Director of the Institute shall, insofar as practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of children affected by arthritis and musculoskeletal diseases.

**(e) Period of support; additional periods**

Support of a center under this section may be for a period of not to exceed five years. Such pe-

riod may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

**(f) Treatment and rehabilitation of children**

Not later than October 1, 1993, the Director shall establish a multipurpose arthritis and musculoskeletal disease center for the purpose of expanding the level of research into the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculoskeletal diseases.

(July 1, 1944, ch. 373, title IV, § 441, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 851; amended Pub. L. 100-607, title I, § 137, Nov. 4, 1988, 102 Stat. 3056; Pub. L. 103-43, title VII, § 701(c), June 10, 1993, 107 Stat. 162.)

AMENDMENTS

1993—Subsec. (f). Pub. L. 103-43 added subsec. (f).

1988—Subsec. (b)(2)(A). Pub. L. 100-607 inserted “and rehabilitation from” after “and treatment of”.

**§ 285d-6a. Lupus**

**(a) In general**

The Director of the Institute shall expand and intensify research and related activities of the Institute with respect to lupus.

**(b) Coordination with other institutes**

The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by the other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to lupus.

**(c) Programs for lupus**

In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the causes of, and to find a cure for, lupus. Activities under such subsection shall include conducting and supporting the following:

(1) Research to determine the reasons underlying the elevated prevalence of lupus in women, including African-American women.

(2) Basic research concerning the etiology and causes of the disease.

(3) Epidemiological studies to address the frequency and natural history of the disease and the differences among the sexes and among racial and ethnic groups with respect to the disease.

(4) The development of improved diagnostic techniques.

(5) Clinical research for the development and evaluation of new treatments, including new biological agents.

(6) Information and education programs for health care professionals and the public.

(July 1, 1944, ch. 373, title IV, § 441A, as added Pub. L. 106-505, title V, § 511, Nov. 13, 2000, 114 Stat. 2342; amended Pub. L. 109-482, title I, § 103(b)(22), Jan. 15, 2007, 120 Stat. 3688.)

## AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482 struck out heading and text of subsec. (d). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2003.”

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

## FINDINGS

Pub. L. 106-505, title V, §502, Nov. 13, 2000, 114 Stat. 2342, provided that: “The Congress finds that—

“(1) lupus is a serious, complex, inflammatory, autoimmune disease of particular concern to women;

“(2) lupus affects women nine times more often than men;

“(3) there are three main types of lupus: systemic lupus, a serious form of the disease that affects many parts of the body; discoid lupus, a form of the disease that affects mainly the skin; and drug-induced lupus caused by certain medications;

“(4) lupus can be fatal if not detected and treated early;

“(5) the disease can simultaneously affect various areas of the body, such as the skin, joints, kidneys, and brain, and can be difficult to diagnose because the symptoms of lupus are similar to those of many other diseases;

“(6) lupus disproportionately affects African-American women, as the prevalence of the disease among such women is three times the prevalence among white women, and an estimated 1 in 250 African-American women between the ages of 15 and 65 develops the disease;

“(7) it has been estimated that between 1,400,000 and 2,000,000 Americans have been diagnosed with the disease, and that many more have undiagnosed cases;

“(8) current treatments for the disease can be effective, but may lead to damaging side effects;

“(9) many victims of the disease suffer debilitating pain and fatigue, making it difficult to maintain employment and lead normal lives; and

“(10) in fiscal year 1996, the amount allocated by the National Institutes of Health for research on lupus was \$33,000,000, which is less than one-half of 1 percent of the budget for such Institutes.”

**§ 285d-7. Advisory Board****(a) Establishment**

The Secretary shall establish in the Institute the National Arthritis and Musculoskeletal and Skin Diseases Advisory Board (hereafter in this section referred to as the “Advisory Board”).

**(b) Membership; ex officio members**

The Advisory Board shall be composed of twenty appointed members and nonvoting, ex officio members, as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to arthritis, musculoskeletal diseases, and skin diseases; and

(B) eight members from the general public who are knowledgeable with respect to such diseases, including one member who is a person who has such a disease, one person who is the parent of an adult with such a disease,

and two members who are parents of children with arthritis.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in health education, nursing, data systems, public information, or community program development.

(2) The following shall be ex officio members of the Advisory Board:

(A) the Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Director of the Centers for Disease Control and Prevention, the Under Secretary for Health of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

**(c) Compensation**

Members of the Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Advisory Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Advisory Board.

**(d) Term of office; vacancy**

The term of office of an appointed member of the Advisory Board is four years. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

**(e) Chairman**

The members of the Advisory Board shall select a chairman from among the appointed members.

**(f) Executive director, professional and clerical staff; administrative support services and facilities**

The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

**(g) Meetings**

The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

**(h) Duties and functions**

The Advisory Board shall—

(1) review and evaluate the implementation of the plan prepared under section 285d-1(a) of this title and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting arthritis, musculoskeletal diseases and skin diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies for Federal agencies involved in the implementation of such plan, the interagency coordinating committees for such diseases established under section 285d-4 of this title, and with key non-Federal entities involved in activities affecting the control of such diseases.

**(i) Subcommittees; establishment and membership**

In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

**(j) Termination of predecessor board; time within which to appoint members**

The National Arthritis Advisory Board in existence on November 20, 1985, shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Board established under subsection (a) before the expiration of 90 days after November 20, 1985. The member of the Board in existence on November 20, 1985, may be appointed, in accordance with subsections (b) and (d), to the Advisory Board established under subsection (a).

(July 1, 1944, ch. 373, title IV, § 442, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 852; amended Pub. L. 102-405, title III, § 302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 102-531, title III, § 312(d)(7), Oct. 27, 1992, 106 Stat. 3504; Pub. L. 103-43, title VII, § 701(d), title XX, § 2008(b)(7), June 10, 1993, 107 Stat. 162, 211; Pub. L. 109-482, title I, § 104(b)(1)(I), Jan. 15, 2007, 120 Stat. 3693.)

## AMENDMENTS

2007—Subsecs. (j), (k). Pub. L. 109-482 redesignated subsec. (k) as (j) and struck out former subsec. (j) which required the Advisory Board to prepare an annual report for the Secretary and set out the subjects for report.

1993—Subsec. (a). Pub. L. 103-43, § 701(d)(1), inserted “and Musculoskeletal and Skin Diseases” after “Arthritis”.

Subsec. (b). Pub. L. 103-43, §§ 701(d)(2), 2008(b)(7), substituted “twenty” for “eighteen” in introductory provisions, “eight” for “six” and “including one member who is a person who has such a disease, one person who is the parent of an adult with such a disease, and two members who are parents of children with arthritis” for “including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease” in par. (1)(B), and “Department of Veterans Affairs” for “Veterans’ Administration” in par. (2)(A).

Subsec. (j)(5). Pub. L. 103-43, § 701(d)(3), added par. (5). 1992—Subsec. (b)(2)(A). Pub. L. 102-531 substituted “Centers for Disease Control and Prevention” for “Centers for Disease Control”.

Pub. L. 102-405 substituted “Under Secretary for Health” for “Chief Medical Director”.

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

## TERMINATION OF ADVISORY BOARDS

Advisory boards established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a board established by the President or an officer of the Federal Government, such board is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a board established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

## REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

**§ 285d-8. Juvenile arthritis and related conditions****(a) Expansion and coordination of activities**

The Director of the Institute, in coordination with the Director of the National Institute of Allergy and Infectious Diseases, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning juvenile arthritis and related conditions.

**(b) Coordination**

The Directors referred to in subsection (a) shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee.

(July 1, 1944, ch. 373, title IV, § 442A, as added Pub. L. 106-310, div. A, title III, § 301(a), Oct. 17, 2000, 114 Stat. 1111; amended Pub. L. 109-482, title I, § 103(b)(23), Jan. 15, 2007, 120 Stat. 3688.)

## AMENDMENTS

2007—Subsec. (c). Pub. L. 109-482 struck out heading and text of subsec. (c). Text read as follows: “For the

purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.”

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

SUBPART 5—NATIONAL INSTITUTE ON AGING

**§ 285e. Purpose of Institute**

The general purpose of the National Institute on Aging (hereafter in this subpart referred to as the “Institute”) is the conduct and support of biomedical, social, and behavioral research, training, health information dissemination, and other programs with respect to the aging process and the diseases and other special problems and needs of the aged.

(July 1, 1944, ch. 373, title IV, § 443, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 854.)

STUDY OF MALNUTRITION IN ELDERLY

Pub. L. 103-43, title XIX, § 1902, June 10, 1993, 107 Stat. 201, directed Secretary of Health and Human Services, acting through National Institute on Aging, to conduct a 3-year study on health benefits and cost-effectiveness of nutrition screening and intervention activities of the elderly, and a 3-year study to determine extent of malnutrition in elderly individuals in hospitals and long-term care facilities and in elderly individuals who are living independently, provided for creation of advisory panel to oversee studies, provided for submission to Congress of reports containing findings of such studies, and provided for termination of advisory panel 3 years after June 10, 1993.

STUDY OF PERSONNEL FOR HEALTH NEEDS OF ELDERLY

Section 8 of Pub. L. 99-158 directed Secretary to conduct a study on the adequacy and availability of personnel to meet the current and projected health needs (including needs for home and community-based care) of elderly Americans through the year 2020, and report the results of the study, with recommendations, to Congress by Mar. 1, 1987.

**§ 285e-1. Special functions**

**(a) Education and training of adequate numbers of personnel**

In carrying out the training responsibilities under this chapter or any other Act for health and allied health professions personnel, the Secretary shall take appropriate steps to insure the education and training of adequate numbers of allied health, nursing, and paramedical personnel in the field of health care for the aged.

**(b) Scientific studies**

The Director of the Institute shall conduct scientific studies to measure the impact on the biological, medical, social, and psychological aspects of aging of programs and activities assisted or conducted by the Department of Health and Human Services.

**(c) Public information and education programs**

The Director of the Institute shall carry out public information and education programs designed to disseminate as widely as possible the findings of research sponsored by the Institute, other relevant aging research and studies, and

other information about the process of aging which may assist elderly and near-elderly persons in dealing with, and all Americans in understanding, the problems and processes associated with growing older.

**(d) Grants for research relating to Alzheimer’s Disease**

The Director of the Institute shall make grants to public and private nonprofit institutions to conduct research relating to Alzheimer’s Disease.

(July 1, 1944, ch. 373, title IV, § 444, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 854.)

**§ 285e-2. Alzheimer’s Disease centers**

**(a) Cooperative agreements and grants for establishing and supporting**

(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities (including university medical centers) to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support (including staffing) for centers for basic and clinical research (including multidisciplinary research) into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for Alzheimer’s disease.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute’s advisory council.

**(b) Use of Federal payments under cooperative agreement or grant**

(1) Federal payments made under a cooperative agreement or grant under subsection (a) may, with respect to Alzheimer’s disease, be used for—

(A) diagnostic examinations, patient assessments, patient care costs, and other costs necessary for conducting research;

(B) training, including training for allied health professionals;

(C) diagnostic and treatment clinics designed to meet the special needs of minority and rural populations and other underserved populations;

(D) activities to educate the public; and

(E) the dissemination of information.

(2) For purposes of paragraph (1), the term “training” does not include research training for which Ruth L. Kirschstein National Research Service Awards may be provided under section 288 of this title.

**(c) Support period; additional periods**

Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, § 445, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 855; amended

Pub. L. 101-557, title II, §201, Nov. 15, 1990, 104 Stat. 2767; Pub. L. 107-206, title I, §804(c), Aug. 2, 2002, 116 Stat. 874.)

#### AMENDMENTS

2002—Subsec. (b)(2). Pub. L. 107-206 substituted “Ruth L. Kirschstein National Research Service Awards” for “National Research Service Awards”.

1990—Subsec. (a)(1). Pub. L. 101-557, §201(1), inserted “(including university medical centers)” after “non-profit entities”, “(including staffing)” after “operating support”, and “(including multidisciplinary research)” after “clinical research” and substituted “Alzheimer’s disease” for “Alzheimer’s Disease”.

Subsec. (b). Pub. L. 101-557, §201(2), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: “Federal payments made under a cooperative agreement or grant under subsection (a) of this section may be used for—

“(1) construction (notwithstanding any limitation under section 289e of this title);

“(2) staffing and other basic operating costs, including such patient care costs as are required for research;

“(3) training, including training for allied health professionals; and

“(4) demonstration purposes.

As used in this subsection, the term ‘construction’ does not include the acquisition of land, and the term ‘training’ does not include research training for which National Research Service Awards may be provided under section 288 of this title.”

#### ALZHEIMER’S DISEASE RESEARCH

Pub. L. 100-175, title III, Nov. 29, 1987, 101 Stat. 972, provided that:

##### “SEC. 301. REQUIREMENT FOR CLINICAL TRIALS.

“(a) IN GENERAL.—The Director of the National Institute on Aging shall provide for the conduct of clinical trials on the efficacy of the use of such promising therapeutic agents as have been or may be discovered and recommended for further scientific analysis by the National Institute on Aging and the Food and Drug Administration to treat individuals with Alzheimer’s disease, to retard the progression of symptoms of Alzheimer’s disease, or to improve the functioning of individuals with such disease.

“(b) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to affect adversely any research being conducted as of the date of the enactment of this Act [Nov. 29, 1987].

##### “SEC. 302. AUTHORIZATION OF APPROPRIATIONS.

“For the purpose of carrying out section 301, there is authorized to be appropriated \$2,000,000 for fiscal year 1988.”

#### ALZHEIMER’S DISEASE REGISTRY

Section 12 of Pub. L. 99-158, which was formerly set out as a note under this section, was renumbered section 445G of the Public Health Service Act by Pub. L. 103-43, title VIII, §801(a), June 10, 1993, 107 Stat. 163, and is classified to section 285e-9 of this title.

### § 285e-3. Claude D. Pepper Older Americans Independence Centers

#### (a) Development and expansion of centers

The Director of the Institute shall enter into cooperative agreements with, and make grants to, public and private nonprofit entities for the development or expansion of not less than 10 centers of excellence in geriatric research and training of researchers. Each such center shall be known as a Claude D. Pepper Older Americans Independence Center.

#### (b) Functions of centers

Each center developed or expanded under this section shall—

(1) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director; and

(2) conduct—

(A) research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause, which research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals; and

(B) programs to develop individuals capable of conducting research described in subparagraph (A).

#### (c) Geographic distribution of centers

In making cooperative agreements and grants under this section for the development or expansion of centers, the Director of the Institute shall ensure that, to the extent practicable, any such centers are distributed equitably among the principal geographic regions of the United States.

#### (d) “Independence” defined

For purposes of this section, the term “independence”, with respect to diseases, disorders, and complications of aging, means the functional ability of individuals to perform activities of daily living or instrumental activities of daily living without assistance or supervision.

(July 1, 1944, ch. 373, title IV, §445A, as added Pub. L. 100-607, title I, §141, Nov. 4, 1988, 102 Stat. 3056; amended Pub. L. 101-557, title II, §202, Nov. 15, 1990, 104 Stat. 2767.)

#### AMENDMENTS

1990—Pub. L. 101-557, §202(a)(1), substituted “Claude D. Pepper Older Americans Independence Centers” for “Centers of geriatric research and training” in section catchline.

Subsec. (a). Pub. L. 101-557, §202(a)(2), (b)(1)(A), inserted “not less than 10” before “centers of excellence” and inserted provision designating centers as Claude D. Pepper Older Americans Independence Centers.

Subsec. (b)(2)(A). Pub. L. 101-557, §202(b)(1)(B), inserted before semicolon at end “, including menopause, which research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals”.

Subsec. (b)(2)(B). Pub. L. 101-557, §202(b)(2), substituted “research described in subparagraph (A)” for “research concerning aging and concerning such diseases, disorders, and complications.”

Subsec. (d). Pub. L. 101-557, §202(c), added subsec. (d).

### § 285e-4. Awards for leadership and excellence in Alzheimer’s disease and related dementias

#### (a) Senior researchers in biomedical research

The Director of the Institute shall make awards to senior researchers who have made distinguished achievements in biomedical research in areas relating to Alzheimer’s disease and re-

lated dementias. Awards under this section shall be used by the recipients to support research in areas relating to such disease and dementias, and may be used by the recipients to train junior researchers who demonstrate exceptional promise to conduct research in such areas.

**(b) Eligible centers**

The Director of the Institute may make awards under this section to researchers at centers supported under section 285e-2 of this title and to researchers at other public and nonprofit private entities.

**(c) Required recommendation**

The Director of the Institute shall make awards under this section only to researchers who have been recommended for such awards by the National Advisory Council on Aging.

**(d) Selection procedures**

The Director of the Institute shall establish procedures for the selection of the recipients of awards under this section.

**(e) Term of award; renewal**

Awards under this section shall be made for a one-year period, and may be renewed for not more than six additional consecutive one-year periods.

(July 1, 1944, ch. 373, title IV, § 445B, formerly Pub. L. 99-660, title IX, § 931, Nov. 14, 1986, 100 Stat. 3807; renumbered § 445B of act July 1, 1944; amended Pub. L. 100-607, title I, § 142(a), (d)(1), Nov. 4, 1988, 102 Stat. 3057.)

CODIFICATION

Section was formerly classified to section 11231 of this title prior to renumbering by Pub. L. 100-607.

AMENDMENTS

1988—Pub. L. 100-607, § 142(a), renumbered section 11231 of this title as this section.

Subsec. (a). Pub. L. 100-607, § 142(d)(1)(A), substituted “the Institute” for “the National Institute on Aging”.

Subsec. (b). Pub. L. 100-607, § 142(d)(1)(B), substituted “the Institute” for “the National Institute on Aging” and made technical amendment to reference to section 285e-2 of this title to correct reference to corresponding provision of original act.

Subsecs. (c), (d). Pub. L. 100-607, § 142(d)(1)(C), substituted “the Institute” for “the National Institute on Aging”.

AVAILABILITY OF APPROPRIATIONS

Pub. L. 100-607, title I, § 142(b), Nov. 4, 1988, 102 Stat. 3057, provided that: “With respect to amounts made available in appropriation Acts for the purpose of carrying out the programs transferred by subsection (a) to the Public Health Service Act [sections 285e-4 to 285e-8 of this title], such subsection may not be construed to affect the availability of such funds for such purpose.”

**§ 285e-5. Research relevant to appropriate services for individuals with Alzheimer’s disease and related dementias and their families**

**(a) Grants for research**

The Director of the Institute shall conduct, or make grants for the conduct of, research relevant to appropriate services for individuals with Alzheimer’s disease and related dementias and their families.

**(b) Preparation of plan; contents; revision**

(1) Within 6 months after November 14, 1986, the Director of the Institute shall prepare and

transmit to the Chairman of the Council on Alzheimer’s Disease (in this section referred to as the “Council”) a plan for the research to be conducted under subsection (a). The plan shall—

(A) provide for research concerning—

(i) the epidemiology of, and the identification of risk factors for, Alzheimer’s disease and related dementias; and

(ii) the development and evaluation of reliable and valid multidimensional diagnostic and assessment procedures and instruments; and

(B) ensure that research carried out under the plan is coordinated with, and uses, to the maximum extent feasible, resources of, other Federal programs relating to Alzheimer’s disease and related dementias, including centers supported under section 285e-2 of this title, centers supported by the National Institute of Mental Health on the psychopathology of the elderly, relevant activities of the Administration on Aging, other programs and centers involved in research on Alzheimer’s disease and related dementias supported by the Department, and other programs relating to Alzheimer’s disease and related dementias which are planned or conducted by Federal agencies other than the Department, State or local agencies, community organizations, or private foundations.

(2) Within one year after transmitting the plan required under paragraph (1), and annually thereafter, the Director of the Institute shall prepare and transmit to the Chairman of the Council such revisions of such plan as the Director considers appropriate.

**(c) Consultation for preparation and revision of plan**

In preparing and revising the plan required by subsection (b), the Director of the Institute shall consult with the Chairman of the Council and the heads of agencies within the Department.

**(d) Grants for promoting independence and preventing secondary disabilities**

the<sup>1</sup> Director of the Institute may develop, or make grants to develop—

(1) model techniques to—

(A) promote greater independence, including enhanced independence in performing activities of daily living and instrumental activities of daily living, for persons with Alzheimer’s disease and related disorders; and

(B) prevent or reduce the severity of secondary disabilities, including confusional episodes, falls, bladder and bowel incontinence, and adverse effects of prescription and over-the-counter medications, in such persons; and

(2) model curricula for health care professionals, health care paraprofessionals, and family caregivers, for training and application in the use of such techniques.

**(e) “Council on Alzheimer’s Disease” defined**

For purposes of this section, the term “Council on Alzheimer’s Disease” means the council established in section 11211(a)<sup>2</sup> of this title.

<sup>1</sup> So in original. Probably should be capitalized.

<sup>2</sup> See References in Text note below.

(July 1, 1944, ch. 373, title IV, §445C, formerly Pub. L. 99-660, title IX, §941, Nov. 14, 1986, 100 Stat. 3808; renumbered §445C of act July 1, 1944; amended Pub. L. 100-607, title I, §142(a), (d)(2), Nov. 4, 1988, 102 Stat. 3057, 3058; Pub. L. 102-507, §9, Oct. 24, 1992, 106 Stat. 3287; Pub. L. 103-43, title VIII, §804, June 10, 1993, 107 Stat. 164.)

## REFERENCES IN TEXT

Section 11211 of this title, referred to in subsec. (e), was repealed by Pub. L. 105-362, title VI, §601(a)(2)(E), Nov. 10, 1998, 112 Stat. 3286.

## CODIFICATION

Section was formerly classified to section 11241 of this title prior to renumbering by Pub. L. 100-607.

## AMENDMENTS

1993—Subsec. (b)(1). Pub. L. 103-43, §804(1), inserted “on Alzheimer’s Disease (in this section referred to as the ‘Council’)” after “Council”.

Subsec. (e). Pub. L. 103-43, §804(2), added subsec. (e).

1992—Subsec. (d). Pub. L. 102-507 added subsec. (d).

1988—Pub. L. 100-607, §142(a), renumbered section 11241 of this title as this section.

Subsec. (a). Pub. L. 100-607, §142(d)(2)(A), substituted “the Institute” for “the National Institute on Aging”.

Subsec. (b)(1). Pub. L. 100-607, §142(d)(2)(B)(i)(I), in introductory provisions, substituted “the date of enactment of the Alzheimer’s Disease and Related Dementias Services Research Act of 1986” for “the date of enactment of this Act”, which for purposes of codification was translated as “November 14, 1986”, thus requiring no change in text.

Pub. L. 100-607, §142(d)(2)(B)(i)(II), in introductory provisions, substituted “the Institute” for “the National Institute on Aging”.

Subsec. (b)(1)(B). Pub. L. 100-607, §142(d)(2)(B)(ii), made technical amendment to reference to section 285e-2 of this title to correct reference to corresponding provision of original act.

Subsecs. (b)(2), (c). Pub. L. 100-607, §142(d)(2)(B)(iii), (C), substituted “the Institute” for “the National Institute on Aging”.

**§ 285e-6. Dissemination of research results**

The Director of the Institute shall disseminate the results of research conducted under section 285e-5 of this title and this section to appropriate professional entities and to the public.

(July 1, 1944, ch. 373, title IV, §445D, formerly Pub. L. 99-660, title IX, §942, Nov. 14, 1986, 100 Stat. 3809; renumbered §445D of act July 1, 1944; amended Pub. L. 100-607, title I, §142(a), (d)(3), Nov. 4, 1988, 102 Stat. 3057, 3058.)

## CODIFICATION

Section was formerly classified to section 11242 of this title prior to renumbering by Pub. L. 100-607.

## AMENDMENTS

1988—Pub. L. 100-607, §142(a), renumbered section 11242 of this title as this section.

Pub. L. 100-607, §142(d)(3), substituted “the Institute” for “the National Institute on Aging” and “section 285e-5 of this title and this section” for “this part”.

**§ 285e-7. Clearinghouse on Alzheimer’s Disease****(a) Establishment; purpose; duties; publication of summary**

The Director of the Institute shall establish the Clearinghouse on Alzheimer’s Disease (hereinafter referred to as the “Clearinghouse”). The purpose of the Clearinghouse is the dissemina-

tion of information concerning services available for individuals with Alzheimer’s disease and related dementias and their families. The Clearinghouse shall—

(1) compile, archive, and disseminate information concerning research, demonstration, evaluation, and training programs and projects concerning Alzheimer’s disease and related dementias; and

(2) annually publish a summary of the information compiled under paragraph (1) during the preceding 12-month period, and make such information available upon request to appropriate individuals and entities, including educational institutions, research entities, and Federal and public agencies.

**(b) Fee for information**

The Clearinghouse may charge an appropriate fee for information provided through the toll-free telephone line established under subsection (a)(3).<sup>1</sup>

**(c) Summaries of research findings from other agencies**

The Director of the Institute, the Director of the National Institute of Mental Health, and the Director of the National Center for Health Services Research and Health Care Technology Assessment shall provide to the Clearinghouse summaries of the findings of research conducted under part D.

(July 1, 1944, ch. 373, title IV, §445E, formerly Pub. L. 99-660, title IX, §951, Nov. 14, 1986, 100 Stat. 3813; renumbered §445E of act July 1, 1944, and amended Pub. L. 100-607, title I, §142(a), (d)(4), Nov. 4, 1988, 102 Stat. 3057, 3058.)

## REFERENCES IN TEXT

Part D, referred to in subsec. (c), probably means part D of title IX of Pub. L. 99-660, Nov. 14, 1986, 100 Stat. 3808, as amended, which is classified to subchapter IV (§11251 et seq.) of chapter 118 of this title. Prior to renumbering by Pub. L. 100-607, this section was part of title IX of Pub. L. 99-660.

## CODIFICATION

Section was formerly classified to section 11281 of this title prior to renumbering by Pub. L. 100-607.

## AMENDMENTS

1988—Pub. L. 100-607, §142(a), renumbered section 11281 of this title as this section.

Subsec. (a). Pub. L. 100-607, §142(d)(4)(A), substituted “the Institute” for “the National Institute on Aging” in introductory provisions.

Subsec. (c). Pub. L. 100-607, §142(d)(4)(B), substituted “the Institute” for “the National Institute on Aging” and “part D” for “part E”.

**§ 285e-8. Dissemination project****(a) Grant or contract for establishment**

The Director of the Institute shall make a grant to, or enter into a contract with, a national organization representing individuals with Alzheimer’s disease and related dementias for the conduct of the activities described in subsection (b).

**(b) Project activities**

The organization receiving a grant or contract under this section shall—

<sup>1</sup> So in original. No subsec. (a)(3) has been enacted.

(1) establish a central computerized information system to—

(A) compile and disseminate information concerning initiatives by State and local governments and private entities to provide programs and services for individuals with Alzheimer's disease and related dementias; and

(B) translate scientific and technical information concerning such initiatives into information readily understandable by the general public, and make such information available upon request; and

(2) establish a national toll-free telephone line to make available the information described in paragraph (1), and information concerning Federal programs, services, and benefits for individuals with Alzheimer's disease and related dementias and their families.

**(c) Fees for information; exception**

The organization receiving a grant or contract under this section may charge appropriate fees for information provided through the toll-free telephone line established under subsection (b)(2), and may make exceptions to such fees for individuals and organizations who are not financially able to pay such fees.

**(d) Application for grant or contract; contents**

In order to receive a grant or contract under this section, an organization shall submit an application to the Director of the Institute. Such application shall contain—

(1) information demonstrating that such organization has a network of contacts which will enable such organization to receive information necessary to the operation of the central computerized information system described in subsection (b)(1);

(2) information demonstrating that, by the end of fiscal year 1991, such organization will be financially able to, and will, carry out the activities described in subsection (b) without a grant or contract from the Federal Government; and

(3) such other information as the Director may prescribe.

(July 1, 1944, ch. 373, title IV, §445F, formerly Pub. L. 99-660, title IX, §952, Nov. 14, 1986, 100 Stat. 3813; renumbered §445F of act July 1, 1944, and amended Pub. L. 100-607, title I, §142(a), (d)(5), Nov. 4, 1988, 102 Stat. 3057, 3058.)

CODIFICATION

Section was formerly classified to section 11282 of this title prior to renumbering by Pub. L. 100-607.

AMENDMENTS

1988—Pub. L. 100-607, §142(a), renumbered section 11282 of this title as this section.

Subsecs. (a), (d). Pub. L. 100-607, §142(d)(5), substituted "the Institute" for "the National Institute on Aging".

**§ 285e-9. Alzheimer's disease registry**

**(a) In general**

The Director of the Institute may make a grant to develop a registry for the collection of epidemiological data about Alzheimer's disease and its incidence in the United States, to train

personnel in the collection of such data, and for other matters respecting such disease.

**(b) Qualifications**

To qualify for a grant under subsection (a) an applicant shall—

(1) be an accredited school of medicine or public health which has expertise in the collection of epidemiological data about individuals with Alzheimer's disease and in the development of disease registries, and

(2) have access to a large patient population, including a patient population representative of diverse ethnic backgrounds.

(July 1, 1944, ch. 373, title IV, §445G, formerly Pub. L. 99-158, §12, Nov. 20, 1985, 99 Stat. 885, as renumbered §445G and amended Pub. L. 103-43, title VIII, §801, June 10, 1993, 107 Stat. 163.)

CODIFICATION

Section was formerly set out as a note under section 285e-2 of this title prior to renumbering by Pub. L. 103-43.

AMENDMENTS

1993—Pub. L. 103-43, §801(b)(1), reenacted section catchline without change.

Subsec. (a). Pub. L. 103-43, §801(b)(1), substituted in heading "In general" for "Grant authority" and in text substituted "Director of the Institute" for "Director of the National Institute on Aging".

Subsec. (c). Pub. L. 103-43, §801(b)(2), struck out subsec. (c) which authorized appropriations of \$2,500,000 for grants to remain available until expended or through fiscal year 1989, whichever occurred first.

**§ 285e-10. Aging processes regarding women**

The Director of the Institute, in addition to other special functions specified in section 285e-1 of this title and in cooperation with the Directors of the other national research institutes and agencies of the National Institutes of Health, shall conduct research into the aging processes of women, with particular emphasis given to the effects of menopause and the physiological and behavioral changes occurring during the transition from pre- to post-menopause, and into the diagnosis, disorders, and complications related to aging and loss of ovarian hormones in women.

(July 1, 1944, ch. 373, title IV, §445H, as added Pub. L. 103-43, title VIII, §802, June 10, 1993, 107 Stat. 163; amended Pub. L. 105-340, title I, §105, Oct. 31, 1998, 112 Stat. 3193; Pub. L. 109-482, title I, §103(b)(24), Jan. 15, 2007, 120 Stat. 3688.)

AMENDMENTS

2007—Pub. L. 109-482 struck out subsec. (a) designation before "The Director" and subsec. (b) which read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriation that is available for such purpose."

1998—Pub. L. 105-340 designated existing provisions as subsec. (a) and added subsec. (b).

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 285e-10a. Alzheimer's clinical research and training awards**

**(a) In general**

The Director of the Institute is authorized to establish and maintain a program to enhance and promote the translation of new scientific knowledge into clinical practice related to the diagnosis, care and treatment of individuals with Alzheimer's disease.

**(b) Support of promising clinicians**

In order to foster the application of the most current developments in the etiology, pathogenesis, diagnosis, prevention and treatment of Alzheimer's disease, amounts made available under this section shall be directed to the support of promising clinicians through awards for research, study, and practice at centers of excellence in Alzheimer's disease research and treatment.

**(c) Excellence in certain fields**

Research shall be carried out under awards made under subsection (b) in environments of demonstrated excellence in neuroscience, neurobiology, geriatric medicine, and psychiatry and shall foster innovation and integration of such disciplines or other environments determined suitable by the Director of the Institute.

(July 1, 1944, ch. 373, title IV, §445I, as added Pub. L. 106-505, title VIII, §801(2), Nov. 13, 2000, 114 Stat. 2349; amended Pub. L. 109-482, title I, §103(b)(25), Jan. 15, 2007, 120 Stat. 3688.)

PRIOR PROVISIONS

A prior section 445I of act July 1, 1944, was renumbered section 445J and was classified to section 285e-11 of this title prior to repeal by Pub. L. 109-482.

AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482 struck out heading and text of subsec. (d). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated \$2,250,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 through 2005."

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 285e-11. Repealed. Pub. L. 109-482, title I, § 103(b)(26), Jan. 15, 2007, 120 Stat. 3688**

Section, act July 1, 1944, ch. 373, title IV, §445J, formerly §445I, as added Pub. L. 103-43, title VIII, §803, June 10, 1993, 107 Stat. 163; renumbered §445J, Pub. L. 106-505, title VIII, §801(1), Nov. 13, 2000, 114 Stat. 2349, authorized appropriations to carry out this subpart.

EFFECTIVE DATE OF REPEAL

Repeal applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

SUBPART 6—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

**§ 285f. Purpose of Institute**

The general purpose of the National Institute of Allergy and Infectious Diseases is the conduct

and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases, including tropical diseases.

(July 1, 1944, ch. 373, title IV, §446, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 855; amended Pub. L. 103-43, title IX, §901, June 10, 1993, 107 Stat. 164.)

AMENDMENTS

1993—Pub. L. 103-43 inserted before period at end " , including tropical diseases".

**§ 285f-1. Research centers regarding chronic fatigue syndrome**

(a) The Director of the Institute, after consultation with the advisory council for the Institute, may make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct basic and clinical research on chronic fatigue syndrome.

(b) Each center assisted under this section shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

(July 1, 1944, ch. 373, title IV, §447, as added Pub. L. 103-43, title IX, §902(a), June 10, 1993, 107 Stat. 164.)

CODIFICATION

Another section 447 of act July 1, 1944, was renumbered section 447A and is classified to section 285f-2 of this title.

EXTRAMURAL STUDY SECTION

Pub. L. 103-43, title IX, §902(b), June 10, 1993, 107 Stat. 164, provided that: "Not later than 6 months after the date of enactment of this Act [June 10, 1993], the Secretary of Health and Human Services shall establish an extramural study section for chronic fatigue syndrome research."

RESEARCH ACTIVITIES ON CHRONIC FATIGUE SYNDROME

Pub. L. 103-43, title XIX, §1903, June 10, 1993, 107 Stat. 203, directed Secretary of Health and Human Services to, not later than Oct. 1, 1993, and annually thereafter for next 3 years, prepare and submit to Congress a report that summarizes research activities conducted or supported by National Institutes of Health concerning chronic fatigue syndrome, with information concerning grants made, cooperative agreements or contracts entered into, intramural activities, research priorities and needs, and plan to address such priorities and needs.

**§ 285f-2. Research and research training regarding tuberculosis**

In carrying out section 285f of this title, the Director of the Institute shall conduct or support research and research training regarding the cause, diagnosis, early detection, prevention and treatment of tuberculosis.

(July 1, 1944, ch. 373, title IV, §447A, formerly §447, as added Pub. L. 103-183, title III, §302(a), Dec. 14, 1993, 107 Stat. 2235; renumbered §447A, Pub. L. 105-392, title IV, §401(b)(3), Nov. 13, 1998, 112 Stat. 3587; amended Pub. L. 109-482, title I, §103(b)(27), Jan. 15, 2007, 120 Stat. 3688.)

## AMENDMENTS

2007—Pub. L. 109-482 struck out subsec. (a) designation before “In carrying out” and subsec. (b) which read as follows: “For the purpose of carrying out subsection (a) of this section, there are authorized to be appropriated \$50,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998. Such authorization is in addition to any other authorization of appropriations that is available for such purpose.”

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

## RESEARCH THROUGH FOOD AND DRUG ADMINISTRATION

Pub. L. 103-183, title III, §303, Dec. 14, 1993, 107 Stat. 2235, provided that: “The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall implement a tuberculosis drug and device research program under which the Commissioner may—

- “(1) provide assistance to other Federal agencies for the development of tuberculosis protocols;
- “(2) review and evaluate medical devices designed for the diagnosis and control of airborne tuberculosis; and
- “(3) conduct research concerning drugs or devices to be used in diagnosing, controlling and preventing tuberculosis.”

### § 285f-3. Sexually transmitted disease clinical research and training awards

#### (a) In general

The Director of the Institute is authorized to establish and maintain a program to enhance and promote the translation of new scientific knowledge into clinical practice related to the diagnosis, care and treatment of individuals with sexually transmitted diseases.

#### (b) Support of promising clinicians

In order to foster the application of the most current developments in the etiology, pathogenesis, diagnosis, prevention and treatment of sexually transmitted diseases, amounts made available under this section shall be directed to the support of promising clinicians through awards for research, study, and practice at centers of excellence in sexually transmitted disease research and treatment.

#### (c) Excellence in certain fields

Research shall be carried out under awards made under subsection (b) in environments of demonstrated excellence in the etiology and pathogenesis of sexually transmitted diseases and shall foster innovation and integration of such disciplines or other environments determined suitable by the Director of the Institute.

(July 1, 1944, ch. 373, title IV, §447B, as added Pub. L. 106-505, title IX, §901, Nov. 13, 2000, 114 Stat. 2349; amended Pub. L. 109-482, title I, §103(b)(28), Jan. 15, 2007, 120 Stat. 3688.)

## AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482 struck out heading and text of subsec. (d). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated \$2,250,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 through 2005.”

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

### § 285f-4. Microbicide research and development

The Director of the Institute, acting through the head of the Division of AIDS, shall, consistent with the peer-review process of the National Institutes of Health, carry out research on, and development of, safe and effective methods for use by women to prevent the transmission of the human immunodeficiency virus, which may include microbicides.

(July 1, 1944, ch. 373, title IV, §447C, as added Pub. L. 110-293, title II, §203(c), July 30, 2008, 122 Stat. 2941.)

### SUBPART 7—EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

## AMENDMENTS

2007—Pub. L. 110-154, §1(b)(7), Dec. 21, 2007, 121 Stat. 1827, substituted “Eunice Kennedy Shriver National Institute of Child Health and Human Development” for “National Institute of Child Health and Human Development” in subpart heading.

### § 285g. Purpose of Institute

The general purpose of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to gynecologic health, maternal health, child health, intellectual disabilities, human growth and development, including prenatal development, population research, and special health problems and requirements of mothers and children.

(July 1, 1944, ch. 373, title IV, §448, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 856; amended Pub. L. 106-554, §1(a)(1) [title II, §215], Dec. 21, 2000, 114 Stat. 2763, 2763A-28; Pub. L. 110-154, §1(d), Dec. 21, 2007, 121 Stat. 1828; Pub. L. 111-256, §2(f)(2), Oct. 5, 2010, 124 Stat. 2644.)

## AMENDMENTS

2010—Pub. L. 111-256 substituted “intellectual disabilities” for “mental retardation.”

2000—Pub. L. 106-554 inserted “gynecologic health,” after “with respect to”.

## CHANGE OF NAME

“Eunice Kennedy Shriver National Institute of Child Health and Human Development” substituted for “National Institute of Child Health and Human Development” in text, on authority of section 1(d) of Pub. L. 110-154, set out below.

Pub. L. 110-154, §1(d), Dec. 21, 2007, 121 Stat. 1828, provided that: “Any reference in any law, regulation, order, document, paper, or other record of the United States to the ‘National Institute of Child Health and Human Development’ shall be deemed to be a reference to the ‘Eunice Kennedy Shriver National Institute of Child Health and Human Development.’”

### EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT; FINDINGS

Pub. L. 110-154, §1(a), Dec. 21, 2007, 121 Stat. 1826, as amended by Pub. L. 111-256, §2(h), Oct. 5, 2010, 124 Stat.

2644, provided that: “Congress makes the following findings:

“(1) Since it was established by Congress in 1962 at the request of President John F. Kennedy, the National Institute of Child Health and Human Development has achieved an outstanding record of achievement in catalyzing a concentrated attack on the unsolved health problems of children and of mother-infant relationships by fulfilling its mission to—

“(A) ensure that every individual is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability; and

“(B) ensure the health, productivity, independence, and well-being of all individuals through optimal rehabilitation.

“(2) The National Institute of Child Health and Human Development has made unparalleled contributions to the advancement of child health and human development, including significant efforts to—

“(A) reduce dramatically the rates of Sudden Infant Death Syndrome, infant mortality, and maternal HIV transmission;

“(B) develop the Haemophilus Influenza B (Hib) vaccine, credited with nearly eliminating the incidence of intellectual disabilities; and

“(C) conduct intramural research, support extramural research, and train thousands of child health and human development researchers who have contributed greatly to dramatic gains in child health throughout the world.

“(3) The vision, drive, and tenacity of one woman, Eunice Kennedy Shriver, was instrumental in proposing, passing, and enacting legislation to establish the National Institute of Child Health and Human Development (Public Law 87-838) [see Tables for classification] on October 17, 1962.

“(4) It is befitting and appropriate to recognize the substantial achievements of Eunice Kennedy Shriver, a tireless advocate for children with special needs, whose foresight in creating the National Institute of Child Health and Human Development gave life to the words of President Kennedy, who wished to ‘encourage imaginative research into the complex processes of human development from conception to old age.’”

[For definition of “intellectual disabilities” in section 1(a) of Pub. L. 110-154, set out above, see Definitions note below.]

#### LONG-TERM CHILD DEVELOPMENT STUDY

Pub. L. 106-310, div. A, title X, §1004, Oct. 17, 2000, 114 Stat. 1130, as amended by Pub. L. 108-446, title III, §301, Dec. 3, 2004, 118 Stat. 2803; Pub. L. 109-482, title I, §104(b)(3)(E), Jan. 15, 2007, 120 Stat. 3694; Pub. L. 110-154, §1(d), Dec. 21, 2007, 121 Stat. 1828, provided that:

“(a) PURPOSE.—It is the purpose of this section to authorize the Eunice Kennedy Shriver National Institute of Child Health and Human Development to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children’s health and development.

“(b) IN GENERAL.—The Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency, and the Department of Education) to—

“(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

“(2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.

“(c) REQUIREMENT.—The study under subsection (b) shall—

“(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological and psychosocial environmental influences on children’s well-being;

“(2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures;

“(3) consider health disparities among children which may include the consideration of prenatal exposures; and

“(4) be conducted in compliance with section 444 of the General Education Provisions Act (20 U.S.C. 1232g), including the requirement of prior parental consent for the disclosure of any education records, except without the use of authority or exceptions granted to authorized representatives of the Secretary of Education for the evaluation of Federally-supported education programs or in connection with the enforcement of the Federal legal requirements that relate to such programs.

“[(d) Repealed. Pub. L. 109-482, title I, §104(b)(3)(E), Jan. 15, 2007, 120 Stat. 3694.]

“(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section \$18,000,000 for fiscal year 2001, and such sums as may be necessary for each [sic] the fiscal years 2002 through 2005.”

#### NATIONAL COMMISSION TO PREVENT INFANT MORTALITY; COMPOSITION; VOLUNTARY SERVICES; DURATION

Pub. L. 100-436, title IV, Sept. 20, 1988, 102 Stat. 1709, provided that the National Commission to Prevent Infant Mortality was to be composed of sixteen members, including seven at large members, and that it had power to accept voluntary and uncompensated services, notwithstanding section 1342 of title 31, and was to continue operating, notwithstanding sections 208 and 209 of Pub. L. 99-660 (formerly set out below).

#### NATIONAL COMMISSION TO PREVENT INFANT MORTALITY

Pub. L. 99-660, title II, Nov. 14, 1986, 100 Stat. 3752, known as the National Commission to Prevent Infant Mortality Act of 1986, established National Commission to Prevent Infant Mortality to examine and make recommendation on government and private resources, policies, and programs which impact on infant mortality, required Commission to submit recommendations to President and Congress no later than one year after Nov. 14, 1986, and terminated Commission 90 days after submission of recommendations.

#### DEFINITIONS

For meaning of references to an intellectual disability and to individuals with intellectual disabilities in provisions amended by section 2 of Pub. L. 111-256, see section 2(k) of Pub. L. 111-256, set out as a note under section 1400 of Title 20, Education.

#### § 285g-1. Sudden infant death syndrome research

The Director of the Institute shall conduct and support research which specifically relates to sudden infant death syndrome.

(July 1, 1944, ch. 373, title IV, §449, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 856.)

#### § 285g-2. Research on intellectual disabilities

The Director of the Institute shall conduct and support research and related activities into the causes, prevention, and treatment of intellectual disabilities.

(July 1, 1944, ch. 373, title IV, §450, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 856; amended Pub. L. 111-256, §2(f)(3), Oct. 5, 2010, 124 Stat. 2644.)

## AMENDMENTS

2010—Pub. L. 111-256 amended section generally. Prior to amendment, text read as follows: “The Director of the Institute shall conduct and support research and related activities into the causes, prevention, and treatment of mental retardation.”

## DEFINITIONS

For meaning of references to an intellectual disability and to individuals with intellectual disabilities in provisions amended by section 2 of Pub. L. 111-256, see section 2(k) of Pub. L. 111-256, set out as a note under section 1400 of Title 20, Education.

**§ 285g-3. Associate Director for Prevention; appointment; function**

There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of health problems of mothers and children. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(July 1, 1944, ch. 373, title IV, § 451, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 856; amended Pub. L. 105-362, title VI, § 601(a)(1)(E), Nov. 10, 1998, 112 Stat. 3285.)

## AMENDMENTS

1998—Pub. L. 105-362 struck out subsec. (a) designation and struck out subsec. (b) which read as follows: “The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b of this title a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.”

**§ 285g-4. National Center for Medical Rehabilitation Research**

**(a) Establishment of Center**

There shall be in the Institute an agency to be known as the National Center for Medical Rehabilitation Research (hereafter in this section referred to as the “Center”). The Director of the Institute shall appoint a qualified individual to serve as Director of the Center. The Director of the Center shall report directly to the Director of the Institute.

**(b) Purpose**

The general purpose of the Center is the conduct, support, and coordination of research and research training (including research on the development of orthotic and prosthetic devices), the dissemination of health information, and other programs with respect to the rehabilitation of individuals with physical disabilities resulting from diseases or disorders of the neurological, musculoskeletal, cardiovascular, pulmonary, or any other physiological system (hereafter in this section referred to as “medical rehabilitation”).

**(c) Authority of Director**

(1) In carrying out the purpose described in subsection (b), the Director of the Center may—

(A) provide for clinical trials regarding medical rehabilitation;

(B) provide for research regarding model systems of medical rehabilitation;

(C) coordinate the activities within the Center with similar activities of other agencies of the Federal Government, including the other agencies of the National Institutes of Health, and with similar activities of other public entities and of private entities;

(D) support multidisciplinary medical rehabilitation research conducted or supported by more than one such agency;

(E) in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

(i) establish technical and scientific peer review groups in addition to those appointed under section 282(b)(16) of this title; and

(ii) appoint the members of peer review groups established under subparagraph (A); and

(F) support medical rehabilitation research and training centers.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under subparagraph (E).

(2) In carrying out this section, the Director of the Center may make grants and enter into cooperative agreements and contracts.

**(d) Research Plan**

(1) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall develop a comprehensive plan (referred to in this section as the “Research Plan”) for the conduct, support, and coordination of medical rehabilitation research.

(2) The Research Plan shall—

(A) identify current medical rehabilitation research activities conducted or supported by the Federal Government, opportunities and needs for additional research, and priorities for such research;

(B) make recommendations for the coordination of such research conducted or supported by the National Institutes of Health and other agencies of the Federal Government; and

(C) include goals and objectives for conducting, supporting, and coordinating medical rehabilitation research, consistent with the purpose described in subsection (b).

(3)(A) Not later than 18 months after the date of the enactment of the National Institutes of Health Revitalization Amendments of 1990, the Director of the Institute shall transmit the Research Plan to the Director of NIH, who shall submit the Plan to the President and the Congress.

(B) Subparagraph (A) shall be carried out independently of the process of reporting that is required in sections 283 and 284b<sup>1</sup> of this title.

(4) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall revise and update the Research Plan periodically, as appropriate, or not less than every 5 years. Not later than 30 days after the Research Plan is so revised and up-

<sup>1</sup> See References in Text note below.

dated, the Director of the Center shall transmit the revised and updated Research Plan to the President, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives.

(5) The Director of the Center, in consultation with the Director of the Institute, shall, prior to revising and updating the Research Plan, prepare a report for the coordinating committee established under subsection (e) and the advisory board established under subsection (f) that describes and analyzes the progress during the preceding fiscal year in achieving the goals and objectives described in paragraph (2)(C) and includes expenditures for rehabilitation research at the National Institutes of Health. The report shall include recommendations for revising and updating the Research Plan, and such initiatives as the Director of the Center and the Director of the Institute determine appropriate. In preparing the report, the Director of the Center and the Director of the Institute shall consult with the Director of the National Institutes of Health.

**(e) Medical Rehabilitation Coordinating Committee**

(1) The Director of NIH shall establish a committee to be known as the Medical Rehabilitation Coordinating Committee (hereafter in this section referred to as the “Coordinating Committee”).

(2) The Coordinating Committee shall periodically host a scientific conference or workshop on medical rehabilitation research and make recommendations to the Director of the Institute and the Director of the Center with respect to the content of the Research Plan and with respect to the activities of the Center that are carried out in conjunction with other agencies of the National Institutes of Health and with other agencies of the Federal Government.

(3) The Coordinating Committee shall be composed of the Director of the Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director of the National Institutes of Health, the Director of the Center, the Director of the Institute, and the Directors of the National Institute on Aging, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Heart, Lung, and Blood Institute, the National Institute of Neurological Disorders and Stroke, and such other national research institutes and such representatives of other agencies of the Federal Government as the Director of NIH determines to be appropriate.

(4) The Coordinating Committee shall be chaired by the Director of the Center.

**(f) National Advisory Board on Medical Rehabilitation Research**

(1) Not later than 90 days after the date of the enactment of the National Institutes of Health Revitalization Amendments of 1990, the Director of NIH shall establish a National Advisory Board on Medical Rehabilitation Research (hereafter in this section referred to as the “Advisory Board”).

(2) The Advisory Board shall review and assess Federal research priorities, activities, and find-

ings regarding medical rehabilitation research, and shall advise the Director of the Center and the Director of the Institute on the provisions of the Research Plan.

(3)(A) The Director of NIH shall appoint to the Advisory Board 18 qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, 12 shall be representatives of health and scientific disciplines with respect to medical rehabilitation and 6 shall be individuals representing the interests of individuals undergoing, or in need of, medical rehabilitation.

(B) The following officials shall serve as ex officio members of the Advisory Board:

- (i) The Director of the Center.
- (ii) The Director of the Institute.
- (iii) The Director of the National Institute on Aging.

(iv) The Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

(v) The Director of the National Institute on Deafness and Other Communication Disorders.

(vi) The Director of the National Heart, Lung, and Blood Institute.

(vii) The Director of the National Institute of Neurological Disorders and Stroke.

(viii) The Director of the National Institute on Disability and Rehabilitation Research.

(ix) The Director of the Division of Program Coordination, Planning, and Strategic Initiatives.

(x) The Commissioner for Rehabilitation Services Administration.

(xi) The Assistant Secretary of Defense (Health Affairs).

(xii) The Under Secretary for Health of the Department of Veterans Affairs.

(4) The members of the Advisory Board shall, from among the members appointed under paragraph (3)(A), designate an individual to serve as the chair of the Advisory Board.

**(g) Review and coordination of medical rehabilitation research programs**

(1) The Secretary and the heads of other Federal agencies shall jointly review the programs carried out (or proposed to be carried out) by each such official with respect to medical rehabilitation research and, as appropriate, enter into agreements preventing duplication among such programs.

(2) The Secretary shall, as appropriate, enter into interagency agreements relating to the coordination of medical rehabilitation research conducted by agencies of the National Institutes of Health and other agencies of the Federal Government.

**(h) “Medical rehabilitation research” defined**

For purposes of this section, the term “medical rehabilitation research” means the science of mechanisms and interventions that prevent, improve, restore, or replace lost, underdeveloped, or deteriorating function.

(July 1, 1944, ch. 373, title IV, §452, as added Pub. L. 101-613, §3(a), Nov. 16, 1990, 104 Stat. 3227; amended Pub. L. 102-405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 109-482, title I, §102(f)(1)(B), Jan. 15, 2007, 120 Stat. 3685; Pub. L.

114-255, div. A, title II, §2040(a), (b)(1), Dec. 13, 2016, 130 Stat. 1069, 1070.)

#### REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (c)(1), is Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, as amended, which is set out in the Appendix to Title 5, Government Organization and Employees.

The date of the enactment of the National Institutes of Health Revitalization Amendments of 1990, referred to in subsecs. (d)(3)(A) and (f)(1), probably means the date of enactment of the National Institutes of Health Amendments of 1990, Pub. L. 101-613, which was approved Nov. 16, 1990.

Section 284b of this title, referred to in subsec. (d)(3)(B), was repealed by Pub. L. 109-482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

#### AMENDMENTS

2016—Pub. L. 114-255, §2040(b)(1), made technical amendment to directory language of Pub. L. 101-613, §3(a), which enacted this section.

Subsec. (b). Pub. L. 114-255, §2040(a)(1), substituted “conduct, support, and coordination” for “conduct and support”.

Subsec. (c)(1)(C). Pub. L. 114-255, §2040(a)(2), substituted “within the Center” for “of the Center”.

Subsec. (d)(1). Pub. L. 114-255, §2040(a)(3)(A), added par. (1) and struck out former par. (1), which read as follows: “In consultation with the Director of the Center, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), the Director of the Institute shall develop a comprehensive plan for the conduct and support of medical rehabilitation research (hereafter in this section referred to as the ‘Research Plan’).”

Subsec. (d)(2)(C). Pub. L. 114-255, §2040(a)(3)(B), added subpar. (C).

Subsec. (d)(4). Pub. L. 114-255, §2040(a)(3)(C), added par. (4) and struck out former par. (4) which read as follows: “The Director of the Institute shall periodically revise and update the Research Plan as appropriate, after consultation with the Director of the Center, the coordinating committee established under subsection (e), and the advisory board established under subsection (f). A description of any revisions in the Research Plan shall be contained in each report prepared under section 284b of this title by the Director of the Institute.”

Subsec. (d)(5). Pub. L. 114-255, §2040(a)(3)(D), added par. (5).

Subsec. (e)(2). Pub. L. 114-255, §2040(a)(4)(A), inserted “periodically host a scientific conference or workshop on medical rehabilitation research and” after “The Coordinating Committee shall”.

Subsec. (e)(3). Pub. L. 114-255, §2040(a)(4)(B), inserted “the Director of the Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director of the National Institutes of Health,” after “shall be composed of”.

Subsec. (f)(3)(B)(ix) to (xii). Pub. L. 114-255, §2040(a)(5), added cl. (ix) and redesignated former cls. (ix) to (xi) as (x) to (xii), respectively.

Subsecs. (g), (h). Pub. L. 114-255, §2040(a)(6), added subsecs. (g) and (h).

2007—Subsec. (c)(1)(E)(i). Pub. L. 109-482 substituted “section 282(b)(16)” for “section 282(b)(6)”.

1992—Subsec. (f)(3)(B)(xi). Pub. L. 102-405 substituted “Under Secretary for Health of the Department of Veterans Affairs” for “Chief Medical Director of the Department of Veterans Affairs”.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### TRANSFER OF FUNCTIONS

Functions which the Director of the National Institute on Disability and Rehabilitation Research exer-

cised before July 22, 2014 (including all related functions of any officer or employee of the National Institute on Disability and Rehabilitation Research), transferred to the National Institute on Disability, Independent Living, and Rehabilitation Research, see subsection (n) of section 3515e of Title 42, The Public Health and Welfare.

#### PREVENTING DUPLICATIVE PROGRAMS OF MEDICAL REHABILITATION RESEARCH

Pub. L. 101-613, §3(b), Nov. 16, 1990, 104 Stat. 3230, which required the Secretary of Health and Human Services and the heads of other Federal agencies to jointly review medical rehabilitation research programs and enter into agreements for preventing duplication among such programs not later than one year after November 16, 1990, was repealed by Pub. L. 114-255, div. A, title II, §2040(b)(2), Dec. 13, 2016, 130 Stat. 1070. See subsecs. (g) and (h) of this section.

#### TERMINATION OF ADVISORY BOARDS

Advisory boards established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a board established by the President or an officer of the Federal Government, such board is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a board established by Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

### § 285g-5. Research centers with respect to contraception and infertility

#### (a) Grants and contracts

The Director of the Institute, after consultation with the advisory council for the Institute, shall make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct activities for the purpose of improving methods of contraception and centers to conduct activities for the purpose of improving methods of diagnosis and treatment of infertility.

#### (b) Number of centers

In carrying out subsection (a), the Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the establishment of three centers with respect to contraception and for two centers with respect to infertility.

#### (c) Duties

(1) Each center assisted under this section shall, in carrying out the purpose of the center involved—

(A) conduct clinical and other applied research, including—

(i) for centers with respect to contraception, clinical trials of new or improved drugs and devices for use by males and females (including barrier methods); and

(ii) for centers with respect to infertility, clinical trials of new or improved drugs and devices for the diagnosis and treatment of infertility in males and females;

(B) develop protocols for training physicians, scientists, nurses, and other health and allied health professionals;

(C) conduct training programs for such individuals;

(D) develop model continuing education programs for such professionals; and

(E) disseminate information to such professionals and the public.

(2) A center may use funds provided under subsection (a) to provide stipends for health and allied health professionals enrolled in programs described in subparagraph (C) of paragraph (1), and to provide fees to individuals serving as subjects in clinical trials conducted under such paragraph.

**(d) Coordination of information**

The Director of the Institute shall, as appropriate, provide for the coordination of information among the centers assisted under this section.

**(e) Facilities**

Each center assisted under subsection (a) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

**(f) Period of support**

Support of a center under subsection (a) may be for a period not exceeding 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, §452A, as added Pub. L. 103-43, title X, §1001, June 10, 1993, 107 Stat. 165; amended Pub. L. 109-482, title I, §103(b)(29), Jan. 15, 2007, 120 Stat. 3688.)

AMENDMENTS

2007—Subsec. (g). Pub. L. 109-482 struck out subsec. (g) which read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated \$30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.”

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 285g-6. Program regarding obstetrics and gynecology**

The Director of the Institute shall establish and maintain within the Institute an intramural laboratory and clinical research program in obstetrics and gynecology.

(July 1, 1944, ch. 373, title IV, §452B, as added Pub. L. 103-43, title X, §1011, June 10, 1993, 107 Stat. 166.)

**§ 285g-7. Child health research centers**

The Director of the Institute shall develop and support centers for conducting research with respect to child health. Such centers shall give priority to the expeditious transfer of advances

from basic science to clinical applications and improving the care of infants and children.

(July 1, 1944, ch. 373, title IV, §452C, as added Pub. L. 103-43, title X, §1021, June 10, 1993, 107 Stat. 167.)

**§ 285g-8. Prospective longitudinal study on adolescent health**

**(a) In general**

Not later than October 1, 1993, the Director of the Institute shall commence a study for the purpose of providing information on the general health and well-being of adolescents in the United States, including, with respect to such adolescents, information on—

(1) the behaviors that promote health and the behaviors that are detrimental to health; and

(2) the influence on health of factors particular to the communities in which the adolescents reside.

**(b) Design of study**

**(1) In general**

The study required in subsection (a) shall be a longitudinal study in which a substantial number of adolescents participate as subjects. With respect to the purpose described in such subsection, the study shall monitor the subjects throughout the period of the study to determine the health status of the subjects and any change in such status over time.

**(2) Population-specific analyses**

The study required in subsection (a) shall be conducted with respect to the population of adolescents who are female, the population of adolescents who are male, various socioeconomic populations of adolescents, and various racial and ethnic populations of adolescents. The study shall be designed and conducted in a manner sufficient to provide for a valid analysis of whether there are significant differences among such populations in health status and whether and to what extent any such differences are due to factors particular to the populations involved.

**(c) Coordination with Women’s Health Initiative**

With respect to the national study of women being conducted by the Secretary and known as the Women’s Health Initiative, the Secretary shall ensure that such study is coordinated with the component of the study required in subsection (a) that concerns adolescent females, including coordination in the design of the 2 studies.

(July 1, 1944, ch. 373, title IV, §452D, as added Pub. L. 103-43, title X, §1031, June 10, 1993, 107 Stat. 167.)

**§ 285g-9. Fragile X**

**(a) Expansion and coordination of research activities**

The Director of the Institute, after consultation with the advisory council for the Institute, shall expand, intensify, and coordinate the activities of the Institute with respect to research on the disease known as fragile X.

**(b) Research centers****(1) In general**

The Director of the Institute shall make grants or enter into contracts for the development and operation of centers to conduct research for the purposes of improving the diagnosis and treatment of, and finding the cure for, fragile X.

**(2) Number of centers****(A) In general**

In carrying out paragraph (1), the Director of the Institute shall, to the extent that amounts are appropriated, and subject to subparagraph (B), provide for the establishment of at least three fragile X research centers.

**(B) Peer review requirement**

The Director of the Institute shall make a grant to, or enter into a contract with, an entity for purposes of establishing a center under paragraph (1) only if the grant or contract has been recommended after technical and scientific peer review required by regulations under section 289a of this title.

**(3) Activities**

The Director of the Institute, with the assistance of centers established under paragraph (1), shall conduct and support basic and biomedical research into the detection and treatment of fragile X.

**(4) Coordination among centers**

The Director of the Institute shall, as appropriate, provide for the coordination of the activities of the centers assisted under this section, including providing for the exchange of information among the centers.

**(5) Certain administrative requirements**

Each center assisted under paragraph (1) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

**(6) Duration of support**

Support may be provided to a center under paragraph (1) for a period not exceeding 5 years. Such period may be extended for one or more additional periods, each of which may not exceed 5 years, if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period be extended.

(July 1, 1944, ch. 373, title IV, §452E, as added Pub. L. 106-310, div. A, title II, §201, Oct. 17, 2000, 114 Stat. 1109; amended Pub. L. 109-482, title I, §103(b)(30), Jan. 15, 2007, 120 Stat. 3688.)

## AMENDMENTS

2007—Subsec. (b)(7). Pub. L. 109-482 struck out heading and text of par. (7). Text read as follows: “For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.”

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or

subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 285g-10. Investment in tomorrow’s pediatric researchers**

In order to ensure the future supply of researchers dedicated to the care and research needs of children, the Director of the Institute, after consultation with the Administrator of the Health Resources and Services Administration, shall support activities to provide for—

(1) an increase in the number and size of institutional training grants to institutions supporting pediatric training; and

(2) an increase in the number of career development awards for health professionals who intend to build careers in pediatric basic and clinical research, including pediatric pharmacological research.

(July 1, 1944, ch. 373, title IV, §452G, as added Pub. L. 106-310, div. A, title X, §1002(a), Oct. 17, 2000, 114 Stat. 1128; amended Pub. L. 109-482, title I, §103(b)(31), Jan. 15, 2007, 120 Stat. 3688; Pub. L. 110-85, title V, §503(a), Sept. 27, 2007, 121 Stat. 890.)

## AMENDMENTS

2007—Pub. L. 109-482 struck out subsec. (a) designation and heading before “In order to” and struck out heading and text of subsec. (b). Text read as follows: “For the purpose of carrying out subsection (a) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.”

Par. (2). Pub. L. 110-85 inserted “, including pediatric pharmacological research” before period at end.

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

## SUBPART 8—NATIONAL INSTITUTE OF DENTAL RESEARCH

**§ 285h. Purpose of Institute**

The general purpose of the National Institute of Dental Research is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, prevention, and methods of diagnosis and treatment of dental and oral diseases and conditions.

(July 1, 1944, ch. 373, title IV, §453, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 856.)

## SUBPART 9—NATIONAL EYE INSTITUTE

**§ 285i. Purpose of Institute**

The general purpose of the National Eye Institute (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind. Subject to section 285i-1 of this title, the Director of the Institute may carry out a program of grants for public and private nonprofit vision research facilities.

(July 1, 1944, ch. 373, title IV, §455, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 856; amended Pub. L. 103-43, title XI, §1101(b), June 10, 1993, 107 Stat. 169.)

AMENDMENTS

1993—Pub. L. 103-43 substituted “Subject to section 285i-1 of this title, the Director” for “The Director” in second sentence.

**§ 285i-1. Clinical research on eye care and diabetes**

**(a) Program of grants**

The Director of the Institute, in consultation with the advisory council for the Institute, may award research grants to one or more Diabetes Eye Research Institutions for the support of programs in clinical or health services aimed at—

- (1) providing comprehensive eye care services for people with diabetes, including a full complement of preventive, diagnostic and treatment procedures;
- (2) developing new and improved techniques of patient care through basic and clinical research;
- (3) assisting in translation of the latest research advances into clinical practice; and
- (4) expanding the knowledge of the eye and diabetes through further research.

**(b) Use of funds**

Amounts received under a grant awarded under this section shall be used for the following:

- (1) Establishing the biochemical, cellular, and genetic mechanisms associated with diabetic eye disease and the earlier detection of pending eye abnormalities. The focus of work under this paragraph shall require that ophthalmologists have training in the most up-to-date molecular and cell biological methods.
- (2) Establishing new frontiers in technology, such as video-based diagnostic and research resources, to—
  - (A) provide improved patient care;
  - (B) provide for the evaluation of retinal physiology and its affect on diabetes; and
  - (C) provide for the assessment of risks for the development and progression of diabetic eye disease and a more immediate evaluation of various therapies aimed at preventing diabetic eye disease.

Such technologies shall be designed to permit evaluations to be performed both in humans and in animal models.

(3) The translation of the results of vision research into the improved care of patients with diabetic eye disease. Such translation shall require the application of institutional resources that encompass patient care, clinical research and basic laboratory research.

(4) The conduct of research concerning the outcomes of eye care treatments and eye health education programs as they relate to patients with diabetic eye disease, including the evaluation of regional approaches to such research.

**(c) Authorized expenditures**

The purposes for which a grant under subsection (a) may be expended include equipment for the research described in such subsection.

(July 1, 1944, ch. 373, title IV, §456, as added Pub. L. 103-43, title XI, §1101(a), June 10, 1993, 107 Stat. 168.)

SUBPART 10—NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

AMENDMENTS

1988—Pub. L. 100-553, §2(2), Oct. 28, 1988, 102 Stat. 2769, and Pub. L. 100-607, title I, §101(2), Nov. 4, 1988, 102 Stat. 3049, made identical amendments to subpart heading, substituting “Neurological Disorders” for “Neurological and Communicative Disorders”. Pub. L. 100-690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238, amended subpart heading to read as if the amendment by Pub. L. 100-607 had not been enacted.

**§ 285j. Purpose of Institute**

The general purpose of the National Institute of Neurological Disorders and Stroke (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to neurological disease and disorder and stroke.

(July 1, 1944, ch. 373, title IV, §457, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 857; amended Pub. L. 100-553, §2(3), Oct. 28, 1988, 102 Stat. 2769; Pub. L. 100-607, title I, §101(3), Nov. 4, 1988, 102 Stat. 3049; Pub. L. 100-690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238; Pub. L. 101-93, §5(a), Aug. 16, 1989, 103 Stat. 611.)

AMENDMENTS

1989—Pub. L. 101-93 substituted “disease and” for “disease and and”.

1988—Pub. L. 100-553 and Pub. L. 100-607 made identical amendments, substituting “Neurological Disorders” for “Neurological and Communicative Disorders” and “and disorder and stroke” for “disorder, stroke, and disorders of human communication”. Pub. L. 100-690 amended this section to read as if the amendments by Pub. L. 100-607 had not been enacted.

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by Pub. L. 100-690, see section 2613(b)(1) of Pub. L. 100-690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

**§ 285j-1. Spinal cord regeneration research**

The Director of the Institute shall conduct and support research into spinal cord regeneration.

(July 1, 1944, ch. 373, title IV, §458, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 857.)

INTERAGENCY COMMITTEE ON SPINAL CORD INJURY

Pub. L. 99-158, §7, Nov. 20, 1985, 99 Stat. 881, provided that:

“(a) ESTABLISHMENT.—Within 90 days after the date of enactment of this Act [Nov. 20, 1985], the Secretary of Health and Human Services shall establish in the National Institute of Neurological and Communicative Diseases and Stroke an Interagency Committee on Spinal Cord Injury (hereafter in this section referred to as the ‘Interagency Committee’). The Interagency Committee shall plan, develop, coordinate, and implement comprehensive Federal initiatives in research on spinal cord injury and regeneration.

“(b) COMMITTEE COMPOSITION AND MEETINGS.—(1) The Interagency Committee shall consist of representatives from—

- “(A) the National Institute on Neurological and Communicative Disorders and Stroke;

“(B) the Department of Defense;  
 “(C) the Department of Education;  
 “(D) the Veterans’ Administration;  
 “(E) the Office of Science and Technology Policy;  
 and  
 “(F) the National Science Foundation;  
 designated by the heads of such entities.

“(2) The Interagency Committee shall meet at least four times. The Secretary of Health and Human Services shall select the Chairman of the Interagency Committee from the members of the Interagency Committee.

“(c) REPORT.—Within the 18 months after the date of enactment of this Act [Nov. 20, 1985], the Interagency Committee shall prepare and transmit to the Congress a report concerning its activities under this section. The report shall include a description of research projects on spinal cord injury and regeneration conducted or supported by Federal agencies during such 18-month period, the nature and purpose of each such project, the amounts expended for each such project, and an identification of the entity which conducted the research under each such project.

“(d) TERMINATION.—The Interagency Committee shall terminate 90 days after the date on which the Interagency Committee transmits the report required by subsection (c) to the Congress.”

### § 285j-2. Bioengineering research

The Director of the Institute shall make grants or enter into contracts for research on the means to overcome paralysis of the extremities through electrical stimulation and the use of computers.

(July 1, 1944, ch. 373, title IV, § 459, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 857.)

### § 285j-3. Research on multiple sclerosis

The Director of the Institute shall conduct and support research on multiple sclerosis, especially research on effects of genetics and hormonal changes on the progress of the disease.

(July 1, 1944, ch. 373, title IV, § 460, as added Pub. L. 103-43, title XII, § 1201, June 10, 1993, 107 Stat. 169.)

## SUBPART 11—NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

### § 285k. National Institute of General Medical Sciences

#### (a) General purpose

The general purpose of the National Institute of General Medical Sciences is the conduct and support of research, training, and, as appropriate, health information dissemination, and other programs with respect to general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other national research institutes or are outside the general area of responsibility of any other national research institute.

#### (b) Institutional development award program

(1)(A) In the case of entities described in subparagraph (B), the Director of NIH, acting through the Director of the National Institute of General Medical Sciences, shall establish a program to enhance the competitiveness of such entities in obtaining funds from the national research institutes for conducting biomedical and behavioral research.

(B) The entities referred to in subparagraph (A) are entities that conduct biomedical and behavioral research and are located in a State in which the aggregate success rate for applications to the national research institutes for assistance for such research by the entities in the State has historically constituted a low success rate of obtaining such funds, relative to such aggregate rate for such entities in other States.

(C) With respect to enhancing competitiveness for purposes of subparagraph (A), the Director of NIH, in carrying out the program established under such subparagraph, may—

(i) provide technical assistance to the entities involved, including technical assistance in the preparation of applications for obtaining funds from the national research institutes;

(ii) assist the entities in developing a plan for biomedical or behavioral research proposals; and

(iii) assist the entities in implementing such plan.

(2) The Director of NIH shall establish a program of supporting projects of biomedical or behavioral research whose principal researchers are individuals who have not previously served as the principal researchers of such projects supported by the Director.

(July 1, 1944, ch. 373, title IV, § 461, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 857; amended Pub. L. 112-74, div. F, title II, § 221(b)(5), Dec. 23, 2011, 125 Stat. 1088.)

#### CODIFICATION

Section 282(g) of this title, which was transferred and redesignated as subsec. (b) of this section by Pub. L. 112-74, div. F, title II, § 221(b)(5)(B), Dec. 23, 2011, 125 Stat. 1088, was based on act July 1, 1944, ch. 373, title IV, § 402(g), as added Pub. L. 103-43, title II, § 202, June 10, 1993, 107 Stat. 144.

#### AMENDMENTS

2011—Pub. L. 112-74, § 221(b)(5)(A), substituted “National Institute of General Medical Sciences” for “Purpose of Institute” in section catchline, designated existing provisions as subsec. (a), and inserted subsec. heading.

Subsec. (b). Pub. L. 112-74, § 221(b)(5)(C)(i), (ii), inserted heading and realigned margins.

Pub. L. 112-74, § 221(b)(5)(B), transferred subsec. (g) of section 282 of this title and redesignated it as subsec. (b) of this section. See Codification note above.

Subsec. (b)(1)(A). Pub. L. 112-74, § 221(b)(5)(C)(iii), substituted “acting through the Director of the National Institute of General Medical Sciences” for “acting through the Director of the National Center for Research Resources”.

## SUBPART 12—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

### § 285l. Purpose of Institute

The general purpose of the National Institute of Environmental Health Sciences (in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly.

(July 1, 1944, ch. 373, title IV, § 463, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 857; amended Pub. L. 103-43, title XIII, § 1301(b), June 10, 1993, 107 Stat. 170.)

## AMENDMENTS

1993—Pub. L. 103-43 inserted “(in this subpart referred to as the ‘Institute’)” after “Sciences”.

### § 2851-1. Applied Toxicological Research and Testing Program

(a) There is established within the Institute a program for conducting applied research and testing regarding toxicology, which program shall be known as the Applied Toxicological Research and Testing Program.

(b) In carrying out the program established under subsection (a), the Director of the Institute shall, with respect to toxicology, carry out activities—

(1) to expand knowledge of the health effects of environmental agents;

(2) to broaden the spectrum of toxicology information that is obtained on selected chemicals;

(3) to develop and validate assays and protocols, including alternative methods that can reduce or eliminate the use of animals in acute or chronic safety testing;

(4) to establish criteria for the validation and regulatory acceptance of alternative testing and to recommend a process through which scientifically validated alternative methods can be accepted for regulatory use;

(5) to communicate the results of research to government agencies, to medical, scientific, and regulatory communities, and to the public; and

(6) to integrate related activities of the Department of Health and Human Services.

(July 1, 1944, ch. 373, title IV, § 463A, as added Pub. L. 103-43, title XIII, § 1301(a), June 10, 1993, 107 Stat. 169.)

### § 2851-2. Definitions

In sections 2851-2 to 2851-5 of this title:

#### (1) Alternative test method

The term “alternative test method” means a test method that—

(A) includes any new or revised test method; and

(B)(i) reduces the number of animals required;

(ii) refines procedures to lessen or eliminate pain or distress to animals, or enhances animal well-being; or

(iii) replaces animals with non-animal systems or one animal species with a phylogenetically lower animal species, such as replacing a mammal with an invertebrate.

#### (2) ICCVAM test recommendation

The term “ICCVAM test recommendation” means a summary report prepared by the ICCVAM characterizing the results of a scientific expert peer review of a test method.

(Pub. L. 106-545, § 2, Dec. 19, 2000, 114 Stat. 2721.)

## CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

### § 2851-3. Interagency Coordinating Committee on the Validation of Alternative Methods

#### (a) In general

With respect to the interagency coordinating committee that is known as the Interagency Coordinating Committee on the Validation of Alternative Methods (referred to in sections 2851-2 to 2851-5 of this title as “ICCVAM”) and that was established by the Director of the National Institute of Environmental Health Sciences for purposes of section 2851-1(b) of this title, the Director of the Institute shall designate such committee as a permanent interagency coordinating committee of the Institute under the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods. Sections 2851-2 to 2851-5 of this title may not be construed as affecting the authorities of such Director regarding ICCVAM that were in effect on the day before December 19, 2000, except to the extent inconsistent with sections 2851-2 to 2851-5 of this title.

#### (b) Purposes

The purposes of the ICCVAM shall be to—

(1) increase the efficiency and effectiveness of Federal agency test method review;

(2) eliminate unnecessary duplicative efforts and share experiences between Federal regulatory agencies;

(3) optimize utilization of scientific expertise outside the Federal Government;

(4) ensure that new and revised test methods are validated to meet the needs of Federal agencies; and

(5) reduce, refine, or replace the use of animals in testing, where feasible.

#### (c) Composition

The ICCVAM shall be composed of the heads of the following Federal agencies (or their designees):

(1) Agency for Toxic Substances and Disease Registry.

(2) Consumer Product Safety Commission.

(3) Department of Agriculture.

(4) Department of Defense.

(5) Department of Energy.

(6) Department of the Interior.

(7) Department of Transportation.

(8) Environmental Protection Agency.

(9) Food and Drug Administration.

(10) National Institute for Occupational Safety and Health.

(11) National Institutes of Health.

(12) National Cancer Institute.

(13) National Institute of Environmental Health Sciences.

(14) National Library of Medicine.

(15) Occupational Safety and Health Administration.

(16) Any other agency that develops, or employs tests or test data using animals, or regulates on the basis of the use of animals in toxicity testing.

#### (d) Scientific Advisory Committee

##### (1) Establishment

The Director of the National Institute of Environmental Health Sciences shall establish a Scientific Advisory Committee (referred to in

sections 2851-2 to 2851-5 of this title as the “SAC”) to advise ICCVAM and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods regarding ICCVAM activities. The activities of the SAC shall be subject to provisions of the Federal Advisory Committee Act.

## (2) Membership

### (A) In general

The SAC shall be composed of the following voting members:

(i) At least one knowledgeable representative having a history of expertise, development, or evaluation of new or revised or alternative test methods from each of—

(I) the personal care, pharmaceutical, industrial chemicals, or agriculture industry;

(II) any other industry that is regulated by the Federal agencies specified in subsection (c); and

(III) a national animal protection organization established under section 501(c)(3) of title 26.

(ii) Representatives (selected by the Director of the National Institute of Environmental Health Sciences) from an academic institution, a State government agency, an international regulatory body, or any corporation developing or marketing new or revised or alternative test methodologies, including contract laboratories.

### (B) Nonvoting ex officio members

The membership of the SAC shall, in addition to voting members under subparagraph (A), include as nonvoting ex officio members the agency heads specified in subsection (c) (or their designees).

### (e) Duties

The ICCVAM shall, consistent with the purposes described in subsection (b), carry out the following functions:

(1) Review and evaluate new or revised or alternative test methods, including batteries of tests and test screens, that may be acceptable for specific regulatory uses, including the coordination of technical reviews of proposed new or revised or alternative test methods of interagency interest.

(2) Facilitate appropriate interagency and international harmonization of acute or chronic toxicological test protocols that encourage the reduction, refinement, or replacement of animal test methods.

(3) Facilitate and provide guidance on the development of validation criteria, validation studies and processes for new or revised or alternative test methods and help facilitate the acceptance of such scientifically valid test methods and awareness of accepted test methods by Federal agencies and other stakeholders.

(4) Submit ICCVAM test recommendations for the test method reviewed by the ICCVAM, through expeditious transmittal by the Secretary of Health and Human Services (or the designee of the Secretary), to each appropriate

Federal agency, along with the identification of specific agency guidelines, recommendations, or regulations for a test method, including batteries of tests and test screens, for chemicals or class of chemicals within a regulatory framework that may be appropriate for scientific improvement, while seeking to reduce, refine, or replace animal test methods.

(5) Consider for review and evaluation, petitions received from the public that—

(A) identify a specific regulation, recommendation, or guideline regarding a regulatory mandate; and

(B) recommend new or revised or alternative test methods and provide valid scientific evidence of the potential of the test method.

(6) Make available to the public final ICCVAM test recommendations to appropriate Federal agencies and the responses from the agencies regarding such recommendations.

(7) Prepare reports to be made available to the public on its progress under sections 2851-2 to 2851-5 of this title. The first report shall be completed not later than 12 months after December 19, 2000, and subsequent reports shall be completed biennially thereafter.

(Pub. L. 106-545, § 3, Dec. 19, 2000, 114 Stat. 2721.)

#### REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (d)(1), is Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, as amended, which is set out in the Appendix to Title 5, Government Organization and Employees.

#### CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

#### TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

## § 2851-4. Federal agency action

### (a) Identification of tests

With respect to each Federal agency carrying out a program that requires or recommends acute or chronic toxicological testing, such agency shall, not later than 180 days after receiving an ICCVAM test recommendation, identify and forward to the ICCVAM any relevant test method specified in a regulation or industry-wide guideline which specifically, or in practice requires, recommends, or encourages the use of an animal acute or chronic toxicological test method for which the ICCVAM test recommendation may be added or substituted.

**(b) Alternatives**

Each Federal agency carrying out a program described in subsection (a) shall promote and encourage the development and use of alternatives to animal test methods (including batteries of tests and test screens), where appropriate, for the purpose of complying with Federal statutes, regulations, guidelines, or recommendations (in each instance, and for each chemical class) if such test methods are found to be effective for generating data, in an amount and of a scientific value that is at least equivalent to the data generated from existing tests, for hazard identification, dose-response assessment, or risk assessment purposes.

**(c) Test method validation**

Each Federal agency carrying out a program described in subsection (a) shall ensure that any new or revised acute or chronic toxicity test method, including animal test methods and alternatives, is determined to be valid for its proposed use prior to requiring, recommending, or encouraging the application of such test method.

**(d) Review**

Not later than 180 days after receipt of an ICCVAM test recommendation, a Federal agency carrying out a program described in subsection (a) shall review such recommendation and notify the ICCVAM in writing of its findings.

**(e) Recommendation adoption**

Each Federal agency carrying out a program described in subsection (a), or its specific regulatory unit or units, shall adopt the ICCVAM test recommendation unless such Federal agency determines that—

- (1) the ICCVAM test recommendation is not adequate in terms of biological relevance for the regulatory goal authorized by that agency, or mandated by Congress;
- (2) the ICCVAM test recommendation does not generate data, in an amount and of a scientific value that is at least equivalent to the data generated prior to such recommendation, for the appropriate hazard identification, dose-response assessment, or risk assessment purposes as the current test method recommended or required by that agency;
- (3) the agency does not employ, recommend, or require testing for that class of chemical or for the recommended test endpoint; or
- (4) the ICCVAM test recommendation is unacceptable for satisfactorily fulfilling the test needs for that particular agency and its respective congressional mandate.

(Pub. L. 106-545, § 4, Dec. 19, 2000, 114 Stat. 2723.)

## CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

**§ 285l-5. Application****(a) Application**

Sections 285l-2 to 285l-5 of this title shall not apply to research, including research performed using biotechnology techniques, or research related to the causes, diagnosis, treatment, con-

trol, or prevention of physical or mental diseases or impairments of humans or animals.

**(b) Use of test methods**

Nothing in sections 285l-2 to 285l-5 of this title shall prevent a Federal agency from retaining final authority for incorporating the test methods recommended by the ICCVAM in the manner determined to be appropriate by such Federal agency or regulatory body.

**(c) Limitation**

Nothing in sections 285l-2 to 285l-5 of this title shall be construed to require a manufacturer that is currently not required to perform animal testing to perform such tests. Nothing in sections 285l-2 to 285l-5 of this title shall be construed to require a manufacturer to perform redundant endpoint specific testing.

**(d) Submission of tests and data**

Nothing in sections 285l-2 to 285l-5 of this title precludes a party from submitting a test method or scientific data directly to a Federal agency for use in a regulatory program.

(Pub. L. 106-545, § 5, Dec. 19, 2000, 114 Stat. 2724.)

## CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

**§ 285l-6. Methods of controlling certain insect and vermin populations**

The Director of the Institute shall conduct or support research to identify or develop methods of controlling insect and vermin populations that transmit to humans diseases that have significant adverse health consequences.

(July 1, 1944, ch. 373, title IV, §463B, as added Pub. L. 108-75, § 3, Aug. 15, 2003, 117 Stat. 902.)

SUBPART 13—NATIONAL INSTITUTE ON DEAFNESS  
AND OTHER COMMUNICATION DISORDERS**§ 285m. Purpose of Institute**

The general purpose of the National Institute on Deafness and Other Communication Disorders (hereafter referred to in this subpart as the "Institute") is the conduct and support of research and training, the dissemination of health information, and other programs with respect to disorders of hearing and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell.

(July 1, 1944, ch. 373, title IV, §464, as added Pub. L. 100-553, §2(4), Oct. 28, 1988, 102 Stat. 2769, and Pub. L. 100-607, title I, §101(4), Nov. 4, 1988, 102 Stat. 3049; amended Pub. L. 100-690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238.)

## CODIFICATION

Pub. L. 100-553 and Pub. L. 100-607 contained identical provisions enacting this section. See 1988 Amendment note below.

## AMENDMENTS

1988—Pub. L. 100-690 amended this section to read as if the amendments made by Pub. L. 100-607, which enacted this section, had not been enacted. See Codification note above.

## SHORT TITLE OF 1988 AMENDMENT

For short title of Pub. L. 100-553 which enacted this subpart and amended sections 281 and 285j of this title as the "National Deafness and Other Communication Disorders Act of 1988", see section 1 of Pub. L. 100-553, set out as a note under section 201 of this title.

## EFFECT OF ENACTMENT OF SIMILAR PROVISIONS

Pub. L. 100-690, title II, §2613(b), Nov. 18, 1988, 102 Stat. 4238, provided that:

"(1) Paragraphs (2) and (3) shall take effect immediately after the enactment of both the bill, S. 1727, of the One Hundredth Congress [Pub. L. 100-553, approved Oct. 28, 1988], and the Health Omnibus Programs Extension of 1988 [Pub. L. 100-607, approved Nov. 4, 1988].

"(2)(A) The provisions of the Public Health Service Act referred to in subparagraph (B), as similarly amended by the enactment of the bill, S. 1727, of the One Hundredth Congress, by subtitle A of title I of the Health Omnibus Programs Extension of 1988, and by subsection (a)(1) of this section, are amended to read as if the amendments made by such subtitle A and such subsection (a)(1) had not been enacted.

"(B) The provisions of the Public Health Service Act referred to in subparagraph (A) are—

"(A) sections 401(b)(1) and 457 [42 U.S.C. 281(b)(1), 285j];

"(B) part C of title IV [42 U.S.C. 285 et seq.]; and

"(C) the heading for subpart 10 of such part C [42 U.S.C. prec. 285j].

"(3) Subsection (a)(2) of this section [formerly set out below] is repealed."

## TRANSITIONAL AND SAVINGS PROVISIONS

Pub. L. 100-553, §3, Oct. 28, 1988, 102 Stat. 2774, provided that:

"(a) TRANSFER OF PERSONNEL, ASSETS, AND LIABILITIES.—Personnel employed by the National Institutes of Health in connection with the functions vested under section 2 [enacting this subpart and amending sections 281 and 285j of this title] in the Director of the National Institute on Deafness and Other Communication Disorders, and assets, property, contracts, liabilities, records, unexpended balances of appropriations, authorizations, allocations, and other funds of the National Institutes of Health, arising from or employed, held, used, available to, or to be made available, in connection with such functions shall be transferred to the Director for appropriate allocation. Unexpended funds transferred under this subsection shall be used only for the purposes for which the funds were originally authorized and appropriated.

"(b) SAVINGS PROVISIONS.—With respect to functions vested under section 1 [probably means section 2, enacting this subpart and amending sections 281 and 285j of this title] in the Director of the National Institute on Deafness and Other Communication Disorders, all orders, rules, regulations, grants, contracts, certificates, licenses, privileges, and other determinations, actions, or official documents, that have been issued, made, granted, or allowed to become effective, and that are effective on the date of the enactment of this Act [Oct. 28, 1988], shall continue in effect according to their terms unless changed pursuant to law."

Pub. L. 100-690, title II, §2613(a)(2), Nov. 18, 1988, 102 Stat. 4238, which enacted provisions that were substantially identical to the transitional and savings provisions above, was repealed by section 2613(b)(3) of Pub. L. 100-690.

### § 285m-1. National Deafness and Other Communication Disorders Program

(a) The Director of the Institute, with the advice of the Institute's advisory council, shall establish a National Deafness and Other Communication Disorders Program (hereafter in this section referred to as the "Program"). The Di-

rector or<sup>1</sup> the Institute shall, with respect to the Program, prepare and transmit to the Director of NIH a plan to initiate, expand, intensify and coordinate activities of the Institute respecting disorders of hearing (including tinnitus) and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Director of NIH.

(b) Activities under the Program shall include—

(1) investigation into the etiology, pathology, detection, treatment, and prevention of all forms of disorders of hearing and other communication processes, primarily through the support of basic research in such areas as anatomy, audiology, biochemistry, bioengineering, epidemiology, genetics, immunology, microbiology, molecular biology, the neurosciences, otolaryngology, psychology, pharmacology, physiology, speech and language pathology, and any other scientific disciplines that can contribute important knowledge to the understanding and elimination of disorders of hearing and other communication processes;

(2) research into the evaluation of techniques (including surgical, medical, and behavioral approaches) and devices (including hearing aids, implanted auditory and nonauditory prosthetic devices and other communication aids) used in diagnosis, treatment, rehabilitation, and prevention of disorders of hearing and other communication processes;

(3) research into prevention, and early detection and diagnosis, of hearing loss and speech and language disturbances (including stuttering) and research into preventing the effects of such disorders on learning and learning disabilities with extension of programs for appropriate referral and rehabilitation;

(4) research into the detection, treatment, and prevention of disorders of hearing and other communication processes in the growing elderly population with extension of rehabilitative programs to ensure continued effective communication skills in such population;

(5) research to expand knowledge of the effects of environmental agents that influence hearing or other communication processes; and

(6) developing and facilitating intramural programs on clinical and fundamental aspects of disorders of hearing and all other communication processes.

(July 1, 1944, ch. 373, title IV, §464A, as added Pub. L. 100-553, §2(4), Oct. 28, 1988, 102 Stat. 2769, and Pub. L. 100-607, title I, §101(4), Nov. 4, 1988, 102 Stat. 3049; amended Pub. L. 100-690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238.)

## CODIFICATION

Pub. L. 100-553 and Pub. L. 100-607 contained identical provisions enacting this section. See 1988 Amendment note below.

<sup>1</sup> So in original. Probably should be "of".

## AMENDMENTS

1988—Pub. L. 100-690 amended this section to read as if the amendments made by Pub. L. 100-607, which enacted this section, had not been enacted. See Codification note above.

## EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by Pub. L. 100-690, see section 2613(b)(1) of Pub. L. 100-690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

**§ 285m-2. Data System and Information Clearinghouse**

(a) The Director of the Institute shall establish a National Deafness and Other Communication Disorders Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with disorders of hearing or other communication processes, including where possible, data involving general populations for the purpose of identifying individuals at risk of developing such disorders.

(b) The Director of the Institute shall establish a National Deafness and Other Communication Disorders Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of disorders of hearing and other communication processes by health professionals, patients, industry, and the public.

(July 1, 1944, ch. 373, title IV, § 464B, as added Pub. L. 100-553, § 2(4), Oct. 28, 1988, 102 Stat. 2770, and Pub. L. 100-607, title I, § 101(4), Nov. 4, 1988, 102 Stat. 3050; amended Pub. L. 100-690, title II, § 2613(b)(2), Nov. 18, 1988, 102 Stat. 4238.)

## CODIFICATION

Pub. L. 100-553 and Pub. L. 100-607 contained identical provisions enacting this section. See 1988 Amendment note below.

## AMENDMENTS

1988—Pub. L. 100-690 amended this section to read as if the amendments made by Pub. L. 100-607, which enacted this section, had not been enacted. See Codification note above.

## EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by Pub. L. 100-690, see section 2613(b)(1) of Pub. L. 100-690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

**§ 285m-3. Multipurpose deafness and other communication disorders center****(a) Development, modernization and operation; “modernization” defined**

The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including care required for research) of new and existing centers for studies of disorders of hearing and other communication processes. For purposes of this section, the term “modernization” means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

**(b) Use of facilities; qualifications**

Each center assisted under this section shall—

- (1) use the facilities of a single institution or a consortium of cooperating institutions; and
- (2) meet such qualifications as may be prescribed by the Secretary.

**(c) Requisite programs**

Each center assisted under this section shall, at least, conduct—

- (1) basic and clinical research into the cause<sup>1</sup> diagnosis, early detection, prevention, control and treatment of disorders of hearing and other communication processes and complications resulting from such disorders, including research into rehabilitative aids, implantable biomaterials, auditory speech processors, speech production devices, and other otolaryngologic procedures;
- (2) training programs for physicians, scientists, and other health and allied health professionals;
- (3) information and continuing education programs for physicians and other health and allied health professionals who will provide care for patients with disorders of hearing or other communication processes; and
- (4) programs for the dissemination to the general public of information—

(A) on the importance of early detection of disorders of hearing and other communication processes, of seeking prompt treatment, rehabilitation, and of following an appropriate regimen; and

(B) on the importance of avoiding exposure to noise and other environmental toxic agents that may affect disorders of hearing or other communication processes.

**(d) Stipends**

A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in subsection (c)(2).

**(e) Discretionary programs**

Each center assisted under this section may conduct programs—

- (1) to establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals at risk of developing disorders of hearing or other communication processes; and
- (2) to disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping.

**(f) Equitable geographical distribution; needs of elderly and children**

The Director of the Institute shall, to the extent practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of the elderly, and of children (particularly with respect to their education and training), affected by disorders of hearing or other communication processes.

<sup>1</sup> So in original. Probably should be followed by a comma.

**(g) Period of support; recommended extensions of peer review group**

Support of a center under this section may be for a period not to exceed seven years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director, with the advice of the Institute's advisory council, if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, § 464C, as added Pub. L. 100-553, § 2(4), Oct. 28, 1988, 102 Stat. 2771, and Pub. L. 100-607, title I, § 101(4), Nov. 4, 1988, 102 Stat. 3050; amended Pub. L. 100-690, title II, § 2613(b)(2), Nov. 18, 1988, 102 Stat. 4238.)

CODIFICATION

Pub. L. 100-553 and Pub. L. 100-607 contained identical provisions enacting this section. See 1988 Amendment note below.

AMENDMENTS

1988—Pub. L. 100-690 amended this section to read as if the amendments made by Pub. L. 100-607, which enacted this section, had not been enacted. See Codification note above.

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by Pub. L. 100-690, see section 2613(b)(1) of Pub. L. 100-690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

**§ 285m-4. National Institute on Deafness and Other Communication Disorders Advisory Board**

**(a) Establishment**

The Secretary shall establish in the Institute the National Deafness and Other Communication Disorders Advisory Board (hereafter in this section referred to as the "Advisory Board").

**(b) Composition; qualifications; appointed and ex officio members**

The Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health and rehabilitation professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to deafness and other communication disorders, including not less than two persons with a communication disorder; and

(B) six members from the general public who are knowledgeable with respect to such disorders, including not less than one person with a communication disorder and not less than one person who is a parent of an individual with such a disorder.

Of the appointed members, not less than five shall by virtue of training or experience be knowledgeable in diagnoses and rehabilitation of communication disorders, education of the hearing, speech, or language impaired, public

health, public information, community program development, occupational hazards or communications senses, or the aging process.

(2) The following shall be ex officio members of each Advisory Board:

(A) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute on Deafness and Other Communication Disorders, the Director of the Centers for Disease Control and Prevention, the Under Secretary for Health of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers).

(B) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

**(c) Compensation**

Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

**(d) Term of office; vacancies**

The term of office of an appointed member of the Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

**(e) Chairman**

The members of the Advisory Board shall select a chairman from among the appointed members.

**(f) Personnel; executive director; professional and clerical staff members; consultants; information and administrative support services and facilities**

The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

**(g) Meetings**

The Advisory Board shall meet at the call of the chairman or upon request of the Director of

the Institute, but not less often than four times a year.

**(h) Functions**

The Advisory Board shall—

(1) review and evaluate the implementation of the plan prepared under section 285m-1(a) of this title and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting deafness and other communication disorders, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan and with key non-Federal entities involved in activities affecting the control of such disorders.

**(i) Subcommittee activities; workshops and conferences; collection of data**

In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

**(j) Repealed. Pub. L. 109-482, title I, § 104(b)(1)(J), Jan. 15, 2007, 120 Stat. 3693**

**(k) Commencement of existence**

The National Deafness and Other Communication Disorders Advisory Board shall be established not later than April 1, 1989.

(July 1, 1944, ch. 373, title IV, § 464D, as added Pub. L. 100-553, § 2(4), Oct. 28, 1988, 102 Stat. 2772, and Pub. L. 100-690, title II, § 2613(a)(1), Nov. 18, 1988, 102 Stat. 4235; amended Pub. L. 100-690, title II, § 2613(b)(2), Nov. 18, 1988, 102 Stat. 4238; Pub. L. 101-93, § 5(b), Aug. 16, 1989, 103 Stat. 611; Pub. L. 102-405, title III, § 302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 102-531, title III, § 312(d)(8), Oct. 27, 1992, 106 Stat. 3504; Pub. L. 103-43, title XX, § 2008(b)(8), June 10, 1993, 107 Stat. 211; Pub. L. 109-482, title I, § 104(b)(1)(J), Jan. 15, 2007, 120 Stat. 3693.)

CODIFICATION

Pub. L. 100-553 and section 2613(a)(1) of Pub. L. 100-690 contained identical provisions enacting this section. See 1988 Amendment note below.

AMENDMENTS

2007—Subsec. (j). Pub. L. 109-482 struck out subsec. (j) which read as follows: “The Advisory Board shall prepare an annual report for the Secretary which—

“(1) describes the Advisory Board’s activities in the fiscal year for which the report is made;

“(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the deafness and other communication disorders;

“(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such disorders in such fiscal year; and

“(4) contains the Advisory Board’s recommendations (if any) for changes in the plan prepared under section 285m-1(a) of this title.”

1993—Subsec. (b)(2)(A). Pub. L. 103-43 substituted “Department of Veterans Affairs” for “Veterans’ Administration”.

1992—Subsec. (b)(2)(A). Pub. L. 102-531 substituted “Centers for Disease Control and Prevention” for “Centers for Disease Control”.

Pub. L. 102-405 substituted “Under Secretary for Health” for “Chief Medical Director”.

1989—Subsec. (k). Pub. L. 101-93 substituted “April 1, 1989” for “90 days after the date of the enactment of the National Institute on Deafness and Other Communication Disorders Act”.

1988—Pub. L. 100-690, § 2613(b)(2), amended this section to read as if the amendments made by Pub. L. 100-690, § 2613(a)(1), which enacted this section, had not been enacted. See Codification note above.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by section 2613(b)(2) of Pub. L. 100-690, see section 2613(b)(1) of Pub. L. 100-690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

TERMINATION OF ADVISORY BOARDS

Advisory boards established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a board established by the President or an officer of the Federal Government, such board is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a board established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

**§ 285m-5. Interagency Coordinating Committee**

**(a) Establishment**

The Secretary may establish a committee to be known as the Deafness and Other Communication Disorders Interagency Coordinating Committee (hereafter in this section referred to as the “Coordinating Committee”).

**(b) Functions**

The Coordinating Committee shall, with respect to deafness and other communication disorders—

(1) provide for the coordination of the activities of the national research institutes; and

(2) coordinate the aspects of all Federal health programs and activities relating to

deafness and other communication disorders in order to assure the adequacy and technical soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities.

**(c) Composition**

The Coordinating Committee shall be composed of the directors of each of the national research institutes and divisions involved in research with respect to deafness and other communication disorders and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to deafness and other communication disorders.

**(d) Chairman; meetings**

The Coordinating Committee shall be chaired by the Director of NIH (or the designee of the Director). The Committee shall meet at the call of the chair, but not less often than four times a year.

(July 1, 1944, ch. 373, title IV, §464E, as added Pub. L. 100-553, §2(4), Oct. 28, 1988, 102 Stat. 2774, and Pub. L. 100-690, title II, §2613(a)(1), Nov. 18, 1988, 102 Stat. 4237; amended Pub. L. 100-690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238; Pub. L. 103-43, title XX, §2008(b)(9), June 10, 1993, 107 Stat. 211; Pub. L. 109-482, title I, §104(b)(1)(K), Jan. 15, 2007, 120 Stat. 3693.)

CODIFICATION

Pub. L. 100-553 and section 2613(a)(1) of Pub. L. 100-690 contained identical provisions enacting this section. See 1988 Amendment note below.

AMENDMENTS

2007—Subsec. (e). Pub. L. 109-482 struck out subsec. (e) which read as follows: “Not later than 120 days after the end of each fiscal year, the Coordinating Committee shall prepare and transmit to the Secretary, the Director of NIH, the Director of the Institute, and the advisory council for the Institute a report detailing the activities of the Committee in such fiscal year in carrying out subsection (b) of this section.”

1993—Subsecs. (d), (e). Pub. L. 103-43 inserted “Coordinating” before “Committee” in first sentence of subsec. (d) and before first reference to “Committee” in subsec. (e).

1988—Pub. L. 100-690, §2613(b)(2), amended this section to read as if the amendments made by Pub. L. 100-690, §2613(a)(1), which enacted this section, had not been enacted. See Codification note above.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by section 2613(b)(2) of Pub. L. 100-690, see section 2613(b)(1) of Pub. L. 100-690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

**§ 285m-6. Limitation on administrative expenses**

With respect to amounts appropriated for a fiscal year for the National Institutes of Health, the limitation established in section 284c(a)(1) of this title on the expenditure of such amounts for

administrative expenses shall apply to administrative expenses of the National Institute on Deafness and Other Communication Disorders.

(July 1, 1944, ch. 373, title IV, §464F, as added Pub. L. 100-553, §2(4), Oct. 28, 1988, 102 Stat. 2774, and Pub. L. 100-690, title II, §2613(a)(1), Nov. 18, 1988, 102 Stat. 4238; amended Pub. L. 100-690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238; Pub. L. 103-43, title IV, §403(b)(2), June 10, 1993, 107 Stat. 158.)

CODIFICATION

Pub. L. 100-553 and section 2613(a)(1) of Pub. L. 100-690 contained identical provisions enacting this section. See 1988 Amendment note below.

AMENDMENTS

1993—Pub. L. 103-43 substituted “section 284c(a)(1)” for “section 284c(b)(1)”.

1988—Pub. L. 100-690, §2613(b)(2), amended this section to read as if the amendments made by Pub. L. 100-690, §2613(a)(1), which enacted this section, had not been enacted. See Codification note above.

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by section 2613(b)(2) of Pub. L. 100-690, see section 2613(b)(1) of Pub. L. 100-690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

SUBPART 14—NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

**§ 285n. Purpose of Institute**

**(a) In general**

The general purpose of the National Institute on Alcohol Abuse and Alcoholism (hereafter in this subpart referred to as the “Institute”) is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of alcohol abuse and the treatment of alcoholism.

**(b) Research program**

The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of alcohol abuse and alcoholism. In carrying out the program, the Director of the Institute is authorized to—

(1) collect and disseminate through publications and other appropriate means (including the development of curriculum materials), information as to, and the practical application of, the research and other activities under the program;

(2) make available research facilities of the Public Health Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants to universities, hospitals, laboratories, and other public or nonprofit institutions, and to individuals for such research projects as are recommended by the National Advisory Council on Alcohol Abuse and Alcoholism, giving special consideration to projects relating to—

(A) the relationship between alcohol abuse and domestic violence,

(B) the effects of alcohol use during pregnancy,

(C) the impact of alcoholism and alcohol abuse on the family, the workplace, and systems for the delivery of health services,

(D) the relationship between the abuse of alcohol and other drugs,

(E) the effect on the incidence of alcohol abuse and alcoholism of social pressures, legal requirements respecting the use of alcoholic beverages, the cost of such beverages, and the economic status and education of users of such beverages,

(F) the interrelationship between alcohol use and other health problems,

(G) the comparison of the cost and effectiveness of various treatment methods for alcoholism and alcohol abuse and the effectiveness of prevention and intervention programs for alcoholism and alcohol abuse,

(H) alcoholism and alcohol abuse among women;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) promote the coordination of research programs conducted by the Institute, and similar programs conducted by the National Institute of Drug Abuse and by other departments, agencies, organizations, and individuals, including all National Institutes of Health research activities which are or may be related to the problems of individuals suffering from alcoholism or alcohol abuse or those of their families or the impact of alcohol abuse on other health problems;

(6) conduct an intramural program of biomedical, behavioral, epidemiological, and social research, including research into the most effective means of treatment and service delivery, and including research involving human subjects, which is—

(A) located in an institution capable of providing all necessary medical care for such human subjects, including complete 24-hour medical diagnostic services by or under the supervision of physicians, acute and intensive medical care, including 24-hour emergency care, psychiatric care, and such other care as is determined to be necessary for individuals suffering from alcoholism and alcohol abuse; and

(B) associated with an accredited medical or research training institution;

(7) for purposes of study, admit and treat at institutions, hospitals, and stations of the Public Health Service, persons not otherwise eligible for such treatment;

(8) provide to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical and other scientific research methods to experiments, studies, and surveys in health and medical fields;

(9) enter into contracts under this subchapter without regard to section 3324(a) and (b) of title 31 and section 6101 of title 41; and

(10) adopt, upon recommendation of the National Advisory Council on Alcohol Abuse and Alcoholism, such additional means as he

deems necessary or appropriate to carry out the purposes of this section.

#### (c) Collaboration

The Director of the Institute shall collaborate with the Administrator of the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

(July 1, 1944, ch. 373, title IV, §464H, as added and amended Pub. L. 102-321, title I, §122(a), (b), July 10, 1992, 106 Stat. 358, 359; Pub. L. 102-352, §2(a)(1), Aug. 26, 1992, 106 Stat. 938; Pub. L. 109-482, title I, §103(b)(32), Jan. 15, 2007, 120 Stat. 3688.)

#### CODIFICATION

Section 290bb(b) of this title, which was transferred to subsec. (b) of this section and amended by Pub. L. 102-321, was based on act July 1, 1944, ch. 373, title V, §510, formerly Pub. L. 91-616, title V, §501(b), as added Pub. L. 94-371, §7, July 26, 1976, 90 Stat. 1038; amended Pub. L. 95-622, title II, §268(d), Nov. 9, 1978, 92 Stat. 3437; Pub. L. 96-180, §14(b), Jan. 2, 1980, 93 Stat. 1305; renumbered §510(b) of act July 1, 1944, and amended Apr. 26, 1983, Pub. L. 98-24, §2(b)(9), 97 Stat. 179; Oct. 19, 1984, Pub. L. 98-509, title II, §205(a)(1), 98 Stat. 2361.

In subsec. (b)(9), “section 3324(a) and (b) of title 31 and section 6101 of title 41” substituted for “sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5)” on authority of Pub. L. 97-258, §4(b), Sept. 13, 1982, 96 Stat. 1067, which Act enacted Title 31, Money and Finance, and Pub. L. 111-350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

#### AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482 struck out subsec. (d) which related to authorization of appropriations and allocation for health services research.

1992—Subsec. (a). Pub. L. 102-352 substituted “Institute on Alcohol” for “Institute of Alcohol”.

Subsec. (b). Pub. L. 102-321, §122(b)(1), (2)(A), transferred subsec. (b) of section 290bb of this title to subsec. (b) of this section, substituted “(b) RESEARCH PROGRAM.—The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of alcohol abuse and alcoholism. In carrying out the program, the Director of the Institute is authorized” for “(b) In carrying out the program described in subsection (a) of this section, the Secretary, acting through the Institute, is authorized” in introductory provisions, and substituted a semicolon for period at end of par. (3)(H).

Subsecs. (c), (d). Pub. L. 102-321, §122(b)(2)(B), added subsecs. (c) and (d).

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### EFFECTIVE DATE OF 1992 AMENDMENT

Pub. L. 102-352, §3, Aug. 26, 1992, 106 Stat. 940, provided that: “The amendments made by—

“(1) subsection (a) of section 2 [amending this section and sections 285n-2, 285o, 285o-2, 285p, 290aa-1, 290aa-3, 300x-7, 300x-27, 300x-33, 300x-53, and 300y of this title], shall take effect immediately upon the effectuation of the amendments made by titles I and II of the ADAMHA Reorganization Act [Pub. L. 102-321, see Effective Date of 1992 Amendment note set out under section 236 of this title]; and

“(2) subsections (b) and (c) of section 2 [amending sections 290cc-21, 290cc-28, and 290cc-30 of this title and provisions set out as notes under sections 290aa and 300x of this title], shall take effect on the date of enactment of this Act [Aug. 26, 1992].”

#### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

#### REQUIRED ALLOCATIONS FOR HEALTH SERVICES RESEARCH

Pub. L. 103-43, title XX, §2016(b), June 10, 1993, 107 Stat. 218, provided that, with respect to the allocation for health services research required in former subsec. (d)(2) of this section and former sections 285o(d)(2) and 285p(f)(2) of this title, the term “15 percent” appearing in each of such provisions was deemed to be 12 percent in the case of allocations for fiscal year 1993.

#### STUDY ON FETAL ALCOHOL EFFECT AND FETAL ALCOHOL SYNDROME

Pub. L. 102-321, title VII, §705, July 10, 1992, 106 Stat. 438, directed Secretary of Health and Human Services to enter into a contract with a public or nonprofit private entity to conduct a study on the prevalence of fetal alcohol effect and fetal alcohol syndrome in the general population of the United States and on the adequacy of Federal efforts to reduce the incidence of such conditions (including efforts regarding appropriate training for health care providers in identifying such effect or syndrome), and to ensure that a report outlining this study be submitted to Congress not later than 18 months after July 10, 1992.

#### ALCOHOLISM AND ALCOHOL ABUSE TREATMENT STUDY

Pub. L. 99-570, title IV, §4022, Oct. 27, 1986, 100 Stat. 3207-124, directed Secretary of Health and Human Services, acting through Director of National Institute on Alcohol Abuse and Alcoholism, to conduct a study of alternative approaches for alcoholism and alcohol abuse treatment and rehabilitation and of financing alternatives including policies and experiences of third party insurers and State and municipal governments; to recommend policies and programs for research, planning, administration, and reimbursement for treatment and rehabilitation; to request National Academy of Sciences to conduct such study in consultation with Director of National Institute on Alcohol Abuse and Alcoholism under an arrangement entered into with consent of Academy that actual expenses of Academy will be paid by Secretary and that Academy would submit a final report to Secretary no later than 24 months after the arrangement was entered into; and to transmit a final report to Congress no later than 30 days after receiving Academy's report.

### § 285n-1. Associate Director for Prevention

#### (a) In general

There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of alcohol abuse and alcoholism. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in alcohol abuse and alcoholism or the prevention of such.

#### (b) Biennial report

The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b<sup>1</sup> of this title a description of

the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

(July 1, 1944, ch. 373, title IV, §464I, as added Pub. L. 102-321, title I, §122(c), July 10, 1992, 106 Stat. 359.)

#### REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (b), was repealed by Pub. L. 109-482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

#### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

### § 285n-2. National Alcohol Research Centers; mandatory grant for research of effects of alcohol on elderly

#### (a) Designation; procedures applicable for approval of applications

The Secretary acting through the Institute may designate National Alcohol Research Centers for the purpose of interdisciplinary research relating to alcoholism and other biomedical, behavioral, and social issues related to alcoholism and alcohol abuse. No entity may be designated as a Center unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reasonably require. The Secretary may not approve such an application unless—

(1) the application contains or is supported by reasonable assurances that—

(A) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on alcoholism and other alcohol problems and to provide coordination of such research among such disciplines;

(B) the applicant has available to it sufficient facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application;

(C) the applicant has facilities and personnel to provide training in the prevention and treatment of alcoholism and other alcohol problems;

(D) the applicant has the capacity to train predoctoral and postdoctoral students for careers in research on alcoholism and other alcohol problems;

(E) the applicant has the capacity to conduct courses on alcohol problems and research on alcohol problems for undergraduate and graduate students, and for medical and osteopathic, nursing, social work, and other specialized graduate students; and

(F) the applicant has the capacity to conduct programs of continuing education in such medical, legal, and social service fields as the Secretary may require.<sup>1</sup>

<sup>1</sup> See References in Text note below.

<sup>1</sup> So in original. The period probably should be “; and”.

(2) the application contains a detailed five-year plan for research relating to alcoholism and other alcohol problems.

**(b) Annual grants; amount; limitation on uses**

The Secretary shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term "construction" has the meaning given that term by section 292a(1)<sup>2</sup> of this title. The Secretary shall include in the grants made under this section for fiscal years beginning after September 30, 1981, a grant to a designated Center for research on the effects of alcohol on the elderly.

(July 1, 1944, ch. 373, title IV, §464J, formerly title V, §511, formerly Pub. L. 91-616, title V, §503, formerly §504, as added Pub. L. 94-371, §7, July 26, 1976, 90 Stat. 1039; amended Pub. L. 95-622, title I, §110(d), Nov. 9, 1978, 92 Stat. 3420; Pub. L. 96-180, §16, Jan. 2, 1980, 93 Stat. 1305; renumbered §503 of Pub. L. 91-616 and amended Pub. L. 97-35, title IX, §965(b), (c), Aug. 13, 1981, 95 Stat. 594; renumbered §511 of act July 1, 1944, and amended Pub. L. 98-24, §2(b)(9), Apr. 26, 1983, 97 Stat. 179; Pub. L. 99-570, title IV, §4008, Oct. 27, 1986, 100 Stat. 3207-115; renumbered title IV, §464J and amended Pub. L. 102-321, title I, §122(d), July 10, 1992, 106 Stat. 360; Pub. L. 102-352, §2(a)(2), Aug. 26, 1992, 106 Stat. 938.)

REFERENCES IN TEXT

Section 292a of this title, referred to in subsec. (b), was in the original a reference to section 701 of act July 1, 1944. Section 701 of that Act was omitted in the general revision of subchapter V of this chapter by Pub. L. 102-408, title I, §102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102-408 enacted a new section 701 of act July 1, 1944, relating to statement of purpose, and a new section 702, relating to scope and duration of loan insurance program, which are classified to sections 292 and 292a, respectively, of this title. For provisions relating to definitions, see sections 292o and 295p of this title.

CODIFICATION

Section was formerly classified to section 290bb-1 of this title prior to renumbering by Pub. L. 102-321.

Section was formerly classified to section 4587 of this title prior to renumbering by Pub. L. 98-24.

Section was formerly classified to section 4588 of this title prior to renumbering by Pub. L. 97-35.

AMENDMENTS

1992—Subsec. (b). Pub. L. 102-352 substituted "292a(1)" for "292a(2)".

Pub. L. 102-321, §122(d)(2), struck "or rental" before "of any land".

1986—Subsec. (b). Pub. L. 99-570, §4008(1), which directed that subsec. (b) be amended by striking out "or rental" before "any land", could not be executed because "or rental" appeared before "of any land".

Pub. L. 99-570, §4008(2), struck out "rental," before "purchase".

1983—Subsec. (a). Pub. L. 98-24, §2(b)(9)(B)(i), struck out direction that, insofar as practicable, the Secretary approve applications under this subsection in a manner resulting in an equitable geographic distribution of Centers.

Subsec. (b). Pub. L. 98-24, §2(b)(9)(B)(ii), (iii), struck out provision that no annual grant to any Center might exceed \$1,500,000, and made a technical amendment to reference to section 292a of this title to reflect the transfer of this section to the Public Health Service Act.

Subsec. (c). Pub. L. 98-24, §2(b)(9)(B)(iv), struck out subsec. (c) which authorized \$6,000,000 for each of fiscal years ending Sept. 30, 1977, 1978, and 1979, \$8,000,000 for fiscal year ending Sept. 30, 1980, and \$9,000,000 for fiscal year ending Sept. 30, 1981.

1981—Subsec. (b). Pub. L. 97-35, §965(b), inserted provisions relating to grants made for fiscal years beginning after Sept. 30, 1981.

1980—Subsec. (a). Pub. L. 96-180, §16(a), substituted: in first sentence "biomedical, behavioral, and social issues related to alcoholism and alcohol abuse" for "alcohol problems"; in par. (1)(B) "facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application" for "laboratory facilities and reference services (including reference services that will afford access to scientific alcohol literature)"; and in par. (1)(E) "medical and osteopathic, nursing, social work, and other specialized graduate students; and" for "medical and osteopathic students and physicians"; and added par. (1)(F).

Subsec. (b). Pub. L. 96-180, §16(b), increased annual grant limitation to \$1,500,000 from \$1,000,000.

Subsec. (c). Pub. L. 96-180, §16(c), authorized appropriation of \$8,000,000 and \$9,000,000 for fiscal years ending Sept. 30, 1980, and 1981.

1978—Subsec. (a). Pub. L. 95-622 inserted provision following par. (2) relating to approval of applications under this subsection by the Secretary in a manner which results in equitable geographic distribution of Centers.

EFFECTIVE DATE OF 1992 AMENDMENTS

Amendment by Pub. L. 102-352 effective immediately upon effectuation of amendment made by Pub. L. 102-321, see section 3(1) of Pub. L. 102-352, set out as a note under section 285n of this title.

Amendment by Pub. L. 102-321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as a note under section 236 of this title.

SUBPART 15—NATIONAL INSTITUTE ON DRUG ABUSE

**§ 285o. Purpose of Institute**

**(a) In general**

The general purpose of the National Institute on Drug Abuse (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers.

**(b) Research program**

The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of drug abuse. In carrying out the program, the Director of the Institute shall give special consideration to projects relating to drug abuse among women (particularly with respect to pregnant women).

**(c) Collaboration**

The Director of the Institute shall collaborate with the Substance Abuse and Mental Health Services Administration in focusing the services

<sup>2</sup> See References in Text note below.

research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

(July 1, 1944, ch. 373, title IV, §464L, as added Pub. L. 102-321, title I, §123(a), July 10, 1992, 106 Stat. 360; amended Pub. L. 102-352, §2(a)(3), Aug. 26, 1992, 106 Stat. 938; Pub. L. 109-482, title I, §103(b)(33), Jan. 15, 2007, 120 Stat. 3688.)

#### AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482 struck out subsec. (d) which related to authorization of appropriations and allocation for health services research.

1992—Subsec. (d)(1). Pub. L. 102-352 inserted “other than section 2850-4 of this title,” after “this subpart.”

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102-352 effective immediately upon effectuation of amendment made by Pub. L. 102-321, see section 3(1) of Pub. L. 102-352, set out as a note under section 285n of this title.

#### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

### § 2850-1. Associate Director for Prevention

#### (a) In general

There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of drug abuse. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in drug abuse and the prevention of such abuse.

#### (b) Report

The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b<sup>1</sup> of this title a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

(July 1, 1944, ch. 373, title IV, §464M, as added Pub. L. 102-321, title I, §123(b), July 10, 1992, 106 Stat. 361.)

#### REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (b), was repealed by Pub. L. 109-482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

#### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

### § 2850-2. Drug Abuse Research Centers

#### (a) Authority

The Director of the Institute may designate National Drug Abuse Research Centers for the

purpose of interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse. No entity may be designated as a Center unless an application therefore has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reasonably require. The Secretary may not approve such an application unless—

(1) the application contains or is supported by reasonable assurances that—

(A) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on drug abuse and to provide coordination of such research among such disciplines;

(B) the applicant has available to it sufficient facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application;

(C) the applicant has facilities and personnel to provide training in the prevention and treatment of drug abuse;

(D) the applicant has the capacity to train predoctoral and postdoctoral students for careers in research on drug abuse;

(E) the applicant has the capacity to conduct courses on drug abuse problems and research on drug abuse for undergraduate and graduate students, and medical and osteopathic, nursing, social work, and other specialized graduate students; and

(F) the applicant has the capacity to conduct programs of continuing education in such medical, legal, and social service fields as the Secretary may require.<sup>1</sup>

(2) the application contains a detailed five-year plan for research relating to drug abuse.

#### (b) Grants

The Director of the Institute shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term “construction” has the meaning given that term by section 292a(1)<sup>2</sup> of this title.

#### (c) Drug abuse and addiction research

##### (1) Grants or cooperative agreements

The Director of the Institute may make grants or enter into cooperative agreements to expand the current and ongoing interdisciplinary research and clinical trials with treatment centers of the National Drug Abuse Treatment Clinical Trials Network relating to drug abuse and addiction, including related biomedical, behavioral, and social issues.

##### (2) Use of funds

Amounts made available under a grant or cooperative agreement under paragraph (1) for

<sup>1</sup> See References in Text note below.

<sup>1</sup> So in original. The period probably should be “; and”.

<sup>2</sup> See References in Text note below.

drug abuse and addiction may be used for research and clinical trials relating to—

(A) the effects of drug abuse on the human body, including the brain;

(B) the addictive nature of drugs and how such effects differ with respect to different individuals;

(C) the connection between drug abuse and mental health;

(D) the identification and evaluation of the most effective methods of prevention of drug abuse and addiction;

(E) the identification and development of the most effective methods of treatment of drug addiction, including pharmacological treatments;

(F) risk factors for drug abuse;

(G) effects of drug abuse and addiction on pregnant women and their fetuses; and

(H) cultural, social, behavioral, neurological, and psychological reasons that individuals abuse drugs, or refrain from abusing drugs.

### (3) Research results

The Director shall promptly disseminate research results under this subsection to Federal, State, and local entities involved in combating drug abuse and addiction.

(July 1, 1944, ch. 373, title IV, §464N, as added Pub. L. 102-321, title I, §123(b), July 10, 1992, 106 Stat. 361; amended Pub. L. 102-352, §2(a)(4), Aug. 26, 1992, 106 Stat. 938; Pub. L. 106-310, div. B, title XXXVI, §3631, Oct. 17, 2000, 114 Stat. 1235; Pub. L. 107-273, div. B, title II, §2203, Nov. 2, 2002, 116 Stat. 1794; Pub. L. 109-482, title I, §103(b)(34), Jan. 15, 2007, 120 Stat. 3688.)

#### REFERENCES IN TEXT

Section 292a of this title, referred to in subsec. (b), was in the original a reference to section 701 of act July 1, 1944. Section 701 of that Act was omitted in the general revision of subchapter V of this chapter by Pub. L. 102-408, title I, §102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102-408 enacted a new section 701 of act July 1, 1944, relating to statement of purpose, and a new section 702, relating to scope and duration of loan insurance program, which are classified to sections 292 and 292a, respectively, of this title. For provisions relating to definitions, see sections 292o and 295p of this title.

#### AMENDMENTS

2007—Subsec. (c)(4). Pub. L. 109-482 struck out par. (4) which authorized appropriations and provided they were supplemental to other funding of research on drug abuse.

2002—Subsec. (c). Pub. L. 107-273 amended heading and text of subsec. (c) generally, substituting provisions relating to grants or cooperative agreements for research and clinical trials relating to drug abuse and addiction for similar provisions relating to grants or cooperative agreements for research and clinical trials relating to methamphetamine abuse and addiction.

2000—Subsec. (c). Pub. L. 106-310 added subsec. (c).

1992—Subsec. (b). Pub. L. 102-352 substituted “292a(1)” for “292a(2)”.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102-352 effective immediately upon effectuation of amendment made by Pub. L.

102-321, see section 3(1) of Pub. L. 102-352, set out as a note under section 285n of this title.

#### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

### § 2850-3. Office on AIDS

The Director of the Institute shall establish within the Institute an Office on AIDS. The Office shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

(1) primary prevention of the spread of HIV, including transmission via drug abuse;

(2) drug abuse services research; and

(3) other matters determined appropriate by the Director.

(July 1, 1944, ch. 373, title IV, §464O, as added Pub. L. 102-321, title I, §123(b), July 10, 1992, 106 Stat. 362.)

#### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

#### STUDY BY NATIONAL ACADEMY OF SCIENCES

Section 706 of Pub. L. 102-321 directed Secretary of Health and Human Services to contract for a study or studies relating to programs that provide both sterile hypodermic needles and bleach to individuals in order to reduce the risk of contracting acquired immune deficiency syndrome or related conditions, in order to determine extent to which such programs promote the abuse of drugs or otherwise altered any behaviors constituting a substantial risk of contracting AIDS or hepatitis, or of transmitting such conditions, and further directed Secretary to ensure that a report is submitted to Congress on the results of this study not later than 18 months after July 10, 1992.

### § 2850-4. Medication Development Program

#### (a) Establishment

There is established in the Institute a Medication Development Program through which the Director of such Institute shall—

(1) conduct periodic meetings with the Commissioner of Food and Drugs to discuss measures that may facilitate the approval process of drug abuse treatments;

(2) encourage and promote (through grants, contracts, international collaboration, or otherwise) expanded research programs, investigations, experiments, community trials, and studies, into the development and use of medications to treat drug addiction;

(3) establish or provide for the establishment of research facilities;

(4) report on the activities of other relevant agencies relating to the development and use of pharmacotherapeutic treatments for drug addiction;

(5) collect, analyze, and disseminate data useful in the development and use of pharmacotherapeutic treatments for drug addiction and collect, catalog, analyze, and disseminate through international channels, the results of such research;

(6) directly or through grants, contracts, or cooperative agreements, support training in the fundamental sciences and clinical disciplines related to the pharmacotherapeutic treatment of drug abuse, including the use of training stipends, fellowships, and awards where appropriate; and

(7) coordinate the activities conducted under this section with related activities conducted within the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Mental Health, and other appropriate institutes and shall consult with the Directors of such Institutes.

#### (b) Duties

In carrying out the activities described in subsection (a), the Director of the Institute—

(1) shall collect and disseminate through publications and other appropriate means, information pertaining to the research and other activities under this section;

(2) shall make grants to or enter into contracts and cooperative agreements with individuals and public and private entities to further the goals of the program;

(3) may, in accordance with section 289e of this title, and in consultation with the National Advisory Council on Drug Abuse, acquire, construct, improve, repair, operate, and maintain pharmacotherapeutic research centers, laboratories, and other necessary facilities and equipment, and such other real or personal property as the Director determines necessary, and may, in consultation with such Advisory Council, make grants for the construction or renovation of facilities to carry out the purposes of this section;

(4) may accept voluntary and uncompensated services;

(5) may accept gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible; and

(6) shall take necessary action to ensure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

#### (c) Report

##### (1) In general

Not later than December 31, 1992, and each December 31 thereafter, the Director of the Institute shall submit to the Office of National Drug Control Policy established under section 1501<sup>1</sup> of title 21 a report, in accordance with paragraph (3), that describes the objectives and activities of the program assisted under this section.

##### (2) National Drug Control Strategy

The Director of National Drug Control Policy shall incorporate, by reference or otherwise, each report submitted under this subsection in the National Drug Control Strategy submitted the following February 1 under section 1504<sup>1</sup> of title 21.

#### (d) “Pharmacotherapeutics” defined

For purposes of this section, the term “pharmacotherapeutics” means medications used to treat the symptoms and disease of drug abuse, including medications to—

(1) block the effects of abused drugs;

(2) reduce the craving for abused drugs;

(3) moderate or eliminate withdrawal symptoms;

(4) block or reverse the toxic effect of abused drugs; or

(5) prevent relapse in persons who have been detoxified from drugs of abuse.

(July 1, 1944, ch. 373, title IV, §464P, as added Pub. L. 102-321, title I, §123(b), July 10, 1992, 106 Stat. 362; amended Pub. L. 103-43, title XX, §2008(b)(10), June 10, 1993, 107 Stat. 211; Pub. L. 109-482, title I, §103(b)(35), Jan. 15, 2007, 120 Stat. 3688.)

#### REFERENCES IN TEXT

Sections 1501 and 1504 of title 21, referred to in subsec. (c), were repealed by Pub. L. 100-690, title I, §1009, Nov. 18, 1988, 102 Stat. 4188, as amended.

#### AMENDMENTS

2007—Subsec. (e). Pub. L. 109-482 struck out heading and text of subsec. (e). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated \$85,000,000 for fiscal year 1993, and \$95,000,000 for fiscal year 1994.”

1993—Subsec. (b)(6). Pub. L. 103-43 substituted “Institute” for “Administration”.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

#### REPORT BY INSTITUTE ON MEDICINE

Pub. L. 102-321, title VII, §701, July 10, 1992, 106 Stat. 436, directed Secretary of Health and Human Services to enter into a contract with a public or nonprofit private entity to conduct a study concerning (1) role of the private sector in development of anti-addiction medications, including legislative proposals designed to encourage private sector development of such medications, (2) process by which anti-addiction medications receive marketing approval from Food and Drug Administration, including an assessment of feasibility of expediting marketing approval process in a manner consistent with maintaining safety and effectiveness of such medications, (3) with respect to pharmacotherapeutic treatments for drug addiction (A) recommendations with respect to a national strategy for developing such treatments and improvements in such strategy, (B) state of the scientific knowledge concerning such treatments, and (C) assessment of progress toward development of safe, effective pharmacological treatments for drug addiction, and (4) other related information determined appropriate by the authors of the study, and to submit to Congress a report of the results of such study not later than 18 months after July 10, 1992.

<sup>1</sup> See References in Text note below.

SUBPART 16—NATIONAL INSTITUTE OF MENTAL  
HEALTH

**§ 285p. Purpose of Institute**

**(a) In general**

The general purpose of the National Institute of Mental Health (hereafter in this subpart referred to as the “Institute”) is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the cause, diagnosis, treatment, control and prevention of mental illness.

**(b) Research program**

The research program established under this subpart shall include support for biomedical and behavioral neuroscience and shall be designed to further the treatment and prevention of mental illness, the promotion of mental health, and the study of the psychological, social and legal factors that influence behavior.

**(c) Collaboration**

The Director of the Institute shall collaborate with the Administrator of the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

**(d) Information with respect to suicide**

**(1) In general**

The Director of the Institute shall—

- (A) develop and publish information with respect to the causes of suicide and the means of preventing suicide; and
- (B) make such information generally available to the public and to health professionals.

**(2) Youth suicide**

Information described in paragraph (1) shall especially relate to suicide among individuals under 24 years of age.

**(e) Associate Director for Special Populations**

**(1) In general**

The Director of the Institute shall designate an Associate Director for Special Populations.

**(2) Duties**

The Associate Director for Special Populations shall—

- (A) develop and coordinate research policies and programs to assure increased emphasis on the mental health needs of women and minority populations;
- (B) support programs of basic and applied social and behavioral research on the mental health problems of women and minority populations;
- (C) study the effects of discrimination on institutions and individuals, including majority institutions and individuals;
- (D) support and develop research designed to eliminate institutional discrimination; and
- (E) provide increased emphasis on the concerns of women and minority populations in training programs, service delivery pro-

grams, and research endeavors of the Institute.

(July 1, 1944, ch. 373, title IV, §464R, as added Pub. L. 102-321, title I, §124(a), July 10, 1992, 106 Stat. 364; amended Pub. L. 102-352, §2(a)(5), Aug. 26, 1992, 106 Stat. 938; Pub. L. 109-482, title I, §103(b)(36), Jan. 15, 2007, 120 Stat. 3688.)

AMENDMENTS

2007—Subsec. (f). Pub. L. 109-482 struck out subsec. (f) which authorized appropriations and provided that at least 15% of the appropriated amounts were to carry out health services research relating to mental health.

1992—Subsec. (f)(1). Pub. L. 102-352 struck out “other than section 285o-4 of this title” after “this subpart”.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102-352 effective immediately upon effectuation of amendment made by Pub. L. 102-321, see section 3(1) of Pub. L. 102-352, set out as a note under section 285n of this title.

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

STUDY OF BARRIERS TO INSURANCE COVERAGE OF  
TREATMENT FOR MENTAL ILLNESS AND SUBSTANCE  
ABUSE

Section 704 of Pub. L. 102-321 directed Secretary of Health and Human Services, acting through Director of the National Institute of Mental Health and in consultation with Administrator of Health Care Financing Administration, to conduct a study of the barriers to insurance coverage for the treatment of mental illness and substance abuse and to submit a report to Congress on the results of such study not later than Oct. 1, 1993.

**§ 285p-1. Associate Director for Prevention**

**(a) In general**

There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of mental disorder. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in mental disorder and the prevention of such.

**(b) Report**

The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b<sup>1</sup> of this title a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

(July 1, 1944, ch. 373, title IV, §464S, as added Pub. L. 102-321, title I, §124(b), July 10, 1992, 106 Stat. 365.)

REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (b), was repealed by Pub. L. 109-482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

<sup>1</sup> See References in Text note below.

## EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

**§ 285p-2. Office of Rural Mental Health Research****(a) In general**

There is established within the Institute an office to be known as the Office of Rural Mental Health Research (hereafter in this section referred to as the "Office"). The Office shall be headed by a director, who shall be appointed by the Director of such Institute from among individuals experienced or knowledgeable in the provision of mental health services in rural areas. The Secretary shall carry out the authorities established in this section acting through the Director of the Office.

**(b) Coordination of activities**

The Director of the Office, in consultation with the Director of the Institute and with the Director of the Office of Rural Health Policy, shall—

- (1) coordinate the research activities of the Department of Health and Human Services as such activities relate to the mental health of residents of rural areas; and
- (2) coordinate the activities of the Office with similar activities of public and nonprofit private entities.

**(c) Research, demonstrations, evaluations, and dissemination**

The Director of the Office may, with respect to the mental health of adults and children residing in rural areas—

- (1) conduct research on conditions that are unique to the residents of rural areas, or more serious or prevalent in such residents;
- (2) conduct research on improving the delivery of services in such areas; and
- (3) disseminate information to appropriate public and nonprofit private entities.

**(d) Authority regarding grants and contracts**

The Director of the Office may carry out the authorities established in subsection (c) directly and through grants, cooperative agreements, or contracts with public or nonprofit private entities.

(July 1, 1944, ch. 373, title IV, §464T, as added Pub. L. 102-321, title I, §124(b), July 10, 1992, 106 Stat. 365; amended Pub. L. 109-482, title I, §104(b)(1)(L), Jan. 15, 2007, 120 Stat. 3693.)

## AMENDMENTS

2007—Subsec. (e). Pub. L. 109-482 struck out heading and text of subsec. (e). Text read as follows: "Not later than February 1, 1993, and each fiscal year thereafter, the Director shall submit to the Subcommittee on Health and the Environment of the Committee on Energy and Commerce (of the House of Representatives), and to the Committee on Labor and Human Resources (of the Senate), a report describing the activities of the Office during the preceding fiscal year, including a summary of the activities of demonstration projects and a summary of evaluations of the projects."

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or

subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

## EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

**§ 285p-3. Office on AIDS**

The Director of the Institute shall establish within the Institute an Office on AIDS. The Office shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

- (1) primary prevention of the spread of HIV, including transmission via sexual behavior;
- (2) mental health services research; and
- (3) other matters determined appropriate by the Director.

(July 1, 1944, ch. 373, title IV, §464U, as added Pub. L. 102-321, title I, §124(b), July 10, 1992, 106 Stat. 366.)

## EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

## SUBPART 17—NATIONAL INSTITUTE OF NURSING RESEARCH

**§ 285q. Purpose of Institute**

The general purpose of the National Institute of Nursing Research (in this subpart referred to as the "Institute") is the conduct and support of, and dissemination of information respecting, basic and clinical nursing research, training, and other programs in patient care research.

(July 1, 1944, ch. 373, title IV, §464V, formerly §483, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 867; renumbered §464V and amended Pub. L. 103-43, title XV, §1511(a)(1), (b)(2), June 10, 1993, 107 Stat. 178, 179.)

## CODIFICATION

Section was formerly classified to section 287c of this title prior to renumbering by Pub. L. 103-43.

## AMENDMENTS

1993—Pub. L. 103-43, §1511(a)(1) substituted "Institute" for "Center" in section catchline and "National Institute of Nursing Research (in this subpart referred to as the 'Institute')" for "National Center for Nursing Research (hereafter in this subpart referred to as the 'Center')" in text.

## STUDY ON ADEQUACY OF NUMBER OF NURSES

Section 1512 of Pub. L. 103-43 directed Secretary of Health and Human Services, acting through Director of National Institute of Nursing Research, to enter into a contract with a public or nonprofit private entity to conduct a study for purpose of determining whether and to what extent there is a need for an increase in the number of nurses in hospitals and nursing homes in order to promote the quality of patient care and reduce the incidence among nurses of work-related injuries and stress and to complete such study and submit a report to Congress not later than 18 months after June 10, 1993.

**§ 285q-1. Specific authorities**

To carry out section 285q of this title, the Director of the Institute may provide research training and instruction and establish, in the Institute and other nonprofit institutions, research traineeships and fellowships in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with and the families of individuals with acute and chronic illnesses. The Director of the Institute may provide individuals receiving such training and instruction or such traineeships or fellowships with such stipends and allowances (including amounts for travel and subsistence and dependency allowances) as the Director determines necessary. The Director may make grants to nonprofit institutions to provide such training and instruction and traineeships and fellowships.

(July 1, 1944, ch. 373, title IV, § 464W, formerly § 484, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 867; renumbered § 464W and amended Pub. L. 103-43, title XV, § 1511(a)(2), (b)(2), (4)(A), June 10, 1993, 107 Stat. 178, 179.)

**CODIFICATION**

Section was formerly classified to section 287c-1 of this title prior to renumbering by Pub. L. 103-43.

**AMENDMENTS**

1993—Pub. L. 103-43, § 1511(a)(2), (b)(4)(A), substituted “section 285q” for “section 287c” and “Institute” for “Center” wherever appearing.

**§ 285q-2. Advisory council****(a) Appointment; functions and duties; acceptance of conditional gifts; subcommittees**

(1) The Secretary shall appoint an advisory council for the Institute which shall advise, assist, consult with, and make recommendations to the Secretary and the Director of the Institute on matters related to the activities carried out by and through the Institute and the policies respecting such activities.

(2) The advisory council for the Institute may recommend to the Secretary acceptance, in accordance with section 238 of this title, of conditional gifts for study, investigations, and research and for the acquisition of grounds or construction, equipping, or maintenance of facilities for the Institute.

(3) The advisory council for the Institute—

(A)(i) may make recommendations to the Director of the Institute respecting research conducted at the Institute,

(ii) may review applications for grants and cooperative agreements for research or training and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the Institute is con-

cerned and with the approval of the Director of the Institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

**(b) Membership; ex officio members; compensation**

(1) The advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary.

(2) The ex officio members of the advisory council shall consist of—

(A) the Secretary, the Director of NIH, the Director of the Institute, the chief nursing officer of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs, the Director of the Division of Nursing of the Health Resources and Services Administration (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of the advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including public health and the behavioral or social sciences) relevant to the activities of the Institute. Of the members appointed pursuant to this subparagraph, at least seven shall be professional nurses who are recognized experts in the area of clinical practice, education, or research.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of the advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of the advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule.

**(c) Term of office; vacancy; reappointment**

The term of office of an appointed member of the advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date

of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

**(d) Chairman; selection; term of office**

The chairman of the advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the Institute to be the chairman of the advisory council. The term of office of the chairman shall be two years.

**(e) Meetings**

The advisory council shall meet at the call of the chairman or upon the request of the Director of the Institute, but at least three times each fiscal year. The location of the meetings of the advisory council is subject to the approval of the Director of the Institute.

**(f) Executive secretary; staff; orientation and training for new members**

The Director of the Institute shall designate a member of the staff of the Institute to serve as the executive secretary of the advisory council. The Director of the Institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of the Institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

**(g) Material for inclusion in biennial report; additional reports**

The advisory council may prepare, for inclusion in the triennial report made under section 283 of this title (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the Institute in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Institute. The advisory council may prepare such additional reports as it may determine appropriate.

(July 1, 1944, ch. 373, title IV, §464X, formerly §485, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 867; amended Pub. L. 101-381, title I, §102(4), Aug. 18, 1990, 104 Stat. 586; Pub. L. 102-54, §13(q)(1)(E), June 13, 1991, 105 Stat. 279; renumbered §464X and amended Pub. L. 103-43, title XV, §1511(a)(3), (b)(2), (4)(B), title XX, §§2008(b)(13), 2010(b)(5), June 10, 1993, 107 Stat. 178, 179, 211, 214; Pub. L. 114-255, div. A, title II, §2042(h)(2), Dec. 13, 2016, 130 Stat. 1073.)

CODIFICATION

Section was formerly classified to section 285c-2 of this title prior to renumbering by Pub. L. 103-43.

AMENDMENTS

2016—Subsec. (g). Pub. L. 114-255 substituted “triennial report made under section 283 of this title” for “biennial report made under section 285q-3 of this title.”

1993—Subsec. (a). Pub. L. 103-43, §1511(a)(3)(A), substituted “Institute” for “Center” wherever appearing.

Subsec. (a)(2). Pub. L. 103-43, §2010(b)(5), which directed the substitution of “section 238” for “section

300aaa” in section 287c-2(a)(2) of this title, was executed to subsec. (a)(2) of this section to reflect the probable intent of Congress and the renumbering of this section. See Codification note above.

Subsec. (b)(2)(A). Pub. L. 103-43, §2008(b)(13), which directed the substitution of “Department of Veterans Affairs” for “Veterans’ Administration” in section 287c-2(b)(2)(A) of this title could not be executed because the words “Veterans’ Administration” do not appear in subsec. (b)(2)(A) of this section subsequent to amendment by Pub. L. 102-54 and because of the renumbering of this section. See Codification note above and 1991 Amendment note below.

Pub. L. 103-43, §§1511(a)(3)(B)(i), substituted “Institute” for “Center”.

Subsec. (b)(3)(A). Pub. L. 103-43, §1511(a)(3)(B)(ii), substituted “Institute” for “Center”.

Subsecs. (d) to (f). Pub. L. 103-43, §1511(a)(3)(C), substituted “Institute” for “Center” wherever appearing.

Subsec. (g). Pub. L. 103-43, §1511(a)(3)(C), (b)(4)(B), substituted “section 285q-3” for “section 287c-3” and “Institute” for “Center” in two places.

1991—Subsec. (b)(2)(A). Pub. L. 102-54 substituted “chief nursing officer of the Department of Veterans Affairs” for “Chief Nursing Officer of the Veterans’ Administration”.

1990—Subsec. (a)(2). Pub. L. 101-381 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

**§285q-3. Repealed. Pub. L. 114-255, div. A, title II, §2042(h)(1), Dec. 13, 2016, 130 Stat. 1073**

Section, July 1, 1944, ch. 373, title IV, §464Y, formerly §486, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 869; renumbered §485A, renumbered §464Y, and amended Pub. L. 103-43, title I, §141(a)(1), title XV, §1511(a)(4), (b)(2), (4)(C), June 10, 1993, 107 Stat. 136, 179, related to biennial report of activities of the National Institute of Nursing Research.

SUBPART 18—NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

**§285r. Purpose of the Institute**

**(a) In general**

The general purpose of the National Institute of Biomedical Imaging and Bioengineering (in

this section referred to as the “Institute”) is the conduct and support of research, training, the dissemination of health information, and other programs with respect to biomedical imaging, biomedical engineering, and associated technologies and modalities with biomedical applications (in this section referred to as “biomedical imaging and bioengineering”).

**(b) National Biomedical Imaging and Bioengineering Program**

(1) The Director of the Institute, with the advice of the Institute’s advisory council, shall establish a National Biomedical Imaging and Bioengineering Program (in this section referred to as the “Program”).

(2) Activities under the Program shall include the following with respect to biomedical imaging and bioengineering:

(A) Research into the development of new techniques and devices.

(B) Related research in physics, engineering, mathematics, computer science, and other disciplines.

(C) Technology assessments and outcomes studies to evaluate the effectiveness of biologicals, materials, processes, devices, procedures, and informatics.

(D) Research in screening for diseases and disorders.

(E) The advancement of existing imaging and bioengineering modalities, including imaging, biomaterials, and informatics.

(F) The development of target-specific agents to enhance images and to identify and delineate disease.

(G) The development of advanced engineering and imaging technologies and techniques for research from the molecular and genetic to the whole organ and body levels.

(H) The development of new techniques and devices for more effective interventional procedures (such as image-guided interventions).

(3)(A) With respect to the Program, the Director of the Institute shall prepare and transmit to the Secretary and the Director of NIH a plan to initiate, expand, intensify, and coordinate activities of the Institute with respect to biomedical imaging and bioengineering. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Secretary and the Director of NIH.

(B) The plan under subparagraph (A) shall include the recommendations of the Director of the Institute with respect to the following:

(i) Where appropriate, the consolidation of programs of the National Institutes of Health for the express purpose of enhancing support of activities regarding basic biomedical imaging and bioengineering research.

(ii) The coordination of the activities of the Institute with related activities of the other agencies of the National Institutes of Health and with related activities of other Federal agencies.

**(c) Membership**

The establishment under section 284a of this title of an advisory council for the Institute is subject to the following:

(1) The number of members appointed by the Secretary shall be 12.

(2) Of such members—

(A) six members shall be scientists, engineers, physicians, and other health professionals who represent disciplines in biomedical imaging and bioengineering and who are not officers or employees of the United States; and

(B) six members shall be scientists, engineers, physicians, and other health professionals who represent other disciplines and are knowledgeable about the applications of biomedical imaging and bioengineering in medicine, and who are not officers or employees of the United States.

(3) In addition to the ex officio members specified in section 284a(b)(2) of this title, the ex officio members of the advisory council shall include the Director of the Centers for Disease Control and Prevention, the Director of the National Science Foundation, and the Director of the National Institute of Standards and Technology (or the designees of such officers).

(July 1, 1944, ch. 373, title IV, §464z, as added Pub. L. 106-580, §3(a), Dec. 29, 2000, 114 Stat. 3089; amended Pub. L. 109-482, title I, §103(b)(37), Jan. 15, 2007, 120 Stat. 3688.)

AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482 struck out subsec. (d) which related to appropriations for fiscal years 2001 to 2003.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

EFFECTIVE DATE

Pub. L. 106-580, §4, Dec. 29, 2000, 114 Stat. 3092, provided that: “This Act [enacting this subpart, amending section 281 of this title, and enacting provisions set out as notes under this section and section 201 of this title] takes effect October 1, 2000, or upon the date of the enactment of this Act [Dec. 29, 2000], whichever occurs later.”

FINDINGS

Pub. L. 106-580, §2, Dec. 29, 2000, 114 Stat. 3088, provided that: “The Congress makes the following findings:

“(1) Basic research in imaging, bioengineering, computer science, informatics, and related fields is critical to improving health care but is fundamentally different from the research in molecular biology on which the current national research institutes at the National Institutes of Health (‘NIH’) are based. To ensure the development of new techniques and technologies for the 21st century, these disciplines therefore require an identity and research home at the NIH that is independent of the existing institute structure.

“(2) Advances based on medical research promise new, more effective treatments for a wide variety of diseases, but the development of new, noninvasive imaging techniques for earlier detection and diagnosis of disease is essential to take full advantage of such new treatments and to promote the general improvement of health care.

“(3) The development of advanced genetic and molecular imaging techniques is necessary to continue

the current rapid pace of discovery in molecular biology.

“(4) Advances in telemedicine, and teleradiology in particular, are increasingly important in the delivery of high quality, reliable medical care to rural citizens and other underserved populations. To fulfill the promise of telemedicine and related technologies fully, a structure is needed at the NIH to support basic research focused on the acquisition, transmission, processing, and optimal display of images.

“(5) A number of Federal departments and agencies support imaging and engineering research with potential medical applications, but a central coordinating body, preferably housed at the NIH, is needed to coordinate these disparate efforts and facilitate the transfer of technologies with medical applications.

“(6) Several breakthrough imaging technologies, including magnetic resonance imaging (‘MRI’) and computed tomography (‘CT’), have been developed primarily abroad, in large part because of the absence of a home at the NIH for basic research in imaging and related fields. The establishment of a central focus for imaging and bioengineering research at the NIH would promote both scientific advance and United States economic development.

“(7) At a time when a consensus exists to add significant resources to the NIH in coming years, it is appropriate to modernize the structure of the NIH to ensure that research dollars are expended more effectively and efficiently and that the fields of medical science that have contributed the most to the detection, diagnosis, and treatment of disease in recent years receive appropriate emphasis.

“(8) The establishment of a National Institute of Biomedical Imaging and Bioengineering at the NIH would accelerate the development of new technologies with clinical and research applications, improve coordination and efficiency at the NIH and throughout the Federal Government, reduce duplication and waste, lay the foundation for a new medical information age, promote economic development, and provide a structure to train the young researchers who will make the pathbreaking discoveries of the next century.”

#### ESTABLISHMENT OF INSTITUTE AND ADVISORY COUNCIL

Pub. L. 106-580, §3(b)-(d), Dec. 29, 2000, 114 Stat. 3091, provided that:

“(b) USE OF EXISTING RESOURCES.—In providing for the establishment of the National Institute of Biomedical Imaging and Bioengineering pursuant to the amendment made by subsection (a) [enacting this subpart], the Director of the National Institutes of Health (referred to in this subsection as ‘NIH’)—

“(1) may transfer to the National Institute of Biomedical Imaging and Bioengineering such personnel of NIH as the Director determines to be appropriate;

“(2) may, for quarters for such Institute, utilize such facilities of NIH as the Director determines to be appropriate; and

“(3) may obtain administrative support for the Institute from the other agencies of NIH, including the other national research institutes.

“(c) CONSTRUCTION OF FACILITIES.—None of the provisions of this Act [enacting this subpart, amending section 281 of this title, and enacting provisions set out as notes under this section and section 201 of this title] or the amendments made by the Act may be construed as authorizing the construction of facilities, or the acquisition of land, for purposes of the establishment or operation of the National Institute of Biomedical Imaging and Bioengineering.

“(d) DATE CERTAIN FOR ESTABLISHMENT OF ADVISORY COUNCIL.—Not later than 90 days after the effective date of this Act [Dec. 29, 2000] under section 4 [set out above], the Secretary of Health and Human Services shall complete the establishment of an advisory council for the National Institute of Biomedical Imaging and Bioengineering in accordance with section 406 of

the Public Health Service Act [42 U.S.C. 284a] and in accordance with section 464z of such Act (as added by subsection (a) of this section) [42 U.S.C. 285r].”

#### SUBPART 19—NATIONAL HUMAN GENOME RESEARCH INSTITUTE

##### AMENDMENTS

2007—Pub. L. 109-482, title I, §101(c)(1)-(3), Jan. 15, 2007, 120 Stat. 3681, redesignated subpart 3 of part E of this subchapter as this subpart.

#### § 285s. Purpose of Institute

##### (a) General purpose

The general purpose of the National Human Genome Research Institute (in this subpart referred to as the “Institute”) is to characterize the structure and function of the human genome, including the mapping and sequencing of individual genes. Such purpose includes—

(1) planning and coordinating the research goal of the genome project;

(2) reviewing and funding research proposals;

(3) developing training programs;

(4) coordinating international genome research;

(5) communicating advances in genome science to the public; and

(6) reviewing and funding proposals to address the ethical and legal issues associated with the genome project (including legal issues regarding patents).

##### (b) Research training

The Director of the Institute may conduct and support research training—

(1) for which fellowship support is not provided under section 288 of this title; and

(2) that is not residency training of physicians or other health professionals.

##### (c) Amount available for ethical and legal issues

(1) Except as provided in paragraph (2), of the amounts appropriated to carry out subsection (a) for a fiscal year, the Director of the Institute shall make available not less than 5 percent for carrying out paragraph (6) of such subsection.

(2) With respect to providing funds under subsection (a)(6) for proposals to address the ethical issues associated with the genome project, paragraph (1) shall not apply for a fiscal year if the Director of the Institute certifies to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, that the Director has determined that an insufficient number of such proposals meet the applicable requirements of sections 289 and 289a of this title.

(July 1, 1944, ch. 373, title IV, §464z-1, formerly §485B, as added Pub. L. 103-43, title XV, §1521(2), June 10, 1993, 107 Stat. 180; renumbered §464z-1 and amended Pub. L. 109-482, title I, §101(c)(4), Jan. 15, 2007, 120 Stat. 3681.)

##### CODIFICATION

Section was formerly classified to section 287c of this title prior to renumbering by Pub. L. 109-482.

##### AMENDMENTS

2007—Pub. L. 109-482, §101(c)(4)(C), substituted “Institute” for “Center” wherever appearing in section catchline and text.

Subsec. (a). Pub. L. 109-482, §101(c)(4)(B), substituted “National Human Genome Research Institute” for “National Center for Human Genome Research” in introductory provisions.

#### CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104-14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### SUBPART 20—NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

##### AMENDMENTS

2010—Pub. L. 111-148, title X, §10334(c)(1)(A)–(C), (D)(ii), Mar. 23, 2010, 124 Stat. 973, redesignated subpart 6 of part E of this subchapter as this subpart and substituted “National Institute on Minority Health and Health Disparities” for “National Center on Minority Health and Health Disparities” in heading.

#### § 285t. Purpose of Institute

##### (a) In general

The general purpose of the National Institute on Minority Health and Health Disparities (in this subpart referred to as the “Institute”) is the conduct and support of research, training, dissemination of information, and other programs with respect to minority health conditions and other populations with health disparities.

##### (b) Priorities

The Director of the Institute shall in expending amounts appropriated under this subpart give priority to conducting and supporting minority health disparities research.

##### (c) Minority health disparities research

For purposes of this subpart:

(1) The term “minority health disparities research” means basic, clinical, and behavioral research on minority health conditions (as defined in paragraph (2)), including research to prevent, diagnose, and treat such conditions.

(2) The term “minority health conditions”, with respect to individuals who are members of minority groups, means all diseases, disorders, and conditions (including with respect to mental health and substance abuse)—

(A) unique to, more serious, or more prevalent in such individuals;

(B) for which the factors of medical risk or types of medical intervention may be different for such individuals, or for which it is unknown whether such factors or types are different for such individuals; or

(C) with respect to which there has been insufficient research involving such individuals as subjects or insufficient data on such individuals.

(3) The term “minority group” has the meaning given the term “racial and ethnic minority group” in section 300u-6 of this title.

(4) The terms “minority” and “minorities” refer to individuals from a minority group.

##### (d) Health disparity populations

For purposes of this subpart:

(1) A population is a health disparity population if, as determined by the Director of the Institute after consultation with the Director of the Agency for Healthcare Research and Quality, there is a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population.

(2) The Director shall give priority consideration to determining whether minority groups qualify as health disparity populations under paragraph (1).

(3) The term “health disparities research” means basic, clinical, and behavioral research on health disparity populations (including individual members and communities of such populations) that relates to health disparities as defined under paragraph (1), including the causes of such disparities and methods to prevent, diagnose, and treat such disparities.

##### (e) Coordination of activities

The Director of the Institute shall act as the primary Federal official with responsibility for coordinating all minority health disparities research and other health disparities research conducted or supported by the National Institutes of Health, and—

(1) shall represent the health disparities research program of the National Institutes of Health, including the minority health disparities research program, at all relevant Executive branch task forces, committees and planning activities; and

(2) shall maintain communications with all relevant Public Health Service agencies, including the Indian Health Service, and various other departments of the Federal Government to ensure the timely transmission of information concerning advances in minority health disparities research and other health disparities research between these various agencies for dissemination to affected communities and health care providers.

##### (f) Collaborative comprehensive plan and budget

###### (1) In general

Subject to the provisions of this section and other applicable law, the Director of NIH, the Director of the Institute, and the directors of the other agencies of the National Institutes of Health in collaboration (and in consultation with the advisory council for the Institute) shall—

(A) establish a comprehensive plan and budget for the conduct and support of all minority health disparities research and other health disparities research activities of the

agencies of the National Institutes of Health (which plan and budget shall be first established under this subsection not later than 12 months after November 22, 2000);

(B) ensure that the plan and budget establish priorities among the health disparities research activities that such agencies are authorized to carry out;

(C) ensure that the plan and budget establish objectives regarding such activities, describes the means for achieving the objectives, and designates the date by which the objectives are expected to be achieved;

(D) ensure that, with respect to amounts appropriated for activities of the Institute, the plan and budget give priority in the expenditure of funds to conducting and supporting minority health disparities research;

(E) ensure that all amounts appropriated for such activities are expended in accordance with the plan and budget;

(F) review the plan and budget not less than annually, and revise the plan and budget as appropriate;

(G) ensure that the plan and budget serve as a broad, binding statement of policies regarding minority health disparities research and other health disparities research activities of the agencies, but do not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other details of the daily administration of such activities, in accordance with the plan and budget; and

(H) promote coordination and collaboration among the agencies conducting or supporting minority health or other health disparities research.

**(2) Certain components of plan and budget**

With respect to health disparities research activities of the agencies of the National Institutes of Health, the Director of the Institute shall ensure that the plan and budget under paragraph (1) provide for—

(A) basic research and applied research, including research and development with respect to products;

(B) research that is conducted by the agencies;

(C) research that is supported by the agencies;

(D) proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and

(E) behavioral research and social sciences research, which may include cultural and linguistic research in each of the agencies.

**(3) Minority health disparities research**

The plan and budget under paragraph (1) shall include a separate statement of the plan and budget for minority health disparities research.

**(g) Participation in clinical research**

The Director of the Institute shall work with the Director of NIH and the directors of the agencies of the National Institutes of Health to carry out the provisions of section 289a-2 of this title that relate to minority groups.

**(h) Research endowments**

**(1) In general**

The Director of the Institute may carry out a program to facilitate minority health disparities research and other health disparities research by providing for research endowments—

(1)<sup>1</sup> at centers of excellence under section 293 of this title; and

(2)<sup>2</sup> at centers of excellence under section 285t-1 of this title.

**(2) Eligibility**

The Director of the Institute may provide for a research endowment under paragraph (1) only if the institution involved meets the following conditions:

(A) The institution does not have an endowment that is worth in excess of an amount equal to 50 percent of the national median of endowment funds at institutions that conduct similar biomedical research or training of health professionals.

(B) The application of the institution under paragraph (1) regarding a research endowment has been recommended pursuant to technical and scientific peer review and has been approved by the advisory council under subsection (j).

**(i) Certain activities**

In carrying out subsection (a), the Director of the Institute—

(1) shall assist the Director of NIH in carrying out section 283k(c)(2) of this title and in committing resources for construction at Institutions of Emerging Excellence under such section;

(2) shall establish projects to promote cooperation among Federal agencies, State, local, tribal, and regional public health agencies, and private entities in health disparities research; and

(3) may utilize information from previous health initiatives concerning minorities and other health disparity populations.

**(j) Advisory council**

**(1) In general**

The Secretary shall, in accordance with section 284a of this title, establish an advisory council to advise, assist, consult with, and make recommendations to the Director of the Institute on matters relating to the activities described in subsection (a), and with respect to such activities to carry out any other functions described in section 284a of this title for advisory councils under such section. Functions under the preceding sentence shall include making recommendations on budgetary allocations made in the plan under subsection (f), and shall include reviewing reports under subsection (k) before the reports are submitted under such subsection.

**(2) Membership**

With respect to the membership of the advisory council under paragraph (1), a majority of

<sup>1</sup> So in original. Probably should be "(A)".

<sup>2</sup> So in original. Probably should be "(B)".

the members shall be individuals with demonstrated expertise regarding minority health disparity and other health disparity issues; representatives of communities impacted by minority and other health disparities shall be included; and a diversity of health professionals shall be represented. The membership shall in addition include a representative of the Office of Behavioral and Social Sciences Research under section 283c of this title.

**(k) Intra-National Institutes of Health coordination**

The Director of the Institute, as the primary Federal official with responsibility for coordinating all research and activities conducted or supported by the National Institutes of Health on minority health and health disparities, shall plan, coordinate, review, and evaluate research and other activities conducted or supported by the national research institutes and national centers. The Director of the Institute may foster partnerships between the national research institutes and national centers and may encourage the funding of collaborative research projects to achieve the goals of the National Institutes of Health that are related to minority health and health disparities.

(July 1, 1944, ch. 373, title IV, § 464z-3, formerly § 485E, as added Pub. L. 106-525, title I, § 101(a), Nov. 22, 2000, 114 Stat. 2497; amended Pub. L. 109-482, title I, §§ 103(b)(44), 104(b)(1)(N), Jan. 15, 2007, 120 Stat. 3688, 3693; renumbered § 464z-3 and amended Pub. L. 111-148, title X, § 10334(c)(1)(D), (2), Mar. 23, 2010, 124 Stat. 973; Pub. L. 112-74, div. F, title II, § 221(d)(3), Dec. 23, 2011, 125 Stat. 1090; Pub. L. 114-255, div. A, title II, § 2038(f), Dec. 13, 2016, 130 Stat. 1066.)

CODIFICATION

Section was formerly classified to section 287c-31 of this title prior to renumbering by Pub. L. 111-148.

AMENDMENTS

2016—Subsec. (h). Pub. L. 114-255, § 2038(f)(1), redesignated subsec. (h) relating to interagency coordination as (k).

Subsec. (k). Pub. L. 114-255 redesignated subsec. (h) relating to interagency coordination as (k), in heading substituted “Intra-National Institutes of Health” for “Interagency”, in text substituted “as the primary Federal official” for “as the primary Federal officials” and “national research institutes and national centers” for “Institutes and Centers of the National Institutes of Health”, inserted a comma after “review”, and inserted at end “The Director of the Institute may foster partnerships between the national research institutes and national centers and may encourage the funding of collaborative research projects to achieve the goals of the National Institutes of Health that are related to minority health and health disparities.”

2011—Subsec. (i)(1). Pub. L. 112-74 substituted “Director of NIH” for “Director of the National Institute for Research Resources” and “283k(c)(2)” for “287a-1(c)(3)” and inserted “under such section” after “Institutions of Emerging Excellence”.

2010—Pub. L. 111-148, § 10334(c)(1)(D)(iii), substituted “Institute” for “Center” in section catchline.

Subsec. (a). Pub. L. 111-148, § 10334(c)(1)(D)(ii), (iii), substituted “National Institute on Minority Health and Health Disparities” for “National Center on Minority Health and Health Disparities” and “Institute” for “Center”.

Subsecs. (b), (d) to (g). Pub. L. 111-148, § 10334(c)(1)(D)(iii), substituted “Institute” for “Center” wherever appearing.

Subsec. (h). Pub. L. 111-148, § 10334(c)(2)(C), added at end subsec. (h) relating to interagency coordination.

Subsec. (h)(1). Pub. L. 111-148, § 10334(c)(2)(A), in par. (1) of subsec. (h) relating to research endowments, substituted “research endowments—

“(1) at centers of excellence under section 293 of this title; and

“(2) at centers of excellence under section 285t-1 of this title.”

for “research endowments at centers of excellence under section 293 of this title.”

Pub. L. 111-148, § 10334(c)(1)(D)(iii), in par. (1) of subsec. (h) relating to research endowments, substituted “Institute” for “Center”.

Subsec. (h)(2). Pub. L. 111-148, § 10334(c)(1)(D)(iii), in par. (2) of subsec. (h) relating to research endowments, substituted “Institute” for “Center” in introductory provisions.

Subsec. (h)(2)(A). Pub. L. 111-148, § 10334(c)(2)(B), in par. (2)(A) of subsec. (h) relating to research endowments, substituted “median” for “average”.

Subsecs. (i), (j). Pub. L. 111-148, § 10334(c)(1)(D)(iii), substituted “Institute” for “Center” wherever appearing.

2007—Subsec. (k). Pub. L. 109-482, § 104(b)(1)(N), struck out heading and text of subsec. (k). Text read as follows: “The Director of the Center shall prepare an annual report on the activities carried out or to be carried out by the Center, and shall submit each such report to the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Commerce of the House of Representatives, the Secretary, and the Director of NIH. With respect to the fiscal year involved, the report shall—

“(1) describe and evaluate the progress made in health disparities research conducted or supported by the national research institutes;

“(2) summarize and analyze expenditures made for activities with respect to health disparities research conducted or supported by the National Institutes of Health;

“(3) include a separate statement applying the requirements of paragraphs (1) and (2) specifically to minority health disparities research; and

“(4) contain such recommendations as the Director considers appropriate.”

Subsec. (l). Pub. L. 109-482, § 103(b)(44), struck out heading and text of subsec. (l). Text read as follows: “For the purpose of carrying out this subpart, there are authorized to be appropriated \$100,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005. Such authorization of appropriations is in addition to other authorizations of appropriations that are available for the conduct and support of minority health disparities research or other health disparities research by the agencies of the National Institutes of Health.”

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

FINDINGS

Pub. L. 106-525, § 2, Nov. 22, 2000, 114 Stat. 2495, provided that: “The Congress finds as follows:

“(1) Despite notable progress in the overall health of the Nation, there are continuing disparities in the burden of illness and death experienced by African Americans, Hispanics, Native Americans, Alaska Natives, and Asian Pacific Islanders, compared to the United States population as a whole.

“(2) The largest numbers of the medically underserved are white individuals, and many of them have the same health care access problems as do members of minority groups. Nearly 20,000,000 white individuals live below the poverty line with many living in nonmetropolitan, rural areas such as Appalachia,

where the high percentage of counties designated as health professional shortage areas (47 percent) and the high rate of poverty contribute to disparity outcomes. However, there is a higher proportion of racial and ethnic minorities in the United States represented among the medically underserved.

“(3) There is a national need for minority scientists in the fields of biomedical, clinical, behavioral, and health services research. Ninety percent of minority physicians educated at Historically Black Medical Colleges live and serve in minority communities.

“(4) Demographic trends inspire concern about the Nation’s ability to meet its future scientific, technological, and engineering workforce needs. Historically, non-Hispanic white males have made up the majority of the United States scientific, technological, and engineering workers.

“(5) The Hispanic and Black population will increase significantly in the next 50 years. The scientific, technological, and engineering workforce may decrease if participation by underrepresented minorities remains the same.

“(6) Increasing rates of Black and Hispanic workers can help ensure a strong scientific, technological, and engineering workforce.

“(7) Individuals such as underrepresented minorities and women in the scientific, technological, and engineering workforce enable society to address its diverse needs.

“(8) If there had not been a substantial increase in the number of science and engineering degrees awarded to women and underrepresented minorities over the past few decades, the United States would be facing even greater shortages in scientific, technological, and engineering workers.

“(9) In order to effectively promote a diverse and strong 21st century scientific, technological, and engineering workforce, Federal agencies should expand or add programs that effectively overcome barriers such as educational transition from one level to the next and student requirements for financial resources.

“(10) Federal agencies should work in concert with the private nonprofit sector to emphasize the recruitment and retention of qualified individuals from ethnic and gender groups that are currently underrepresented in the scientific, technological, and engineering workforce.

“(11) Behavioral and social sciences research has increased awareness and understanding of factors associated with health care utilization and access, patient attitudes toward health services, and risk and protective behaviors that affect health and illness. These factors have the potential to then be modified to help close the health disparities gap among ethnic minority populations. In addition, there is a shortage of minority behavioral science researchers and behavioral health care professionals. According to the National Science Foundation, only 15.5 percent of behavioral research-oriented psychology doctorate degrees were awarded to minority students in 1997. In addition, only 17.9 percent of practice-oriented psychology doctorate degrees were awarded to ethnic minorities.”

PUBLIC AWARENESS AND DISSEMINATION OF  
INFORMATION ON HEALTH DISPARITIES

Pub. L. 106-525, title V, §501, Nov. 22, 2000, 114 Stat. 2510, provided that:

“(a) PUBLIC AWARENESS ON HEALTH DISPARITIES.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall conduct a national campaign to inform the public and health care professionals about health disparities in minority and other underserved populations by disseminating information and materials available on specific diseases affecting these populations and programs and activities to address these disparities. The campaign shall—

“(1) have a specific focus on minority and other underserved communities with health disparities; and

“(2) include an evaluation component to assess the impact of the national campaign in raising awareness of health disparities and information on available resources.

“(b) DISSEMINATION OF INFORMATION ON HEALTH DISPARITIES.—The Secretary shall develop and implement a plan for the dissemination of information and findings with respect to health disparities under titles I, II, III, and IV of this Act [see Tables for classification]. The plan shall—

“(1) include the participation of all agencies of the Department of Health and Human Services that are responsible for serving populations included in the health disparities research; and

“(2) have agency-specific strategies for disseminating relevant findings and information on health disparities and improving health care services to affected communities.”

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

§ 285t-1. Centers of excellence for research education and training

(a) In general

The Director of the Institute shall make awards of grants or contracts to designated biomedical and behavioral research institutions under paragraph (1) of subsection (c), or to consortia under paragraph (2) of such subsection, for the purpose of assisting the institutions in supporting programs of excellence in biomedical and behavioral research training for individuals who are members of minority health disparity populations or other health disparity populations.

(b) Required use of funds

An award may be made under subsection (a) only if the applicant involved agrees that the grant will be expended—

(1) to train members of minority health disparity populations or other health disparity populations as professionals in the area of biomedical or behavioral research or both; or

(2) to expand, remodel, renovate, or alter existing research facilities or construct new research facilities for the purpose of conducting minority health disparities research and other health disparities research.

(c) Centers of excellence

(1) In general

For purposes of this section, a designated biomedical and behavioral research institution is a biomedical and behavioral research institution that—

(A) has a significant number of members of minority health disparity populations or

other health disparity populations enrolled as students in the institution (including individuals accepted for enrollment in the institution);

(B) has been effective in assisting such students of the institution to complete the program of education or training and receive the degree involved;

(C) has made significant efforts to recruit minority students to enroll in and graduate from the institution, which may include providing means-tested scholarships and other financial assistance as appropriate; and

(D) has made significant recruitment efforts to increase the number of minority or other members of health disparity populations serving in faculty or administrative positions at the institution.

**(2) Consortium**

Any designated biomedical and behavioral research institution involved may, with other biomedical and behavioral institutions (designated or otherwise), including tribal health programs, form a consortium to receive an award under subsection (a).

**(3) Application of criteria to other programs**

In the case of any criteria established by the Director of the Institute for purposes of determining whether institutions meet the conditions described in paragraph (1), this section may not, with respect to minority health disparity populations or other health disparity populations, be construed to authorize, require, or prohibit the use of such criteria in any program other than the program established in this section.

**(d) Duration of grant**

The period during which payments are made under a grant under subsection (a) may not exceed 5 years. Such payments shall be subject to annual approval by the Director of the Institute and to the availability of appropriations for the fiscal year involved to make the payments.

**(e) Maintenance of effort**

**(1) In general**

With respect to activities for which an award under subsection (a) is authorized to be expended, the Director of the Institute may not make such an award to a designated research institution or consortium for any fiscal year unless the institution, or institutions in the consortium, as the case may be, agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the institutions involved for the fiscal year preceding the fiscal year for which such institutions receive such an award.

**(2) Use of Federal funds**

With respect to any Federal amounts received by a designated research institution or consortium and available for carrying out activities for which an award under subsection (a) is authorized to be expended, the Director of the Institute may make such an award only if the institutions involved agree that the institutions will, before expending the award,

expend the Federal amounts obtained from sources other than the award.

**(f) Certain expenditures**

The Director of the Institute may authorize a designated biomedical and behavioral research institution to expend a portion of an award under subsection (a) for research endowments.

**(g) Definitions**

For purposes of this section:

(1) The term “designated biomedical and behavioral research institution” has the meaning indicated for such term in subsection (c)(1). Such term includes any health professions school receiving an award of a grant or contract under section 293 of this title.

(2) The term “program of excellence” means any program carried out by a designated biomedical and behavioral research institution with an award under subsection (a), if the program is for purposes for which the institution involved is authorized in subsection (b) to expend the grant.

(July 1, 1944, ch. 373, title IV, §464z-4, formerly §485F, as added Pub. L. 106-525, title I, §102, Nov. 22, 2000, 114 Stat. 2501; amended Pub. L. 109-482, title I, §103(b)(45), Jan. 15, 2007, 120 Stat. 3688; renumbered §464z-4 and amended Pub. L. 111-148, title X, §10334(c)(1)(D)(i), (iii), Mar. 23, 2010, 124 Stat. 973.)

CODIFICATION

Section was formerly classified to section 287c-32 of this title prior to renumbering by Pub. L. 111-148.

AMENDMENTS

2010—Subsecs. (a), (c)(3) to (f). Pub. L. 111-148, §10334(c)(1)(D)(iii), substituted “Institute” for “Center” wherever appearing.

2007—Subsec. (h). Pub. L. 109-482 struck out heading and text of subsec. (h). Text read as follows: “For the purpose of making grants under subsection (a) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.”

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 285t-2. Repealed. Pub. L. 114-255, div. A, title II, § 2022(c)(1), Dec. 13, 2016, 130 Stat. 1054**

Section, July 1, 1944, ch. 373, title IV, §464z-5, formerly §485G, as added Pub. L. 106-525, title I, §103, Nov. 22, 2000, 114 Stat. 2503; amended Pub. L. 109-482, title I, §103(b)(46), Jan. 15, 2007, 120 Stat. 3688; renumbered §464z-5 and amended Pub. L. 111-148, title X, §10334(c)(1)(D)(i), (iii), Mar. 23, 2010, 124 Stat. 973, related to loan repayment program for minority health disparities research.

**§ 285t-3. General provisions regarding the Institute**

The Secretary, acting through the Director of the National Institutes of Health, shall provide administrative support and support services to the Director of the Institute and shall ensure that such support takes maximum advantage of existing administrative structures at the agencies of the National Institutes of Health.

(July 1, 1944, ch. 373, title IV, § 464z-6, formerly § 485H, as added Pub. L. 106-525, title I, § 104, Nov. 22, 2000, 114 Stat. 2503; amended Pub. L. 109-482, title I, § 104(b)(1)(O), Jan. 15, 2007, 120 Stat. 3693; renumbered § 464z-6 and amended Pub. L. 111-148, title X, § 10334(c)(1)(D)(i), (iii), Mar. 23, 2010, 124 Stat. 973.)

#### CODIFICATION

Section was formerly classified to section 287c-34 of this title prior to renumbering by Pub. L. 111-148.

#### AMENDMENTS

2010—Pub. L. 111-148, § 10334(c)(1)(D)(iii), substituted “Institute” for “Center” in section catchline and text.  
2007—Pub. L. 109-482 struck out subsec. (a) designation and heading before “The Secretary” and struck out subsec. (b) which related to evaluation of this subpart not later than 5 years after Nov. 22, 2000, and report on such evaluation not later than 1 year after its commencement.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

### PART D—NATIONAL LIBRARY OF MEDICINE

#### SUBPART 1—GENERAL PROVISIONS

### § 286. National Library of Medicine

#### (a) Purpose and establishment

In order to assist the advancement of medical and related sciences and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health, there is established the National Library of Medicine (hereafter in this part referred to as the “Library”).

#### (b) Functions

The Secretary, through the Library and subject to subsection (d), shall—

- (1) acquire and preserve books, periodicals, prints, films, recordings, and other library materials pertinent to medicine;
- (2) organize the materials specified in paragraph (1) by appropriate cataloging, indexing, and bibliographical listings;
- (3) publish and disseminate the catalogs, indexes, and bibliographies referred to in paragraph (2);
- (4) make available, through loans, photographic or other copying procedures, or otherwise, such materials in the Library as the Secretary determines appropriate;
- (5) provide reference and research assistance;
- (6) publicize the availability from the Library of the products and services described in any of paragraphs (1) through (5);
- (7) promote the use of computers and telecommunications by health professionals (including health professionals in rural areas) for the purpose of improving access to biomedical information for health care delivery and medical research; and
- (8) engage in such other activities as the Secretary determines appropriate and as the Library’s resources permit.

#### (c) Exchange, destruction, or disposal of materials not needed

The Secretary may exchange, destroy, or otherwise dispose of any books, periodicals,

films, and other library materials not needed for the permanent use of the Library.

#### (d) Availability of publications, materials, facilities, or services; prescription of rules

(1) The Secretary may, after obtaining the advice and recommendations of the Board of Regents, prescribe rules under which the Library will—

- (A) provide copies of its publications or materials,
- (B) will make available its facilities for research, or
- (C) will make available its bibliographic, reference, or other services,

to public and private entities and individuals.

(2) Rules prescribed under paragraph (1) may provide for making available such publications, materials, facilities, or services—

- (A) without charge as a public service,
- (B) upon a loan, exchange, or charge basis, or
- (C) in appropriate circumstances, under contract arrangements made with a public or other nonprofit entity.

#### (e) Regional medical libraries; establishment

Whenever the Secretary, with the advice of the Board of Regents, determines that—

- (1) in any geographic area of the United States there is no regional medical library adequate to serve such area;
- (2) under criteria prescribed for the administration of section 286b-6 of this title, there is a need for a regional medical library to serve such area; and
- (3) because there is no medical library located in such area which, with financial assistance under section 286b-6 of this title, can feasibly be developed into a regional medical library adequate to serve such area,

the Secretary may establish, as a branch of the Library, a regional medical library to serve the needs of such area.

#### (f) Acceptance and administration of gifts; memorials

Section 238 of this title shall be applicable to the acceptance and administration of gifts made for the benefit of the Library or for carrying out any of its functions, and the Board of Regents shall make recommendations to the Secretary relating to establishment within the Library of suitable memorials to the donors.

#### (g) “Medicine” and “medical” defined

For purposes of this part, the terms “medicine” and “medical”, except when used in section 286a of this title, include preventive and therapeutic medicine, dentistry, pharmacy, hospitalization, nursing, public health, and the fundamental sciences related thereto, and other related fields of study, research, or activity.

(July 1, 1944, ch. 373, title IV, § 465, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 857; amended Pub. L. 99-660, title III, § 311(b)(1), Nov. 14, 1986, 100 Stat. 3779; Pub. L. 100-202, § 101(h) [title II, § 215], Dec. 22, 1987, 101 Stat. 1329-256, 1329-275; Pub. L. 100-607, title II, § 204(2), Nov. 4, 1988, 102 Stat. 3079; Pub. L. 100-690, title II, § 2620(b)(1), Nov. 18, 1988, 102 Stat. 4244; Pub. L. 101-381, title

I, §102(2), Aug. 18, 1990, 104 Stat. 585; Pub. L. 103-43, title XIV, §1401(a), (c)(1), title XX, §2010(b)(3), June 10, 1993, 107 Stat. 170, 214.)

#### AMENDMENTS

1993—Pub. L. 103-43, §1401(c)(1), repealed amendment by Pub. L. 100-202. See 1987 Amendment note below.

Subsec. (b)(6) to (8). Pub. L. 103-43, §1401(a), added pars. (6) and (7) and redesignated former par. (6) as (8).

Subsec. (f). Pub. L. 103-43, §2010(b)(3), substituted "Section 238" for "Section 300aaa".

1990—Subsec. (f). Pub. L. 101-381 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

1988—Subsec. (f). Pub. L. 100-690 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

Pub. L. 100-607 substituted "300aaa" for "300cc".

1987—Pub. L. 100-202, which directed the amendment of "Section 465(B) of 42 U.S.C. 286" by inserting "between (5) and (6) an additional charge to the Secretary to 'publicize the availability of the above products and services of the National Library of Medicine'", was repealed by Pub. L. 103-43, §1401(c)(1).

1986—Subsec. (f). Pub. L. 99-660 substituted "section 300cc of this title" for "section 300aa of this title".

#### EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-690 effective immediately after enactment of Pub. L. 100-607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100-690, set out as a note under section 242m of this title.

#### EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99-660 effective Dec. 22, 1987, see section 323 of Pub. L. 99-660, as amended, set out as an Effective Date note under section 300aa-1 of this title.

#### APPLICABILITY OF CERTAIN NEW AUTHORITY

Pub. L. 103-43, title XIV, §1401(c)(2), June 10, 1993, 107 Stat. 170, provided that: "With respect to the authority established for the National Library of Medicine in section 465(b)(6) of the Public Health Service Act, as added by subsection (a) of this section [42 U.S.C. 286(b)(6)], such authority shall be effective as if the authority had been established on December 22, 1987."

### § 286a. Board of Regents

#### (a) Membership; ex officio members

(1)(A) The Board of Regents of the National Library of Medicine consists of ex officio members and ten members appointed by the Secretary.

(B) The ex officio members are the Surgeons General of the Public Health Service, the Army, the Navy, and the Air Force, the Under Secretary for Health of the Department of Veterans Affairs, the Dean of the Uniformed Services University of the Health Sciences, the Assistant Director for Biological, Behavioral, and Social Sciences of the National Science Foundation, the Director of the National Agricultural Library, and the Librarian of Congress (or their designees).

(C) The appointed members shall be selected from among leaders in the various fields of the fundamental sciences, medicine, dentistry, public health, hospital administration, pharmacology, health communications technology, or scientific or medical library work, or in public affairs. At least six of the appointed members shall be selected from among leaders in the

fields of medical, dental, or public health research or education.

(2) The Board shall annually elect one of the appointed members to serve as chairman until the next election. The Secretary shall designate a member of the Library staff to act as executive secretary of the Board.

#### (b) Recommendations on matters of policy; recommendations included in annual report; use of services of members by Secretary

The Board shall advise, consult with, and make recommendations to the Secretary on matters of policy in regard to the Library, including such matters as the acquisition of materials for the Library, the scope, content, and organization of the Library's services, and the rules under which its materials, publications, facilities, and services shall be made available to various kinds of users. The Secretary shall include in the annual report of the Secretary to the Congress a statement covering the recommendations made by the Board and the disposition thereof. The Secretary may use the services of any member of the Board in connection with matters related to the work of the Library, for such periods, in addition to conference periods, as the Secretary may determine.

#### (c) Term of office; vacancy; reappointment

Each appointed member of the Board shall hold office for a term of four years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the predecessor of such member was appointed shall be appointed for the remainder of such term. None of the appointed members shall be eligible for reappointment within one year after the end of the preceding term of such member.

(July 1, 1944, ch. 373, title IV, §466, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 859; amended Pub. L. 102-405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 103-43, title XX, §2008(b)(11), June 10, 1993, 107 Stat. 211.)

#### AMENDMENTS

1993—Subsec. (a)(1)(B). Pub. L. 103-43 substituted "Department of Veterans Affairs" for "Veterans' Administration".

1992—Subsec. (a)(1)(B). Pub. L. 102-405 substituted "Under Secretary for Health" for "Chief Medical Director".

#### § 286a-1. Library facilities

The Administrator of General Services may acquire, by purchase, condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for suitable and adequate buildings and facilities for use of the Library and to erect thereon, furnish, and equip such buildings and facilities. Amounts appropriated to carry out this section may be used for the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.

(July 1, 1944, ch. 373, title IV, §467, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 859; amended

Pub. L. 109-482, title I, §103(b)(38), Jan. 15, 2007, 120 Stat. 3688.)

#### AMENDMENTS

2007—Pub. L. 109-482 substituted “for suitable and adequate buildings and facilities for use of the Library” for “for such buildings and facilities” and “Amounts appropriated to carry out this section may be used for” for “The amounts authorized to be appropriated by this section include” and struck out first sentence which read as follows: “There are authorized to be appropriated amounts sufficient for the erection and equipment of suitable and adequate buildings and facilities for use of the Library.”

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### § 286a-2. Repealed. Pub. L. 109-482, title I, § 103(b)(39), Jan. 15, 2007, 120 Stat. 3688

Section, act July 1, 1944, ch. 373, title IV, §468, as added Pub. L. 103-43, title XIV, §1402(a), June 10, 1993, 107 Stat. 170, authorized appropriations for this part.

#### EFFECTIVE DATE OF REPEAL

Repeal applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

#### SUBPART 2—FINANCIAL ASSISTANCE

#### § 286b. Repealed. Pub. L. 103-43, title XIV, § 1402(b), June 10, 1993, 107 Stat. 171

Section, act July 1, 1944, ch. 373, title IV, §469, as added Nov. 20, 1985, Pub. L. 99-158, §2, 99 Stat. 860; amended Nov. 4, 1988, Pub. L. 100-607, title I, §146(a), 102 Stat. 3058, authorized appropriations for grants and contracts under sections 286b-3 through 286b-7 of this title.

#### § 286b-1. Definitions

As used in this subpart—

(1) the term “medical library” means a library related to the sciences related to health; and

(2) the term “sciences related to health” includes medicine, osteopathy, dentistry, and public health, and fundamental and applied sciences when related thereto.

(July 1, 1944, ch. 373, title IV, §470, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 860.)

#### § 286b-2. National Medical Libraries Assistance Advisory Board

##### (a) Board of Regents of National Library of Medicine to serve as

The Board of Regents of the National Library of Medicine shall also serve as the National Medical Libraries Assistance Advisory Board (hereafter in this subpart referred to as the “Board”).

##### (b) Functions

The Board shall advise and assist the Secretary in the preparation of general regulations and with respect to policy matters arising in the administration of this subpart.

##### (c) Use of services of members by Secretary

The Secretary may use the services of any member of the Board, in connection with matters related to the administration of this part for such periods, in addition to conference periods, as the Secretary may determine.

##### (d) Compensation

Appointed members of the Board who are not otherwise in the employ of the United States, while attending conferences of the Board or otherwise serving at the request of the Secretary in connection with the administration of this subpart, shall be entitled to receive compensation, per diem in lieu of subsistence, and travel expenses in the same manner and under the same conditions as that prescribed under section 210(c) of this title when attending conferences, traveling, or serving at the request of the Secretary in connection with the Board’s function under this section.

(July 1, 1944, ch. 373, title IV, §471, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 860.)

#### TERMINATION OF ADVISORY BOARDS

Advisory boards established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a board established by the President or an officer of the Federal Government, such board is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a board established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

#### § 286b-3. Grants for training in medical library sciences

The Secretary shall make grants—

(1) to individuals to enable them to accept traineeships and fellowships leading to post-baccalaureate academic degrees in the field of medical library science, in related fields pertaining to sciences related to health, or in the field of the communication of information;

(2) to individuals who are librarians or specialists in information on sciences relating to health, to enable them to undergo intensive training or retraining so as to attain greater competence in their occupations (including competence in the fields of automatic data processing and retrieval);

(3) to assist appropriate public and private nonprofit institutions in developing, expanding, and improving training programs in library science and the field of communications of information pertaining to sciences relating to health; and

(4) to assist in the establishment of internship programs in established medical libraries meeting standards which the Secretary shall prescribe.

(July 1, 1944, ch. 373, title IV, §472, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 860.)

**§ 286b-4. Assistance for projects in sciences related to health, for research and development in medical library science, and for development of education technologies**

**(a) Compilation of existing and original writings on health**

The Secretary shall make grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists for the compilation of existing, or the writing of original, contributions relating to scientific, social, or cultural advancements in sciences related to health. In making such grants, the Secretary shall make appropriate arrangements under which the facilities of the Library and the facilities of libraries of public and private nonprofit institutions of higher learning may be made available in connection with the projects for which such grants are made.

**(b) Medical library science and related activities**

The Secretary shall make grants to appropriate public or private nonprofit institutions and enter into contracts with appropriate persons, for purposes of carrying out projects of research, investigations, and demonstrations in the field of medical library science and related activities and for the development of new techniques, systems, and equipment, for processing, storing, retrieving, and distributing information pertaining to sciences related to health.

**(c) Development of education technologies**

(1) The Secretary shall make grants to public or nonprofit private institutions for the purpose of carrying out projects of research on, and development and demonstration of, new education technologies.

(2) The purposes for which a grant under paragraph (1) may be made include projects concerning—

(A) computer-assisted teaching and testing of clinical competence at health professions and research institutions;

(B) the effective transfer of new information from research laboratories to appropriate clinical applications;

(C) the expansion of the laboratory and clinical uses of computer-stored research databases; and

(D) the testing of new technologies for training health care professionals.

(3) The Secretary may not make a grant under paragraph (1) unless the applicant for the grant agrees to make the projects available with respect to—

(A) assisting in the training of health professions students; and

(B) enhancing and improving the capabilities of health professionals regarding research and teaching.

(July 1, 1944, ch. 373, title IV, § 473, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 861; amended Pub. L. 103-43, title XIV, § 1411, June 10, 1993, 107 Stat. 171.)

AMENDMENTS

1993—Subsec. (c). Pub. L. 103-43 added subsec. (c).

**§ 286b-5. Grants for establishing, expanding, and improving basic resources of medical libraries and related instrumentalities**

(a) The Secretary shall make grants of money, materials, or both, to public or private nonprofit medical libraries and related scientific communication instrumentalities for the purpose of establishing, expanding, and improving their basic medical library or related resources. A grant under this subsection may be used for—

(1) the acquisition of books, journals, photographs, motion picture and other films, and other similar materials;

(2) cataloging, binding, and other services and procedures for processing library resource materials for use by those who are served by the library or related instrumentality;

(3) the acquisition of duplication devices, facsimile equipment, film projectors, recording equipment, and other equipment to facilitate the use of the resources of the library or related instrumentality by those who are served by it; and

(4) the introduction of new technologies in medical librarianship.

(b)(1) The amount of any grant under this section to any medical library or related instrumentality shall be determined by the Secretary on the basis of the scope of library or related services provided by such library or instrumentality in relation to the population and purposes served by it. In making a determination of the scope of services served by any medical library or related instrumentality, the Secretary shall take into account—

(A) the number of graduate and undergraduate students making use of the resources of such library or instrumentality;

(B) the number of physicians and other practitioners in the sciences related to health utilizing the resources of such library or instrumentality;

(C) the type of supportive staffs, if any, available to such library or instrumentality;

(D) the type, size, and qualifications of the faculty of any school with which such library or instrumentality is affiliated;

(E) the staff of any hospital or hospitals or of any clinic or clinics with which such library or instrumentality is affiliated; and

(F) the geographic area served by such library or instrumentality and the availability within such area of medical library or related services provided by other libraries or related instrumentalities.

(2) Grants to such medical libraries or related instrumentalities under this section shall be in such amounts as the Secretary may by regulation prescribe with a view to assuring adequate continuing financial support for such libraries or instrumentalities from other sources during and after the period for which grants are provided, except that in no case shall any grant under this section to a medical library or related instrumentality for any fiscal year exceed \$1,000,000.

(July 1, 1944, ch. 373, title IV, § 474, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 861; amended Pub. L. 100-607, title I, § 146(b), Nov. 4, 1988, 102

Stat. 3058; Pub. L. 103-43, title XIV, §1401(b), June 10, 1993, 107 Stat. 170.)

AMENDMENTS

1993—Subsec. (b)(2). Pub. L. 103-43 substituted “\$1,000,000” for “\$750,000”.

1988—Subsec. (b)(2). Pub. L. 100-607 substituted “\$750,000” for “\$500,000”.

**§ 286b-6. Grants and contracts for establishment of regional medical libraries**

**(a) Existing public or private nonprofit medical libraries**

The Secretary, with the advice of the Board, shall make grants to and enter into contracts with existing public or private nonprofit medical libraries so as to enable each of them to serve as the regional medical library for the geographical area in which it is located.

**(b) Uses for grants and contracts**

The uses for which grants and contracts under this section may be employed include the—

- (1) acquisition of books, journals, and other similar materials;
- (2) cataloging, binding, and other procedures for processing library resource materials for use by those who are served by the library;
- (3) acquisition of duplicating devices and other equipment to facilitate the use of the resources of the library by those who are served by it;
- (4) acquisition of mechanisms and employment of personnel for the speedy transmission of materials from the regional library to local libraries in the geographic area served by the regional library; and
- (5) planning for services and activities under this section.

**(c) Conditions**

(1) Grants and contracts under this section shall only be made to or entered into with medical libraries which agree—

- (A) to modify and increase their library resources, and to supplement the resources of cooperating libraries in the region, so as to be able to provide adequate supportive services to all libraries in the region as well as to individual users of library services; and
- (B) to provide free loan services to qualified users and make available photoduplicated or facsimile copies of biomedical materials which qualified requesters may retain.

(2) The Secretary, in awarding grants and contracts under this section, shall give priority to medical libraries having the greatest potential of fulfilling the needs for regional medical libraries. In determining the priority to be assigned to any medical library, the Secretary shall consider—

- (A) the adequacy of the library (in terms of collections, personnel, equipment, and other facilities) as a basis for a regional medical library; and
- (B) the size and nature of the population to be served in the region in which the library is located.

**(d) Basic resources materials; limitation on grant or contract**

Grants and contracts under this section for basic resource materials to a library may not exceed—

(1) 50 percent of the library’s annual operating expense (exclusive of Federal financial assistance under this part) for the preceding year; or

(2) in case of the first year in which the library receives a grant under this section for basic resource materials, 50 percent of its average annual operating expenses over the past three years (or if it had been in operation for less than three years, its annual operating expenses determined by the Secretary in accordance with regulations).

(July 1, 1944, ch. 373, title IV, §475, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 862.)

**§ 286b-7. Financial support of biomedical scientific publications**

(a) The Secretary, with the advice of the Board, shall make grants to, and enter into appropriate contracts with, public or private nonprofit institutions of higher education and individual scientists for the purpose of supporting biomedical scientific publications of a nonprofit nature and to procure the compilation, writing, editing, and publication of reviews, abstracts, indices, handbooks, bibliographies, and related matter pertaining to scientific works and scientific developments.

(b) Grants under subsection (a) in support of any single periodical publication may not be made for more than three years, except in those cases in which the Secretary determines that further support is necessary to carry out the purposes of subsection (a).

(July 1, 1944, ch. 373, title IV, §476, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 863.)

**§ 286b-8. Grant payments, records, and audit**

(a) Payments under grants made under sections 286b-3, 286b-4, 286b-5, 286b-6, and 286b-7 of this title may be made in advance or by way of reimbursement and in such installments as the Secretary shall prescribe by regulation after consultation with the Board.

(b)(1) Each recipient of a grant under this subpart shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to any grant received under this subpart.

(July 1, 1944, ch. 373, title IV, §477, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 863.)

SUBPART 3—NATIONAL CENTER FOR  
BIOTECHNOLOGY INFORMATION

**§ 286c. Purpose, establishment, functions, and  
funding of National Center for Biotechnology  
Information**

**(a) Establishment**

In order to focus and expand the collection, storage, retrieval, and dissemination of the results of biotechnology research by information systems, and to support and enhance the development of new information technologies to aid in the understanding of the molecular processes that control health and disease, there is established the National Center for Biotechnology Information (hereinafter in this section referred to as the “Center”) in the National Library of Medicine.

**(b) Functions**

The Secretary, through the Center and subject to section 286(d) of this title, shall—

(1) design, develop, implement, and manage automated systems for the collection, storage, retrieval, analysis, and dissemination of knowledge concerning human molecular biology, biochemistry, and genetics;

(2) perform research into advanced methods of computer-based information processing capable of representing and analyzing the vast number of biologically important molecules and compounds;

(3) enable persons engaged in biotechnology research and medical care to use systems developed under paragraph (1) and methods described in paragraph (2); and

(4) coordinate, as much as is practicable, efforts to gather biotechnology information on an international basis.

(July 1, 1944, ch. 373, title IV, § 478, as added Pub. L. 100–607, title I, § 105, Nov. 4, 1988, 102 Stat. 3052; amended Pub. L. 103–43, title XIV, § 1402(b), June 10, 1993, 107 Stat. 171.)

AMENDMENTS

1993—Subsec. (c). Pub. L. 103–43 struck out subsec. (c) which read as follows: “For the purpose of performing the duties specified in subsection (b) of this section, there are authorized to be appropriated \$8,000,000 for fiscal year 1989 and such sums as may be necessary for fiscal year 1990. Funds appropriated under this subsection shall remain available until expended.”

SUBPART 4—NATIONAL INFORMATION CENTER ON  
HEALTH SERVICES RESEARCH AND HEALTH CARE  
TECHNOLOGY

**§ 286d. National Information Center**

**(a) Establishment**

There is established within the Library an entity to be known as the National Information Center on Health Services Research and Health Care Technology (in this section referred to as the “Center”).

**(b) Purpose**

The purpose of the Center is the collection, storage, analysis, retrieval, and dissemination of information on health services research, clinical practice guidelines, and on health care technology, including the assessment of such tech-

nology. Such purpose includes developing and maintaining data bases and developing and implementing methods of carrying out such purpose.

**(c) Electronic, convenient format; criteria for inclusion**

The Director of the Center shall ensure that information under subsection (b) concerning clinical practice guidelines is collected and maintained electronically and in a convenient format. Such Director shall develop and publish criteria for the inclusion of practice guidelines and technology assessments in the information center database.

**(d) Coordination with Director of the Agency for  
Healthcare Research and Quality**

The Secretary, acting through the Center, shall coordinate the activities carried out under this section through the Center with related activities of the Director of the Agency for Healthcare Research and Quality.

(July 1, 1944, ch. 373, title IV, § 478A, as added Pub. L. 103–43, title XIV, § 1421, June 10, 1993, 107 Stat. 171; amended Pub. L. 106–129, § 2(b)(2), Dec. 6, 1999, 113 Stat. 1670.)

AMENDMENTS

1999—Subsec. (d). Pub. L. 106–129 substituted “Director of the Agency for Healthcare Research and Quality” for “Administrator for Health Care Policy and Research”.

CONSTRUCTION

Pub. L. 103–43, § 1422(b), June 10, 1993, 107 Stat. 172, provided that: “The amendments made by section 3 of Public Law 102–410 (106 Stat. 2094) [amending section 299a–1 of this title], by section 1421 of this Act [enacting this section], and by subsection (a) of this section [amending section 299a–1 of this title] may not be construed as terminating the information center on health care technologies and health care technology assessment established under section 904 of the Public Health Service Act [42 U.S.C. 299a–2], as in effect on the day before the date of the enactment of Public Law 102–410 [Oct. 13, 1992]. Such center shall be considered to be the center established in section 478A of the Public Health Service Act [42 U.S.C. 286d], as added by section 1421 of this Act, and shall be subject to the provisions of such section 478A.”

PART E—OTHER AGENCIES OF NIH

SUBPART 1—NATIONAL CENTER FOR ADVANCING  
TRANSLATIONAL SCIENCES

AMENDMENTS

2011—Pub. L. 112–74, div. F, title II, § 221(a)(1)(A), Dec. 23, 2011, 125 Stat. 1086, substituted “advancing translational sciences” for “research resources” in subpart heading.

**§ 287. National Center for Advancing  
Translational Sciences**

**(a) Purpose**

The purpose of the National Center for Advancing Translational Sciences (in this subpart referred to as the “Center”) is to advance translational sciences, including by—

(1) coordinating and developing resources that leverage basic research in support of translational science; and

(2) developing partnerships and working cooperatively to foster synergy in ways that do

not create duplication, redundancy, and competition with industry activities.

**(b) Clinical trial activities**

**(1) In general**

The Center may develop and provide infrastructure and resources for all phases of clinical trials research. Except as provided in paragraph (2), the Center may support clinical trials only through the end of phase IIB.

**(2) Exception**

The Center may support clinical trial activities through the end of phase III for a treatment for a rare disease or condition (as defined in section 360bb of title 21) so long as—

(A) the Center gives public notice for a period of at least 120 days of the Center's intention to support the clinical trial activities in phase III;

(B) no public or private organization provides credible written intent to the Center that the organization has timely plans to further the clinical trial activities or conduct clinical trials of a similar nature beyond phase IIB; and

(C) the Center ensures that support of the clinical trial activities in phase III will not increase the Federal Government's liability beyond the award value of the Center's support.

**(c) Biennial report**

The Center shall publish a report on a biennial basis that, with respect to all research supported by the Center, includes a complete list of—

- (1) the molecules being studied;
- (2) clinical trial activities being conducted;
- (3) the methods and tools in development;
- (4) ongoing partnerships, including—
  - (A) the rationale for each partnership;
  - (B) the status of each partnership;
  - (C) the funding provided by the Center to other entities pursuant to each partnership, and
  - (D) the activities which have been transferred to industry pursuant to each partnership;

(5) known research activity of other entities that is or will expand upon research activity of the Center;

(6) the methods and tools, if any, that have been developed since the last biennial report was prepared; and

(7) the methods and tools, if any, that have been developed and are being utilized by the Food and Drug Administration to support medical product reviews.

**(d) Inclusion of list**

The first biennial report submitted under this section after December 13, 2016, shall include a complete list of all of the methods and tools, if any, which have been developed by research supported by the Center.

**(e) Rule of construction**

Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(July 1, 1944, ch. 373, title IV, § 479, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 864; amended Pub. L. 103-43, title XV, § 1501(2)(B), June 10, 1993, 107 Stat. 172; Pub. L. 112-74, div. F, title II, § 221(a)(1)(C), Dec. 23, 2011, 125 Stat. 1086; Pub. L. 114-255, div. A, title II, §§ 2037, 2042(e), Dec. 13, 2016, 130 Stat. 1063, 1073.)

AMENDMENTS

2016—Subsec. (b)(1). Pub. L. 114-255, § 2037(a)(1), substituted “phase IIB” for “phase IIA”.

Subsec. (b)(2). Pub. L. 114-255, § 2037(a)(2)(A), substituted “phase III” for “phase IIB” in introductory provisions.

Subsec. (b)(2)(A). Pub. L. 114-255, § 2037(a)(2)(B), substituted “phase III” for “phase IIB”.

Subsec. (b)(2)(B). Pub. L. 114-255, § 2037(a)(2)(C), substituted “phase IIB” for “phase IIA”.

Subsec. (b)(2)(C). Pub. L. 114-255, § 2037(a)(2)(D), substituted “phase III” for “phase IIB”.

Subsec. (c). Pub. L. 114-255, § 2042(e), substituted “Biennial” for “Annual” in heading and “a report on a biennial basis” for “an annual report” in introductory provisions.

Subsec. (c)(6), (7). Pub. L. 114-255, § 2037(b)(1), added pars. (6) and (7).

Subsecs. (d), (e). Pub. L. 114-255, § 2037(b)(2), added subsecs. (d) and (e).

2011—Pub. L. 112-74 amended section generally. Prior to amendment, text read as follows: “The general purpose of the National Center for Research Resources (in this subpart referred to as the ‘Center’) is to strengthen and enhance the research environments of entities engaged in health-related research by developing and supporting essential research resources.”

1993—Pub. L. 103-43 substituted “the National Center for Research Resources (in this subpart referred to as the ‘Center’)” for “the Division of Research Resources”.

SHARED INSTRUMENTATION GRANT PROGRAM

Pub. L. 106-505, title III, § 305, Nov. 13, 2000, 114 Stat. 2335, which was formerly set out as a note under this section, was renumbered section 404L of act July 1, 1944, ch. 373, the Public Health Service Act, by Pub. L. 112-74, div. F, title II, § 221(b)(4)(A), Dec. 23, 2011, 125 Stat. 1088, and is classified to section 283n of this title.

**§ 287a. Cures Acceleration Network**

**(a) Definitions**

In this section:

**(1) Biological product**

The term “biological product” has the meaning given such term in section 262 of this title.

**(2) Drug; device**

The terms “drug” and “device” have the meanings given such terms in section 321 of title 21.

**(3) High need cure**

The term “high need cure” means a drug (as that term is defined by section 321(g)(1) of title 21,<sup>1</sup> biological product (as that term is defined by section 262(i)<sup>2</sup> of this title), or device (as that term is defined by section 321(h) of title 21) that, in the determination of the Director of the Center—

(A) is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and

<sup>1</sup> So in original. A closing parenthesis probably should precede the comma.

<sup>2</sup> See References in Text note below.

(B) for which the incentives of the commercial market are unlikely to result in its adequate or timely development.

**(4) Medical product**

The term “medical product” means a drug, device, biological product, or product that is a combination of drugs, devices, and biological products.

**(b) Establishment of the Cures Acceleration Network**

Subject to the appropriation of funds as described in subsection (g), there is established within the Center a program to be known as the Cures Acceleration Network (referred to in this section as “CAN”), which shall—

(1) be under the direction of the Director of the Center, taking into account the recommendations of a CAN Review Board (referred to in this section as the “Board”), described in subsection (d); and

(2) award grants and contracts to eligible entities, as described in subsection (e), to accelerate the development of high need cures, including through the development of medical products and behavioral therapies.

**(c) Functions**

The functions of the CAN are to—

(1) conduct and support revolutionary advances in basic research, translating scientific discoveries from bench to bedside;

(2) award grants and contracts to eligible entities to accelerate the development of high need cures;

(3) provide the resources necessary for government agencies, independent investigators, research organizations, biotechnology companies, academic research institutions, and other entities to develop high need cures;

(4) reduce the barriers between laboratory discoveries and clinical trials for new therapies; and

(5) facilitate review in the Food and Drug Administration for the high need cures funded by the CAN, through activities that may include—

(A) the facilitation of regular and ongoing communication with the Food and Drug Administration regarding the status of activities conducted under this section;

(B) ensuring that such activities are coordinated with the approval requirements of the Food and Drug Administration, with the goal of expediting the development and approval of countermeasures and products; and

(C) connecting interested persons with additional technical assistance made available under section 360bbb-4 of title 21.

**(d) CAN Board**

**(1) Establishment**

There is established a Cures Acceleration Network Review Board (referred to in this section as the “Board”), which shall advise the Director of the Center on the conduct of the activities of the Cures Acceleration Network.

**(2) Membership**

**(A) In general**

**(i) Appointment**

The Board shall be comprised of 24 members who are appointed by the Secretary

and who serve at the pleasure of the Secretary.

**(ii) Chairperson and Vice Chairperson**

The Secretary shall designate, from among the 24 members appointed under clause (i), one Chairperson of the Board (referred to in this section as the “Chairperson”) and one Vice Chairperson.

**(B) Terms**

**(i) In general**

Each member shall be appointed to serve a 4-year term, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member’s predecessor was appointed shall be appointed for the remainder of such term.

**(ii) Consecutive appointments; maximum terms**

A member may be appointed to serve not more than 3 terms on the Board, and may not serve more than 2 such terms consecutively.

**(C) Qualifications**

**(i) In general**

The Secretary shall appoint individuals to the Board based solely upon the individual’s established record of distinguished service in one of the areas of expertise described in clause (ii). Each individual appointed to the Board shall be of distinguished achievement and have a broad range of disciplinary interests.

**(ii) Expertise**

The Secretary shall select individuals based upon the following requirements:

(I) For each of the fields of—

(aa) basic research;

(bb) medicine;

(cc) biopharmaceuticals;

(dd) discovery and delivery of medical products;

(ee) bioinformatics and gene therapy;

(ff) medical instrumentation; and

(gg) regulatory review and approval of medical products,

the Secretary shall select at least 1 individual who is eminent in such fields.

(II) At least 4 individuals shall be recognized leaders in professional venture capital or private equity organizations and have demonstrated experience in private equity investing.

(III) At least 8 individuals shall represent disease advocacy organizations.

**(3) Ex-officio members**

**(A) Appointment**

In addition to the 24 Board members described in paragraph (2), the Secretary shall appoint as ex-officio members of the Board—

(i) a representative of the National Institutes of Health, recommended by the Secretary of the Department of Health and Human Services;

(ii) a representative of the Office of the Assistant Secretary of Defense for Health

Affairs, recommended by the Secretary of Defense;

(iii) a representative of the Office of the Under Secretary for Health for the Veterans Health Administration, recommended by the Secretary of Veterans Affairs;

(iv) a representative of the National Science Foundation, recommended by the Chair of the National Science Board; and

(v) a representative of the Food and Drug Administration, recommended by the Commissioner of Food and Drugs.

**(B) Terms**

Each ex-officio member shall serve a 3-year term on the Board, except that the Chairperson may adjust the terms of the initial ex-officio members in order to provide for a staggered term of appointment for all such members.

**(4) Responsibilities of the Board and the Director of the Center**

**(A) Responsibilities of the Board**

**(i) In general**

The Board shall advise, and provide recommendations to, the Director of the Center with respect to—

(I) policies, programs, and procedures for carrying out the duties of the Director of the Center under this section; and

(II) significant barriers to successful translation of basic science into clinical application (including issues under the purview of other agencies and departments).

**(ii) Report**

In the case that the Board identifies a significant barrier, as described in clause (i)(II), the Board shall submit to the Secretary a report regarding such barrier.

**(B) Responsibilities of the Director of the Center**

With respect to each recommendation provided by the Board under subparagraph (A)(i), the Director of the Center shall respond in writing to the Board, indicating whether such Director will implement such recommendation. In the case that the Director of the Center indicates a recommendation of the Board will not be implemented, such Director shall provide an explanation of the reasons for not implementing such recommendation.

**(5) Meetings**

**(A) In general**

The Board shall meet 4 times per calendar year, at the call of the Chairperson.

**(B) Quorum; requirements; limitations**

**(i) Quorum**

A quorum shall consist of a total of 13 members of the Board, excluding ex-officio members, with diverse representation as described in clause (iii).

**(ii) Chairperson or Vice Chairperson**

Each meeting of the Board shall be attended by either the Chairperson or the Vice Chairperson.

**(iii) Diverse representation**

At each meeting of the Board, there shall be not less than one scientist, one representative of a disease advocacy organization, and one representative of a professional venture capital or private equity organization.

**(6) Compensation and travel expenses**

**(A) Compensation**

Members shall receive compensation at a rate to be fixed by the Chairperson but not to exceed a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5 for each day (including travel time) during which the member is engaged in the performance of the duties of the Board. All members of the Board who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

**(B) Travel expenses**

Members of the Board shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for persons employed intermittently by the Federal Government under section 5703(b)<sup>3</sup> of title 5, while away from their homes or regular places of business in the performance of services for the Board.

**(e) Grant program**

**(1) Supporting innovation**

To carry out the purposes described in this section, the Director of the Center shall award contracts, grants, or cooperative agreements to the entities described in paragraph (2), to—

(A) promote innovation in technologies supporting the advanced research and development and production of high need cures, including through the development of medical products and behavioral therapies.

(B) accelerate the development of high need cures, including through the development of medical products, behavioral therapies, and biomarkers that demonstrate the safety or effectiveness of medical products; or

(C) help the award recipient establish protocols that comply with Food and Drug Administration standards and otherwise permit the recipient to meet regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product.

**(2) Eligible entities**

To receive assistance under paragraph (1), an entity shall—

(A) be a public or private entity, which may include a private or public research institution, an institution of higher education, a medical center, a biotechnology company, a pharmaceutical company, a disease advo-

<sup>3</sup>So in original. Section 5703 of title 5 does not contain a subsec. (b).

cacy organization, a patient advocacy organization, or an academic research institution;

(B) submit an application containing—

(i) a detailed description of the project for which the entity seeks such grant or contract;

(ii) a timetable for such project;

(iii) an assurance that the entity will submit—

(I) interim reports describing the entity's—

(aa) progress in carrying out the project; and

(bb) compliance with all provisions of this section and conditions of receipt of such grant or contract; and

(II) a final report at the conclusion of the grant period, describing the outcomes of the project; and

(iv) a description of the protocols the entity will follow to comply with Food and Drug Administration standards and regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product; and

(C) provide such additional information as the Director of the Center may require.

### **(3) Awards**

#### **(A) The cures acceleration partnership awards**

##### **(i) Initial award amount**

Each award under this subparagraph shall be not more than \$15,000,000 per project for the first fiscal year for which the project is funded, which shall be payable in one payment.

##### **(ii) Funding in subsequent fiscal years**

An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Director of the Center the information required under subparagraphs (B) and (C) of paragraph (2). The Director may fund a project of such eligible entity in an amount not to exceed \$15,000,000 for a fiscal year subsequent to the initial award under clause (i).

##### **(iii) Matching funds**

As a condition for receiving an award under this subsection, an eligible entity shall contribute to the project non-Federal funds in the amount of \$1 for every \$3 awarded under clauses (i) and (ii), except that the Director of the Center may waive or modify such matching requirement in any case where the Director determines that the goals and objectives of this section cannot adequately be carried out unless such requirement is waived.

#### **(B) The cures acceleration grant awards**

##### **(i) Initial award amount**

Each award under this subparagraph shall be not more than \$15,000,000 per project for the first fiscal year for which

the project is funded, which shall be payable in one payment.

##### **(ii) Funding in subsequent fiscal years**

An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Board the information required under subparagraphs (B) and (C) of paragraph (2). The Director of the Center may fund a project of such eligible entity in an amount not to exceed \$15,000,000 for a fiscal year subsequent to the initial award under clause (i).

#### **(C) The cures acceleration flexible research awards**

If the Director of the Center determines that the goals and objectives of this section cannot adequately be carried out through a contract, grant, or cooperative agreement, the Director of the Center shall have flexible research authority to use other transactions to fund projects in accordance with the terms and conditions of this section. Awards made under such flexible research authority for a fiscal year shall not exceed 20 percent of the total funds appropriated under subsection (g)(1) for such fiscal year.

#### **(4) Suspension of awards for defaults, non-compliance with provisions and plans, and diversion of funds; repayment of funds**

The Director of the Center may suspend the award to any entity upon noncompliance by such entity with provisions and plans under this section or diversion of funds.

#### **(5) Audits**

The Director of the Center may enter into agreements with other entities to conduct periodic audits of the projects funded by grants or contracts awarded under this subsection.

#### **(6) Closeout procedures**

At the end of a grant or contract period, a recipient shall follow the closeout procedures under section 74.71 of title 45, Code of Federal Regulations (or any successor regulation).

#### **(7) Review**

A determination by the Director of the Center as to whether a drug, device, or biological product is a high need cure (for purposes of subsection (a)(3)) shall not be subject to judicial review.

#### **(f) Competitive basis of awards**

Any grant, cooperative agreement, or contract awarded under this section shall be awarded on a competitive basis.

#### **(g) Authorization of appropriations**

##### **(1) In general**

For purposes of carrying out this section, there are authorized to be appropriated \$500,000,000 for fiscal year 2010, and such sums as may be necessary for subsequent fiscal years. Funds appropriated under this section shall be available until expended.

##### **(2) Limitation on use of funds otherwise appropriated**

No funds appropriated under this chapter, other than funds appropriated under para-

graph (1), may be allocated to the Cures Acceleration Network.

(July 1, 1944, ch. 373, title IV, § 480, formerly § 402C, as added Pub. L. 111-148, title X, § 10409(d), Mar. 23, 2010, 124 Stat. 978; renumbered § 480 and amended Pub. L. 112-74, div. F, title II, § 221(c)(1), Dec. 23, 2011, 125 Stat. 1089.)

#### REFERENCES IN TEXT

Section 262(i) of this title, referred to in subsec. (a)(3), was in the original “section 262(i)”, and was translated as meaning section 351(i) of act July 1, 1944, ch. 373, to reflect the probable intent of Congress.

#### CODIFICATION

Section was formerly classified to section 282d of this title.

#### PRIOR PROVISIONS

A prior section 287a, July 1, 1944, ch. 373, title IV, § 480, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 864; amended Pub. L. 101-381, title I, § 102(3), Aug. 18, 1990, 104 Stat. 586; Pub. L. 102-405, title III, § 302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 103-43, title XV, § 1501(2)(C), (D), title XX, §§ 2008(b)(12), 2010(b)(4), June 10, 1993, 107 Stat. 172, 173, 211, 214, related to the advisory council for the National Center for Research Resources, prior to repeal by Pub. L. 112-74, div. F, title II, § 221(a)(1)(B), Dec. 23, 2011, 125 Stat. 1086.

#### AMENDMENTS

2011—Pub. L. 112-74, § 221(c)(1)(C), substituted “Director of the Center” for “Director of NIH” wherever appearing.

Subsec. (b), Pub. L. 112-74, § 221(c)(1)(B), substituted “within the Center” for “within the Office of the Director of NIH” in introductory provisions.

Subsec. (d)(4), Pub. L. 112-74, § 221(c)(1)(D), substituted “Director of the Center” for “Director of NIH” in heading.

Subsec. (d)(4)(B), Pub. L. 112-74, § 221(c)(1)(D), substituted “Director of the Center” for “Director of NIH” in heading.

### § 287a-1. Office of Rare Diseases

#### (a) Establishment

There is established within the Center an office to be known as the Office of Rare Diseases (in this section referred to as the “Office”), which shall be headed by a Director (in this section referred to as the “Director”), appointed by the Director of the Center.

#### (b) Duties

##### (1) In general

The Director of the Office shall carry out the following:

(A) The Director shall recommend an agenda for conducting and supporting research on rare diseases through the national research institutes and centers. The agenda shall provide for a broad range of research and education activities, including scientific workshops and symposia to identify research opportunities for rare diseases.

(B) The Director shall, with respect to rare diseases, promote coordination and cooperation among the national research institutes and centers and entities whose research is supported by such institutes.

(C) The Director, in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health,

may enter into cooperative agreements with and make grants for regional centers of excellence on rare diseases in accordance with section 287a-2 of this title.

(D) The Director shall promote the sufficient allocation of the resources of the National Institutes of Health for conducting and supporting research on rare diseases.

(E) The Director shall promote and encourage the establishment of a centralized clearinghouse for rare and genetic disease information that will provide understandable information about these diseases to the public, medical professionals, patients and families.

#### (2) Principal advisor regarding orphan diseases

With respect to rare diseases, the Director shall serve as the principal advisor to the Director of NIH and shall provide advice to other relevant agencies. The Director shall provide liaison with national and international patient, health and scientific organizations concerned with rare diseases.

#### (c) Definition

For purposes of this section, the term “rare disease” means any disease or condition that affects less than 200,000 persons in the United States.

(July 1, 1944, ch. 373, title IV, § 481, formerly § 404F, as added Pub. L. 107-280, § 3, Nov. 6, 2002, 116 Stat. 1989; amended Pub. L. 109-482, title I, §§ 103(b)(5), 104(b)(1)(B), Jan. 15, 2007, 120 Stat. 3687, 3693; renumbered § 481 and amended Pub. L. 112-74, div. F, title II, § 221(c)(2)(A), Dec. 23, 2011, 125 Stat. 1089.)

#### CODIFICATION

Section was formerly classified to section 283h of this title.

#### PRIOR PROVISIONS

A prior section 287a-1, act July 1, 1944, ch. 373, title IV, § 481, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 866; amended Pub. L. 103-43, title XV, § 1501(2)(C), (D), June 10, 1993, 107 Stat. 172, 173, required biennial reports regarding the activities and policies of the National Center for Research Resources, prior to repeal by Pub. L. 112-74, div. F, title II, § 221(a)(1)(B), Dec. 23, 2011, 125 Stat. 1086.

#### AMENDMENTS

2011—Subsec. (a), Pub. L. 112-74, § 221(c)(2)(A)(ii), substituted “within the Center” for “within the Office of the Director of NIH” and “Director of the Center” for “Director of NIH”.

Subsec. (b)(1)(C), Pub. L. 112-74, § 221(c)(2)(A)(iii), substituted “287a-2” for “283i”.

2007—Subsec. (b)(1)(F), (G), Pub. L. 109-482, § 104(b)(1)(B), struck out subpars. (F) and (G) which read as follows:

“(F) The Director shall biennially prepare a report that describes the research and education activities on rare diseases being conducted or supported through the national research institutes and centers, and that identifies particular projects or types of projects that should in the future be conducted or supported by the national research institutes and centers or other entities in the field of research on rare diseases.

“(G) The Director shall prepare the NIH Director’s annual report to Congress on rare disease research conducted by or supported through the national research institutes and centers.”

Subsec. (d). Pub. L. 109-482, §103(b)(5), struck out heading and text of subsec. (d). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and \$4,000,000 for each of the fiscal years 2003 through 2006."

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

FINDINGS AND PURPOSES

Pub. L. 107-280, §2, Nov. 6, 2002, 116 Stat. 1988, provided that:

"(a) FINDINGS.—Congress makes the following findings:

"(1) Rare diseases and disorders are those which affect small patient populations, typically populations smaller than 200,000 individuals in the United States. Such diseases and conditions include Huntington's disease, amyotrophic lateral sclerosis (Lou Gehrig's disease), Tourette syndrome, Crohn's disease, cystic fibrosis, cystinosis, and Duchenne muscular dystrophy.

"(2) For many years, the 25,000,000 Americans suffering from the over 6,000 rare diseases and disorders were denied access to effective medicines because prescription drug manufacturers could rarely make a profit from marketing drugs for such small groups of patients. The prescription drug industry did not adequately fund research into such treatments. Despite the urgent health need for these medicines, they came to be known as 'orphan drugs' because no companies would commercialize them.

"(3) During the 1970s, an organization called the National Organization for Rare Disorders (NORD) was founded to provide services and to lobby on behalf of patients with rare diseases and disorders. NORD was instrumental in pressing Congress for legislation to encourage the development of orphan drugs.

"(4) The Orphan Drug Act [Pub. L. 97-414, see Short Title of 1983 Amendments note set out under section 301 of Title 21, Food and Drugs] created financial incentives for the research and production of such orphan drugs. New Federal programs at the National Institutes of Health and the Food and Drug Administration encouraged clinical research and commercial product development for products that target rare diseases. An Orphan Products Board was established to promote the development of drugs and devices for rare diseases or disorders.

"(5) Before 1983, some 38 orphan drugs had been developed. Since the enactment of the Orphan Drug Act [Jan. 4, 1983], more than 220 new orphan drugs have been approved and marketed in the United States and more than 800 additional drugs are in the research pipeline.

"(6) Despite the tremendous success of the Orphan Drug Act, rare diseases and disorders deserve greater emphasis in the national biomedical research enterprise. The Office of Rare Diseases at the National Institutes of Health was created in 1993, but lacks a statutory authorization.

"(7) The National Institutes of Health has received a substantial increase in research funding from Congress for the purpose of expanding the national investment of the United States in behavioral and biomedical research.

"(8) Notwithstanding such increases, funding for rare diseases and disorders at the National Institutes of Health has not increased appreciably.

"(9) To redress this oversight, the Department of Health and Human Services has proposed the establishment of a network of regional centers of excellence for research on rare diseases.

"(b) PURPOSES.—The purposes of this Act [see Short Title of 2002 Amendments note set out under section 201 of this title] are to—

"(1) amend the Public Health Service Act [42 U.S.C. 201 et seq.] to establish an Office of Rare Diseases at the National Institutes of Health; and

"(2) increase the national investment in the development of diagnostics and treatments for patients with rare diseases and disorders."

**§ 287a-2. Rare disease regional centers of excellence**

**(a) Cooperative agreements and grants**

**(1) In general**

The Director of the Office of Rare Diseases (in this section referred to as the "Director"), in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for regional centers of excellence for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for rare diseases.

**(2) Policies**

A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH.

**(b) Coordination with other institutes**

The Director shall coordinate the activities under this section with similar activities conducted by other national research institutes, centers and agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

**(c) Uses for Federal payments under cooperative agreements or grants**

Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

(3) clinical research and demonstration programs.

**(d) Period of support; additional periods**

Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, §481A, formerly §404G, as added Pub. L. 107-280, §4, Nov. 6, 2002, 116 Stat. 1990; amended Pub. L. 109-482, title I,

§ 103(b)(6), Jan. 15, 2007, 120 Stat. 3687; renumbered § 481A, Pub. L. 112-74, div. F, title II, § 221(c)(3), Dec. 23, 2011, 125 Stat. 1089.)

#### CODIFICATION

Section was formerly classified to section 283i of this title.

#### PRIOR PROVISIONS

A prior section 481A of act July 1, 1944, was renumbered section 404I, and is classified to section 283k of this title.

#### AMENDMENTS

2007—Subsec. (e). Pub. L. 109-482 struck out heading and text of subsec. (e). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and \$20,000,000 for each of the fiscal years 2003 through 2006.”

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

### §§ 287a-3, 287a-3a. Transferred

#### CODIFICATION

Section 287a-3, act July 1, 1944, ch. 373, title IV, § 481B, as added Pub. L. 103-43, title XV, § 1503, June 10, 1993, 107 Stat. 178; amended Pub. L. 105-392, title IV, § 411, Nov. 13, 1998, 112 Stat. 3590; Pub. L. 106-505, title III, § 304, Nov. 13, 2000, 114 Stat. 2335; Pub. L. 109-482, title I, § 103(b)(41), Jan. 15, 2007, 120 Stat. 3688, which related to construction of regional centers for research on primates, was renumbered section 404J of act July 1, 1944, by Pub. L. 112-74, div. F, title II, § 221(b)(2)(A), Dec. 23, 2011, 125 Stat. 1088, and transferred to section 283l of this title.

Section 287a-3a, July 1, 1944, ch. 373, title IV, § 481C, as added Pub. L. 106-551, § 2, Dec. 20, 2000, 114 Stat. 2752; amended Pub. L. 110-170, § 2(a), Dec. 26, 2007, 121 Stat. 2465, which related to sanctuary system for surplus chimpanzees, was renumbered section 404K of act July 1, 1944, by Pub. L. 112-74, div. F, title II, § 221(b)(3)(A), Dec. 23, 2011, 125 Stat. 1088, and transferred to section 283m of this title.

A prior section 481C of act July 1, 1944, was renumbered section 481B of act July 1, 1944, and is classified to section 287a-4 of this title.

### § 287a-4. General clinical research centers

#### (a) Grants

The Director of the Center shall award grants for the establishment of general clinical research centers to provide the infrastructure for clinical research including clinical research training and career enhancement. Such centers shall support clinical studies and career development in all settings of the hospital or academic medical center involved.

#### (b) Activities

In carrying out subsection (a), the Director of National Institutes of Health shall expand the activities of the general clinical research centers through the increased use of telecommunications and telemedicine initiatives.

(July 1, 1944, ch. 373, title IV, § 481B, formerly § 481C, as added Pub. L. 106-505, title II, § 204(a), Nov. 13, 2000, 114 Stat. 2327; amended Pub. L. 109-482, title I, § 103(b)(42), Jan. 15, 2007, 120 Stat. 3688; renumbered § 481D, Pub. L. 110-170, § 2(b),

Dec. 26, 2007, 121 Stat. 2466; renumbered § 481B and amended Pub. L. 112-74, div. F, title II, § 221(c)(4), Dec. 23, 2011, 125 Stat. 1089.)

#### PRIOR PROVISIONS

A prior section 481B of act July 1, 1944, was renumbered section 404J, and is classified to section 283l of this title.

#### AMENDMENTS

2011—Subsec. (a). Pub. L. 112-74, § 221(c)(4)(B), substituted “Director of the Center” for “Director of the National Center for Research Resources”.

2007—Subsec. (c). Pub. L. 109-482 struck out heading and text of subsec. (c). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.”

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### SUBPART 2—JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN HEALTH SCIENCES

### § 287b. General purpose

The general purpose of the John E. Fogarty International Center for Advanced Study in the Health Sciences is to—

(1) facilitate the assembly of scientists and others in the biomedical, behavioral, and related fields for discussion, study, and research relating to the development of health science internationally;

(2) provide research programs, conferences, and seminars to further international cooperation and collaboration in the life sciences;

(3) provide postdoctorate fellowships for research training in the United States and abroad and promote exchanges of senior scientists between the United States and other countries;

(4) coordinate the activities of the National Institutes of Health concerned with the health sciences internationally; and

(5) receive foreign visitors to the National Institutes of Health.

(July 1, 1944, ch. 373, title IV, § 482, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 866.)

#### SUBPART 3—NATIONAL CENTER FOR HUMAN GENOME RESEARCH

#### CODIFICATION

Subpart 3 of part E of title IV of act July 1, 1944, comprising this subpart, was renumbered subpart 19 of part C of title IV by Pub. L. 109-482, title I, § 101(c)(1)–(3), Jan. 15, 2007, 120 Stat. 3681, and is classified to subpart 19 (§ 285s) of part C of this subchapter.

### § 287c. Transferred

#### CODIFICATION

Section, act July 1, 1944, ch. 373, title IV, § 485B, as added Pub. L. 103-43, title XV, § 1521(2), June 10, 1993, 107 Stat. 180, which set out the purpose of the National Center for Human Genome Research, was renumbered section 464z-1 of act July 1, 1944, by Pub. L. 109-482, title I, § 101(c)(4)(A), Jan. 15, 2007, 120 Stat. 3681, and transferred to section 285s of this title.

## PRIOR PROVISIONS

Another prior section 287c, act July 1, 1944, ch. 373, title IV, § 483, as added Nov. 20, 1985, Pub. L. 99-158, § 2, 99 Stat. 867, and amended, which related to purpose of National Center for Nursing Research, was renumbered section 464V of act July 1, 1944, by Pub. L. 103-43, title XV, § 1511(b)(2), June 10, 1993, 107 Stat. 179, and transferred to section 285q of this title.

A prior section 287c-1, act July 1, 1944, ch. 373, title IV, § 484, as added Nov. 20, 1985, Pub. L. 99-158, § 2, 99 Stat. 867, and amended, which related to specific authorities of the Director of the Center, was renumbered section 464W of act July 1, 1944, by Pub. L. 103-43, title XV, § 1511(b)(2), June 10, 1993, 107 Stat. 179, and transferred to section 285q-1 of this title.

A prior section 287c-2, act July 1, 1944, ch. 373, title IV, § 485, as added Nov. 20, 1985, Pub. L. 99-158, § 2, 99 Stat. 867, and amended, which related to the advisory council for the Center, was renumbered section 464X of act July 1, 1944, by Pub. L. 103-43, title XV, § 1511(b)(2), June 10, 1993, 107 Stat. 179, and transferred to section 285q-2 of this title.

A prior section 287c-3, act July 1, 1944, ch. 373, title IV, § 486, as added Nov. 20, 1985, Pub. L. 99-158, § 2, 99 Stat. 869, and amended, which related to biennial report of activities of the Center, was renumbered section 464Y of act July 1, 1944, by Pub. L. 103-43, title XV, § 1511(b)(2), June 10, 1993, 107 Stat. 179, and transferred to section 285q-3 of this title. Section 285q-3 was subsequently repealed by Pub. L. 114-255, div. A, title II, § 2042(h)(1), Dec. 13, 2016, 130 Stat. 1073.

## SUBPART 4—OFFICE OF DIETARY SUPPLEMENTS

## § 287c-11. Dietary supplements

## (a) Establishment

The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.

## (b) Purpose

The purposes of the Office are—

- (1) to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and
- (2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

## (c) Duties

The Director of the Office of Dietary Supplements shall—

- (1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;
- (2) collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine;<sup>1</sup>
- (3) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including—

- (A) dietary intake regulations;
- (B) the safety of dietary supplements;
- (C) claims characterizing the relationship between—
  - (i) dietary supplements; and
  - (ii)(I) prevention of disease or other health-related conditions; and
  - (II) maintenance of health; and
- (D) scientific issues arising in connection with the labeling and composition of dietary supplements;

(4) compile a database of scientific research on dietary supplements and individual nutrients; and

(5) coordinate funding relating to dietary supplements for the National Institutes of Health.

## (d) “Dietary supplement” defined

As used in this section, the term “dietary supplement” has the meaning given the term in section 321(ff) of title 21.

(July 1, 1944, ch. 373, title IV, § 485C, as added Pub. L. 103-417, § 13(a), Oct. 25, 1994, 108 Stat. 4334; amended Pub. L. 109-482, title I, § 103(b)(43), Jan. 15, 2007, 120 Stat. 3688.)

## REFERENCES IN TEXT

The Office of Alternative Medicine, referred to in subsec. (c)(2), probably should be a reference to the National Center for Complementary and Integrative Health. Establishment of the Office of Alternative Medicine was repealed and authority for the National Center for Complementary and Alternative Medicine was enacted by Pub. L. 105-277, div. A, § 101(f) [title VI, § 601], Oct. 21, 1998, 112 Stat. 2681-337, 2681-387. The National Center for Complementary and Alternative Medicine was renamed the National Center for Complementary and Integrative Health by Pub. L. 113-235, div. G, title II, § 224(1), Dec. 16, 2014, 128 Stat. 2490. See section 287c-21 of this title and Prior Provisions note under section 283g of this title.

## AMENDMENTS

2007—Subsec. (e). Pub. L. 109-482 struck out heading and text of subsec. (e). Text read as follows: “There are authorized to be appropriated to carry out this section \$5,000,000 for fiscal year 1994 and such sums as may be necessary for each subsequent fiscal year.”

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

## SUBPART 5—NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH

## AMENDMENTS

2014—Pub. L. 113-235, div. G, title II, § 224(1), Dec. 16, 2014, 128 Stat. 2490, substituted “NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH” for “NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE” in subpart heading.

## § 287c-21. Purpose of Center

## (a) In general

The general purposes of the National Center for Complementary and Integrative Health (in this subpart referred to as the “Center”) are the conduct and support of basic and applied research (including both intramural and extra-

<sup>1</sup> See References in Text note below.

mural research), research training, the dissemination of health information, and other programs with respect to identifying, investigating, and validating complementary and integrative health, diagnostic and prevention modalities, disciplines and systems. The Center shall be headed by a director, who shall be appointed by the Secretary. The Director of the Center shall report directly to the Director of NIH.

**(b) Advisory council**

The Secretary shall establish an advisory council for the Center in accordance with section 284a of this title, except that at least half of the members of the advisory council who are not ex officio members shall include practitioners licensed in one or more of the major systems with which the Center is concerned, and at least 3 individuals representing the interests of individual consumers of complementary and integrative health.

**(c) Integration of new and non-traditional approaches**

In carrying out subsection (a), the Director of the Center shall, as appropriate, study the integration of new and non-traditional approaches to health care treatment and consumption, including but not limited to non-traditional treatment, diagnostic and prevention systems, modalities, and disciplines.

**(d) Appropriate scientific expertise and coordination with institutes and Federal agencies**

The Director of the Center, after consultation with the advisory council for the Center and the division of research grants, shall ensure that scientists with appropriate expertise in research on complementary and integrative health are incorporated into the review, oversight, and management processes of all research projects and other activities funded by the Center. In carrying out this subsection, the Director of the Center, as necessary, may establish review groups with appropriate scientific expertise. The Director of the Center shall coordinate efforts with other Institutes and Federal agencies to ensure appropriate scientific input and management.

**(e) Evaluation of various disciplines and systems**

In carrying out subsection (a), the Director of the Center shall identify and evaluate complementary and integrative health, diagnostic and prevention modalities in each of the disciplines and systems with which the Center is concerned, including each discipline and system in which accreditation, national certification, or a State license is available.

**(f) Ensuring high quality, rigorous scientific review**

In order to ensure high quality, rigorous scientific review of complementary and alternative, diagnostic and prevention modalities, disciplines and systems, the Director of the Center shall conduct or support the following activities:

- (1) Outcomes research and investigations.
- (2) Epidemiological studies.
- (3) Health services research.
- (4) Basic science research.
- (5) Clinical trials.

(6) Other appropriate research and investigational activities.

The Director of NIH, in coordination with the Director of the Center, shall designate specific personnel in each Institute to serve as full-time liaisons with the Center in facilitating appropriate coordination and scientific input.

**(g) Data system; information clearinghouse**

**(1) Data system**

The Director of the Center shall establish a bibliographic system for the collection, storage, and retrieval of worldwide research relating to complementary and integrative health, diagnostic and prevention modalities, disciplines and systems. Such a system shall be regularly updated and publicly accessible.

**(2) Clearinghouse**

The Director of the Center shall establish an information clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of integrative health treatment, diagnostic and prevention practices by health professionals, patients, industry, and the public.

**(h) Research centers**

The Director of the Center, after consultation with the advisory council for the Center, shall provide support for the development and operation of multipurpose centers to conduct research and other activities described in subsection (a) with respect to complementary and integrative health, diagnostic and prevention modalities, disciplines and systems. The provision of support for the development and operation of such centers shall include accredited complementary and integrative health research and education facilities.

**(i) Availability of resources**

After consultation with the Director of the Center, the Director of NIH shall ensure that resources of the National Institutes of Health, including laboratory and clinical facilities, fellowships (including research training fellowship and junior and senior clinical fellowships), and other resources are sufficiently available to enable the Center to appropriately and effectively carry out its duties as described in subsection (a). The Director of NIH, in coordination with the Director of the Center, shall designate specific personnel in each Institute to serve as full-time liaisons with the Center in facilitating appropriate coordination and scientific input.

**(j) Availability of appropriations**

Amounts appropriated to carry out this section for fiscal year 1999 are available for obligation through September 30, 2001. Amounts appropriated to carry out this section for fiscal year 2000 are available for obligation through September 30, 2001.

(July 1, 1944, ch. 373, title IV, §485D, as added Pub. L. 105-277, div. A, §101(f) [title VI, §601(2)], Oct. 21, 1998, 112 Stat. 2681-337, 2681-387; amended Pub. L. 113-235, div. G, title II, §224, Dec. 16, 2014, 128 Stat. 2490.)

AMENDMENTS

2014—Subsec. (a). Pub. L. 113-235, §224(1), (3), substituted “National Center for Complementary and Inte-

grative Health” for “National Center for Complementary and Alternative Medicine” and “complementary and integrative health” for “complementary and alternative treatment”.

Subsec. (b). Pub. L. 113-235, § 224(2), substituted “integrative health” for “alternative medicine”.

Subsec. (c). Pub. L. 113-235, § 224(5), added subsec. (c) and struck out former subsec. (c). Prior to amendment, text read as follows: “In carrying out subsection (a) of this section, the Director of the Center shall, as appropriate, study the integration of alternative treatment, diagnostic and prevention systems, modalities, and disciplines with the practice of conventional medicine as a complement to such medicine and into health care delivery systems in the United States.”

Subsec. (d). Pub. L. 113-235, § 224(2), substituted “integrative health” for “alternative medicine”.

Subsec. (e). Pub. L. 113-235, § 224(3), substituted “complementary and integrative health” for “alternative and complementary medical treatment”.

Subsec. (g)(1). Pub. L. 113-235, § 224(3), substituted “complementary and integrative health” for “complementary and alternative treatment”.

Subsec. (g)(2). Pub. L. 113-235, § 224(4), substituted “integrative health treatment” for “alternative medical treatment”.

Subsec. (h). Pub. L. 113-235, § 224(2), (3), substituted “complementary and integrative health,” for “complementary and alternative treatment,” and “integrative health research” for “alternative medicine research”.

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

EXECUTIVE ORDER No. 13147

Ex. Ord. No. 13147, Mar. 7, 2000, 65 F.R. 13233, as amended by Ex. Ord. No. 13167, Sept. 15, 2000, 65 F.R. 54079 [57079], 65 F.R. 57436, which established White House Commission on Complementary and Alternative Medicine Policy, was revoked by Ex. Ord. No. 13316, § 3(i), Sept. 17, 2003, 68 F.R. 55256, eff. Sept. 30, 2003.

SUBPART 6—TRANSFERRED

CODIFICATION

Subpart 6 of part E of title IV of act July 1, 1944, comprising this subpart, was renumbered subpart 20 of part C of title IV by Pub. L. 111-148, title X, § 10334(c)(1)(A)–(C), Mar. 23, 2010, 124 Stat. 973, and is classified to subpart 20 (§ 285t et seq.) of part C of this subchapter.

§§ 287c-31 to 287c-34. Transferred

CODIFICATION

Section 287c-31, act July 1, 1944, ch. 373, title IV, § 485E, as added Pub. L. 106-525, title I, § 101(a), Nov. 22, 2000, 114 Stat. 2497; amended Pub. L. 109-482, title I, § 103(b)(44), 104(b)(1)(N), Jan. 15, 2007, 120 Stat. 3688, 3693, which set out the purpose of the National Center on Minority Health and Health Disparities, was renum-

bered section 464z-3 of act July 1, 1944, and transferred to section 285t of this title.

Section 287c-32, act July 1, 1944, ch. 373, title IV, § 485F, as added Pub. L. 106-525, title I, § 102, Nov. 22, 2000, 114 Stat. 2501; amended Pub. L. 109-482, title I, § 103(b)(45), Jan. 15, 2007, 120 Stat. 3688, which related to centers of excellence for research education and training, was renumbered section 464z-4 of act July 1, 1944, and transferred to section 285t-1 of this title.

Section 287c-33, act July 1, 1944, ch. 373, title IV, § 485G, as added Pub. L. 106-525, title I, § 103, Nov. 22, 2000, 114 Stat. 2503; amended Pub. L. 109-482, title I, § 103(b)(46), Jan. 15, 2007, 120 Stat. 3688, which related to loan repayment program for minority health disparities research, was renumbered section 464z-5 of act July 1, 1944, and transferred to section 285t-2 of this title, prior to repeal by Pub. L. 114-255, div. A, title II, § 2022(c)(1), Dec. 13, 2016, 130 Stat. 1054.

Section 287c-34, act July 1, 1944, ch. 373, title IV, § 485H, as added Pub. L. 106-525, title I, § 104, Nov. 22, 2000, 114 Stat. 2503; amended Pub. L. 109-482, title I, § 104(b)(1)(O), Jan. 15, 2007, 120 Stat. 3693, which related to administrative support and support services, was renumbered section 464z-6 of act July 1, 1944, and transferred to section 285t-3 of this title.

PART F—RESEARCH ON WOMEN’S HEALTH

§ 287d. Office of Research on Women’s Health

(a) Establishment

There is established within the Office of the Director of NIH an office to be known as the Office of Research on Women’s Health (in this part referred to as the “Office”). The Office shall be headed by a director, who shall be appointed by the Director of NIH and who shall report directly to the Director.

(b) Purpose

The Director of the Office shall—

(1) identify projects of research on women’s health that should be conducted or supported by the national research institutes;

(2) identify multidisciplinary research relating to research on women’s health that should be so conducted or supported;

(3) carry out paragraphs (1) and (2) with respect to the aging process in women, with priority given to menopause;

(4) promote coordination and collaboration among entities conducting research identified under any of paragraphs (1) through (3);

(5) encourage the conduct of such research by entities receiving funds from the national research institutes;

(6) recommend an agenda for conducting and supporting such research;

(7) promote the sufficient allocation of the resources of the national research institutes for conducting and supporting such research;

(8) assist in the administration of section 289a-2 of this title with respect to the inclusion of women as subjects in clinical research; and

(9) prepare the report required in section 287d-2 of this title.

(c) Coordinating Committee

(1) In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women’s Health (in this subsection referred to as the “Coordinating Committee”).

(2) The Coordinating Committee shall be composed of the Directors of the national research

institutes (or the senior-level staff designees of the Directors).

(3) The Director of the Office shall serve as the chair of the Coordinating Committee.

(4) With respect to research on women's health, the Coordinating Committee shall assist the Director of the Office in—

(A) identifying the need for such research, and making an estimate each fiscal year of the funds needed to adequately support the research;

(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities;

(C) supporting the development of methodologies to determine the circumstances in which obtaining data specific to women (including data relating to the age of women and the membership of women in ethnic or racial groups) is an appropriate function of clinical trials of treatments and therapies;

(D) supporting the development and expansion of clinical trials of treatments and therapies for which obtaining such data has been determined to be an appropriate function; and

(E) encouraging the national research institutes to conduct and support such research, including such clinical trials.

**(d) Advisory Committee**

(1) In carrying out subsection (b), the Director of the Office shall establish an advisory committee to be known as the Advisory Committee on Research on Women's Health (in this subsection referred to as the "Advisory Committee").

(2) The Advisory Committee shall be composed of no fewer than 12, and not more than 18 individuals, who are not officers or employees of the Federal Government. The Director of NIH shall make appointments to the Advisory Committee from among physicians, practitioners, scientists, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on research on women's health. A majority of the members of the Advisory Committee shall be women.

(3) The Director of the Office shall serve as the chair of the Advisory Committee.

(4) The Advisory Committee shall—

(A) advise the Director of the Office on appropriate research activities to be undertaken by the national research institutes with respect to—

(i) research on women's health;

(ii) research on gender differences in clinical drug trials, including responses to pharmacological drugs;

(iii) research on gender differences in disease etiology, course, and treatment;

(iv) research on obstetrical and gynecological health conditions, diseases, and treatments; and

(v) research on women's health conditions which require a multidisciplinary approach;

(B) report to the Director of the Office on such research;

(C) provide recommendations to such Director regarding activities of the Office (including recommendations on the development of

the methodologies described in subsection (c)(4)(C) and recommendations on priorities in carrying out research described in subparagraph (A)); and

(D) assist in monitoring compliance with section 289a-2 of this title regarding the inclusion of women in clinical research.

(5)(A) The Advisory Committee shall prepare a biennial report describing the activities of the Committee, including findings made by the Committee regarding—

(i) compliance with section 289a-2 of this title;

(ii) the extent of expenditures made for research on women's health by the agencies of the National Institutes of Health; and

(iii) the level of funding needed for such research.

(B) The report required in subparagraph (A) shall be submitted to the Director of NIH for inclusion in the report required in section 283 of this title.

**(e) Representation of women among researchers**

The Secretary, acting through the Assistant Secretary for Personnel and in collaboration with the Director of the Office, shall determine the extent to which women are represented among senior physicians and scientists of the national research institutes and among physicians and scientists conducting research with funds provided by such institutes, and as appropriate, carry out activities to increase the extent of such representation.

**(f) Definitions**

For purposes of this part:

(1) The term "women's health conditions", with respect to women of all age, ethnic, and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)—

(A) unique to, more serious, or more prevalent in women;

(B) for which the factors of medical risk or types of medical intervention are different for women, or for which it is unknown whether such factors or types are different for women; or

(C) with respect to which there has been insufficient clinical research involving women as subjects or insufficient clinical data on women.

(2) The term "research on women's health" means research on women's health conditions, including research on preventing such conditions.

(July 1, 1944, ch. 373, title IV, § 486, as added Pub. L. 103-43, title I, § 141(a)(3), June 10, 1993, 107 Stat. 136; amended Pub. L. 105-340, title I, § 106, Oct. 31, 1998, 112 Stat. 3193; Pub. L. 111-148, title III, § 3509(c), Mar. 23, 2010, 124 Stat. 534; Pub. L. 114-255, div. A, title II, § 2038(c), Dec. 13, 2016, 130 Stat. 1065.)

AMENDMENTS

2016—Subsec. (c)(2). Pub. L. 114-255 substituted "senior-level staff designees" for "designees".

2010—Subsec. (a). Pub. L. 111-148 inserted "and who shall report directly to the Director" before period at end.

1998—Subsec. (d)(2). Pub. L. 105-340 substituted “NIH” for “the Office”.

#### TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided for by law. See section 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

### § 287d-1. National data system and clearinghouse on research on women's health

#### (a) Data system

(1) The Director of NIH, in consultation with the Director of the Office and the Director of the National Library of Medicine, shall establish a data system for the collection, storage, analysis, retrieval, and dissemination of information regarding research on women's health that is conducted or supported by the national research institutes. Information from the data system shall be available through information systems available to health care professionals and providers, researchers, and members of the public.

(2) The data system established under paragraph (1) shall include a registry of clinical trials of experimental treatments that have been developed for research on women's health. Such registry shall include information on subject eligibility criteria, sex, age, ethnicity or race, and the location of the trial site or sites. Principal investigators of such clinical trials shall provide this information to the registry within 30 days after it is available. Once a trial has been completed, the principal investigator shall provide the registry with information pertaining to the results, including potential toxicities or adverse effects associated with the experimental treatment or treatments evaluated.

#### (b) Clearinghouse

The Director of NIH, in consultation with the Director of the Office and with the National Library of Medicine, shall establish, maintain, and operate a program to provide information on research and prevention activities of the national research institutes that relate to research on women's health.

(July 1, 1944, ch. 373, title IV, § 486A, as added Pub. L. 103-43, title I, § 141(a)(3), June 10, 1993, 107 Stat. 138.)

### § 287d-2. Biennial report

#### (a) In general

With respect to research on women's health, the Director of the Office shall, not later than February 1, 1994, and biennially thereafter, prepare a report—

(1) describing and evaluating the progress made during the preceding 2 fiscal years in re-

search and treatment conducted or supported by the National Institutes of Health;

(2) describing and analyzing the professional status of women physicians and scientists of such Institutes, including the identification of problems and barriers regarding advancements;

(3) summarizing and analyzing expenditures made by the agencies of such Institutes (and by such Office) during the preceding 2 fiscal years; and

(4) making such recommendations for legislative and administrative initiatives as the Director of the Office determines to be appropriate.

#### (b) Inclusion in biennial report of Director of NIH

The Director of the Office shall submit each report prepared under subsection (a) to the Director of NIH for inclusion in the report submitted to the President and the Congress under section 283 of this title.

(July 1, 1944, ch. 373, title IV, § 486B, as added Pub. L. 103-43, title I, § 141(a)(3), June 10, 1993, 107 Stat. 139.)

## PART G—AWARDS AND TRAINING

### AMENDMENTS

1993—Pub. L. 103-43, title I, § 141(a)(2), June 10, 1993, 107 Stat. 136, redesignated part F “Awards and Training” as G. Former part G “General Provisions” redesignated H.

### § 288. Ruth L. Kirschstein National Research Service Awards

#### (a) Biomedical and behavioral research and research training; programs and institutions included; restriction; special consideration

(1) The Secretary shall—

(A) provide Ruth L. Kirschstein National Research Service Awards for—

(i) biomedical and behavioral research at the National Institutes of Health in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the National Institutes of Health and Administration<sup>1</sup> are directed;

(ii) training at the National Institutes of Health and at the Administration<sup>1</sup> of individuals to undertake such research;

(iii) biomedical and behavioral research and health services research (including research in primary medical care) at public and nonprofit private entities; and

(iv) pre-doctoral and post-doctoral training at public and private institutions of individuals to undertake biomedical and behavioral research;

(B) make grants to public and nonprofit private institutions to enable such institutions to make Ruth L. Kirschstein National Research Service Awards for research (and training to undertake biomedical and behavioral research) in the matters described in subparagraph (A)(i) to individuals selected by such institutions; and

<sup>1</sup> So in original. Reference to Administration probably should not appear.

(C) provide contracts for scholarships and loan repayments in accordance with sections 288-4 and 288-5<sup>2</sup> of this title, subject to providing not more than an aggregate 50 such contracts during the fiscal years 1994 through 1996.

A reference in this subsection to the National Institutes of Health shall be considered to include the institutes, agencies, divisions, and bureaus included in the National Institutes of Health or under the Administration,<sup>1</sup> as the case may be.

(2) Ruth L. Kirschstein National Research Service Awards may not be used to support residency training of physicians and other health professionals.

(3) In awarding Ruth L. Kirschstein National Research Service Awards under this section, the Secretary shall take account of the Nation's overall need for biomedical research personnel by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

(4) The Secretary shall carry out paragraph (1) in a manner that will result in the recruitment of women, and individuals from disadvantaged backgrounds (including racial and ethnic minorities), into fields of biomedical or behavioral research and in the provision of research training to women and such individuals.

**(b) Prerequisites for Award; review and approval by appropriate advisory councils; Award period; uses for Award; payments to non-Federal public or nonprofit private institutions**

(1) No Ruth L. Kirschstein National Research Service Award may be made by the Secretary to any individual unless—

(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c); and

(C) in the case of a Ruth L. Kirschstein National Research Service Award for a purpose described in subsection (a)(1)(A)(iii), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institution at which the research or training under the award will be conducted.

An application for an award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

(2) The making of grants under subsection (a)(1)(B) for Ruth L. Kirschstein National Research Service Awards shall be subject to review and approval by the appropriate advisory councils within the Department of Health and Human Services (A) whose activities relate to the research or training under the awards, or (B) for the entity at which such research or training will be conducted.

(3) No grant may be made under subsection (a)(1)(B) unless an application therefor has been

submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section (other than paragraph (1)), Ruth L. Kirschstein National Research Service Awards made under a grant under subsection (a)(1)(B) shall be made in accordance with such regulations as the Secretary shall prescribe.

(4) The period of any Ruth L. Kirschstein National Research Service Award made to any individual under subsection (a) may not exceed—

(A) five years in the aggregate for pre-doctoral training; and

(B) three years in the aggregate for post-doctoral training;

unless the Secretary for good cause shown waives the application of such limit to such individual.

(5) Ruth L. Kirschstein National Research Service Awards shall provide for such stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), adjusted periodically to reflect increases in the cost of living, for the recipients of the awards as the Secretary may deem necessary. A Ruth L. Kirschstein National Research Service Award made to an individual for research or research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

**(c) Health research or teaching; service period; recovery upon noncompliance with service requirement, formula; cancellation or waiver of obligation**

(1) Each individual who is awarded a Ruth L. Kirschstein National Research Service Award for postdoctoral research training shall, in accordance with paragraph (3), engage in research training, research, or teaching that is health-related (or any combination thereof) for the period specified in paragraph (2). Such period shall be served in accordance with the usual patterns of scientific employment.

(2)(A) The period referred to in paragraph (1) is 12 months, or one month for each month for which the individual involved receives a Ruth L. Kirschstein National Research Service Award for postdoctoral research training, whichever is less.

(B) With respect to postdoctoral research training, in any case in which an individual receives a Ruth L. Kirschstein National Research Service Award for more than 12 months, the 13th month and each subsequent month of performing activities under the Award shall be considered to be activities engaged in toward satisfaction of the requirement established in paragraph (1) regarding a period of service.

<sup>2</sup> See References in Text note below.

(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's award, as the Secretary shall by regulation prescribe. The Secretary shall by regulation prescribe the type of research and teaching in which an individual may engage to comply with such requirement and such other requirements respecting research and teaching as the Secretary considers appropriate.

(4)(A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph (3), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A = \phi \left( \frac{t-s}{t} \right)$$

in which "A" is the amount the United States is entitled to recover; "φ" is the sum of the total amount paid under one or more Ruth L. Kirschstein National Research Service Awards to such individual; "t" is the total number of months in such individual's service obligation; and "s" is the number of months of such obligation served by such individual in accordance with paragraphs (1) and (2) of this subsection.

(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any Ruth L. Kirschstein National Research Service Award is paid, there shall accrue to the United States interest on such amount at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount.

(5)(A) Any obligation of an individual under paragraph (1) shall be canceled upon the death of such individual.

(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve substantial hardship to such individual or would be against equity and good conscience.

(July 1, 1944, ch. 373, title IV, § 487, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 869; amended Pub. L. 100-607, title I, § 151, title VI, § 635, Nov. 4, 1988, 102 Stat. 3058, 3148; Pub. L. 101-93, § 5(d), Aug. 16, 1989, 103 Stat. 612; Pub. L. 101-239, title VI, § 6103(e)(7), Dec. 19, 1989, 103 Stat. 2208; Pub. L. 102-321, title I, § 163(b)(4), July 10, 1992, 106 Stat. 376; Pub. L. 103-43, title XVI, §§ 1601, 1602, 1632, 1641, title XX, § 2008(b)(14), June 10, 1993, 107 Stat. 181, 186, 211; Pub. L. 106-129, § 2(b)(2), Dec. 6, 1999, 113 Stat. 1670; Pub. L. 107-206, title I, § 804(a), (b), Aug. 2, 2002, 116 Stat. 874; Pub. L. 109-482, title I, § 103(b)(47), Jan. 15, 2007, 120 Stat. 3688.)

REFERENCES IN TEXT

Section 288-5 of this title, referred to in subsec. (a)(1)(C), was repealed by Pub. L. 114-255, div. A, title II, § 2022(c)(3), Dec. 13, 2016, 130 Stat. 1054.

AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482 struck out subsec. (d) which related to authorization and apportionment of appropriations.

2002—Pub. L. 107-206 inserted "Ruth L. Kirschstein" before "National Research Service Award" and "National Research Service Awards" wherever appearing in section catchline and text.

1999—Subsec. (d)(3). Pub. L. 106-129 substituted "Agency for Healthcare Research and Quality" for "Agency for Health Care Policy and Research".

1993—Subsec. (a)(1)(C). Pub. L. 103-43, § 1632, added subpar. (C).

Subsec. (a)(4). Pub. L. 103-43, § 1601, added par. (4).

Subsec. (c)(1), (2). Pub. L. 103-43, § 1602, added pars. (1) and (2) and struck out former pars. (1) and (2) which read as follows:

"(1) Each individual who is awarded a National Research Service Award (other than an individual who is a pre-baccalaureate student who is awarded a National Research Service Award for research training) shall, in accordance with paragraph (3), engage in health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment, for a period computed in accordance with paragraph (2).

"(2) For each month for which an individual receives a National Research Service Award which is made for a period in excess of twelve months, such individual shall engage in one month of health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment."

Subsec. (d). Pub. L. 103-43, § 1641(1), amended first sentence generally. Prior to amendment, first sentence read as follows: "For the purpose of making payments under National Research Service Awards and under grants for such Awards, there are authorized to be appropriated \$300,000,000 for fiscal year 1989 and such sums as may be necessary for fiscal year 1990."

Subsec. (d)(3). Pub. L. 103-43, §§ 1641(2), 2008(b)(14), substituted "1 percent" for "one-half of one percent" in two places, "293k, 293l, or 293m" for "295g, 295g-4, or 295g-6", and "242b(a)" for "242b(a)(3)".

1992—Subsec. (a)(1). Pub. L. 102-321 struck out "and the Alcohol, Drug Abuse, and Mental Health Administration" before "in matters relating to" in subpar. (A)(i) and struck out "or the Alcohol, Drug Abuse, and Mental Health Administration" before "shall be considered" in last sentence.

1989—Subsec. (d)(3). Pub. L. 101-93 directed that par. (3), as similarly amended by sections 151(2) and 635 of Pub. L. 100-607, be amended to read as if the amendment made by such section 635 had not been enacted. See 1988 Amendment note below.

Subsec. (d)(3)(B). Pub. L. 101-239 substituted "Agency for Health Care Policy and Research" for "National Center for Health Services Research and Health Care Technology Assessment".

1988—Subsec. (d). Pub. L. 100-607, § 151(1), amended first sentence generally. Prior to amendment, first sentence read as follows: "There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such awards \$244,000,000 for fiscal year 1986, \$260,000,000 for fiscal year 1987, and \$275,000,000 for fiscal year 1988."

Subsec. (d)(3). Pub. L. 100-607, §§ 151(2), 635, made identical amendments, inserting "to the Secretary, acting through the Administrator of the Health Resources and Services Administration," after first reference to "available".

CHANGE OF NAME

Pub. L. 107-206, title I, § 804(c), Aug. 2, 2002, 116 Stat. 874, provided that: "Any reference in any law (other

than this Act [see Tables for classification]), regulation, document, record, map, or other paper of the United States to 'National Research Service Awards' shall be considered to be a reference to 'Ruth L. Kirschstein National Research Service Awards'."

**EFFECTIVE DATE OF 2007 AMENDMENT**

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**EFFECTIVE DATE OF 1992 AMENDMENT**

Amendment by Pub. L. 102-321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as a note under section 236 of this title.

**§ 288-1. Intramural loan repayment program**

**(a) In general**

The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2)) of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the National Institutes of Health, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than \$50,000 of the principal and interest of the educational loans of such health professionals.

**(b) Subcategories of research**

**(1) In general**

In carrying out the program under subsection (a), the Director of the National Institutes of Health—

(A) shall continue to focus on—

- (i) general research;
- (ii) research on acquired immune deficiency syndrome; and
- (iii) clinical research conducted by appropriately qualified health professional<sup>1</sup> who are from disadvantaged backgrounds; and

(B) may focus on an area of emerging scientific or workforce need.

**(2) Elimination or establishment of subcategories**

The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

**(c) Limitation**

The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income

(as determined pursuant to guidelines issued by the Director).

**(d) Applicability of certain provisions**

With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of subchapter II, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

**(e) Availability of appropriations**

Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which such amounts are made available.

(July 1, 1944, ch. 373, title IV, §487A, as added Pub. L. 100-607, title VI, §634(a), Nov. 4, 1988, 102 Stat. 3148; amended Pub. L. 103-43, title XVI, §1611(a), June 10, 1993, 107 Stat. 181; Pub. L. 105-392, title IV, §410(a), Nov. 13, 1998, 112 Stat. 3589; Pub. L. 109-482, title I, §103(b)(48), Jan. 15, 2007, 120 Stat. 3688; Pub. L. 114-255, div. A, title II, §2022(a), Dec. 13, 2016, 130 Stat. 1052.)

**AMENDMENTS**

2016—Pub. L. 114-255, §2022(a)(1), amended section catchline generally. Prior to amendment, catchline read as follows: "Loan repayment program for research with respect to acquired immune deficiency syndrome".

Subsec. (a). Pub. L. 114-255, §2022(a)(2), substituted "The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2))" for "The Secretary shall carry out a program", "conduct research" for "conduct", and "\$50,000" for "\$35,000", and struck out "research with respect to acquired immune deficiency syndrome" after "National Institutes of Health,".

Subsecs. (b) to (d). Pub. L. 114-255, §2022(a)(3), (4), added subsecs. (b) and (c) and redesignated former subsec. (b) as (d).

Subsec. (e). Pub. L. 114-255, §2022(a)(5), added subsec. (e).

2007—Subsec. (c). Pub. L. 109-482 struck out heading and text of subsec. (c). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 2001."

1998—Subsec. (a). Pub. L. 105-392, §410(a)(1), substituted "\$35,000" for "\$20,000".

Subsec. (c). Pub. L. 105-392, §410(a)(2), substituted "2001" for "1996".

1993—Pub. L. 103-43 amended section generally, in subsec. (a) redesignating former par. (1) as entire subsec., striking out provisions setting a deadline for implementation of the program and former par. (2) containing a limitation that the health professional have a substantial amount of educational loans relative to income and not have been employed at the National Institutes of Health during the 1-year period preceding Nov. 4, 1988, reenacting subsec. (b) without change, and in subsec. (c) redesignating former par. (1) as entire subsec., substituting authorization of appropriations for fiscal years 1994 through 1996 for authorization of appropriations for fiscal years 1989 through 1991, and striking out former par. (2) relating to continued availability of appropriated amounts.

<sup>1</sup> So in original. Probably should be "professionals".

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

## EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103-43, title XVI, §1611(b), June 10, 1993, 107 Stat. 182, provided that: "The amendment made by subsection (a) [amending this section] does not apply to any agreement entered into under section 487A of the Public Health Service Act [42 U.S.C. 288-1] before the date of the enactment of this Act [June 10, 1993]. Each such agreement continues to be subject to the terms of the agreement in effect on the day before such date."

**§ 288-2. Extramural loan repayment program****(a) In general**

The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2)), of entering into contracts with qualified health professionals under which such health professionals agree to conduct research in consideration of the Federal Government agreeing to repay, for each year of such research, not more than \$50,000 of the principal and interest of the educational loans of such health professionals.

**(b) Subcategories of research****(1) In general**

In carrying out the program under subsection (a), the Director of the National Institutes of Health—

(A) shall continue to focus on—

- (i) contraception or infertility research;
- (ii) pediatric research, including pediatric pharmacological research;
- (iii) minority health disparities research;
- (iv) clinical research; and
- (v) clinical research conducted by appropriately qualified health professional<sup>1</sup> who are from disadvantaged backgrounds; and

(B) may focus on an area of emerging scientific or workforce need.

**(2) Elimination or establishment of subcategories**

The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

**(c) Limitation**

The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director).

<sup>1</sup> So in original. Probably should be "professionals".

**(d) Applicability of certain provisions regarding obligated service**

The provisions of sections 254l-1, 254m, and 254o of this title shall, except as inconsistent with subsection (a) of this section, apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of subchapter II.

**(e) Availability of appropriations**

Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were made available.

(July 1, 1944, ch. 373, title IV, §487B, as added Pub. L. 103-43, title X, §1002, June 10, 1993, 107 Stat. 166; amended Pub. L. 105-392, title IV, §410(b), Nov. 13, 1998, 112 Stat. 3589; Pub. L. 110-154, §1(b)(8), Dec. 21, 2007, 121 Stat. 1827; Pub. L. 114-255, div. A, title II, §2022(b), Dec. 13, 2016, 130 Stat. 1053.)

## AMENDMENTS

2016—Pub. L. 114-255, §2022(b)(1), amended section catchline generally. Prior to amendment, catchline read as follows: "Loan repayment program for research with respect to contraception and infertility".

Subsec. (a). Pub. L. 114-255, §2022(b)(2), inserted heading and, in text, substituted "The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2))," for "The Secretary, in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, shall establish a program" and "research, not more than \$50,000" for "service, not more than \$35,000" and struck out "(including graduate students)" after "qualified health professionals" and "with respect to contraception, or with respect to infertility," after "conduct research".

Subsecs. (b), (c). Pub. L. 114-255, §2022(b)(4), added subsecs. (b) and (c). Former subsecs. (b) and (c) redesignated (d) and (e), respectively.

Subsec. (d). Pub. L. 114-255, §2022(3), (5), redesignated subsec. (b) as (d) and inserted heading.

Subsec. (e). Pub. L. 114-255, §2002(3), (6), redesignated subsec. (c) as (e) and inserted heading.

2007—Subsec. (a). Pub. L. 110-154, which directed substitution of "Eunice Kennedy Shriver National Institute of Child Health and Human Development" for "National Institute on Child Health and Human Development", was executed by making the substitution for "National Institute of Child Health and Human Development" to reflect the probable intent of Congress.

1998—Subsec. (a). Pub. L. 105-392 substituted "\$35,000" for "\$20,000".

**§ 288-3. Repealed. Pub. L. 114-255, div. A, title II, § 2022(c)(2), Dec. 13, 2016, 130 Stat. 1054**

Section, July 1, 1944, ch. 373, title IV, §487C, as added Pub. L. 103-43, title XVI, §1621, June 10, 1993, 107 Stat. 182; amended Pub. L. 105-392, title IV, §410(c), Nov. 13, 1998, 112 Stat. 3589, related to loan repayment program for research generally.

**§ 288-4. Undergraduate scholarship program regarding professions needed by National Research Institutes**

**(a) Establishment of program**

**(1) In general**

Subject to section 288(a)(1)(C) of this title, the Secretary, acting through the Director of NIH, may carry out a program of entering into contracts with individuals described in paragraph (2) under which—

(A) the Director of NIH agrees to provide to the individuals scholarships for pursuing, as undergraduates at accredited institutions of higher education, academic programs appropriate for careers in professions needed by the National Institutes of Health; and

(B) the individuals agree to serve as employees of the National Institutes of Health, for the period described in subsection (c), in positions that are needed by the National Institutes of Health and for which the individuals are qualified.

**(2) Individuals from disadvantaged backgrounds**

The individuals referred to in paragraph (1) are individuals who—

(A) are enrolled or accepted for enrollment as full-time undergraduates at accredited institutions of higher education; and

(B) are from disadvantaged backgrounds.

**(b) Facilitation of interest of students in careers at National Institutes of Health**

In providing employment to individuals pursuant to contracts under subsection (a)(1), the Director of NIH shall carry out activities to facilitate the interest of the individuals in pursuing careers as employees of the National Institutes of Health.

**(c) Period of obligated service**

**(1) Duration of service**

For purposes of subparagraph (B) of subsection (a)(1), the period of service for which an individual is obligated to serve as an employee of the National Institutes of Health is, subject to paragraph (2)(A), 12 months for each academic year for which the scholarship under such subsection is provided.

**(2) Schedule for service**

(A) Subject to subparagraph (B), the Director of NIH may not provide a scholarship under subsection (a) unless the individual applying for the scholarship agrees that—

(i) the individual will serve as an employee of the National Institutes of Health full-time for not less than 10 consecutive weeks of each year during which the individual is attending the educational institution involved and receiving such a scholarship;

(ii) the period of service as such an employee that the individual is obligated to provide under clause (i) is in addition to the period of service as such an employee that the individual is obligated to provide under subsection (a)(1)(B); and

(iii) not later than 60 days after obtaining the educational degree involved, the individual will begin serving full-time as such an

employee in satisfaction of the period of service that the individual is obligated to provide under subsection (a)(1)(B).

(B) The Director of NIH may defer the obligation of an individual to provide a period of service under subsection (a)(1)(B), if the Director determines that such a deferral is appropriate.

**(3) Applicability of certain provisions relating to appointment and compensation**

For any period in which an individual provides service as an employee of the National Institutes of Health in satisfaction of the obligation of the individual under subsection (a)(1)(B) or paragraph (2)(A)(i), the individual may be appointed as such an employee without regard to the provisions of title 5 relating to appointment and compensation.

**(d) Provisions regarding scholarship**

**(1) Approval of academic program**

The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless—

(A) the individual applying for the scholarship has submitted to the Director a proposed academic program for the year and the Director has approved the program; and

(B) the individual agrees that the program will not be altered without the approval of the Director.

**(2) Academic standing**

The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless the individual applying for the scholarship agrees to maintain an acceptable level of academic standing, as determined by the educational institution involved in accordance with regulations issued by the Secretary.

**(3) Limitation on amount**

The Director of NIH may not provide a scholarship under subsection (a) for an academic year in an amount exceeding \$20,000.

**(4) Authorized uses**

A scholarship provided under subsection (a) may be expended only for tuition expenses, other reasonable educational expenses, and reasonable living expenses incurred in attending the school involved.

**(5) Contract regarding direct payments to institution**

In the case of an institution of higher education with respect to which a scholarship under subsection (a) is provided, the Director of NIH may enter into a contract with the institution under which the amounts provided in the scholarship for tuition and other educational expenses are paid directly to the institution.

**(e) Penalties for breach of scholarship contract**

The provisions of section 254o of this title shall apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 254f-1 of this title.

**(f) Requirement of application**

The Director of NIH may not provide a scholarship under subsection (a) unless an application for the scholarship is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

**(g) Availability of authorization of appropriations**

Amounts appropriated for a fiscal year for scholarships under this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

(July 1, 1944, ch. 373, title IV, §487D, as added Pub. L. 103-43, title XVI, §1631, June 10, 1993, 107 Stat. 183.)

**§§ 288-5 to 288-6. Repealed. Pub. L. 114-255, div. A, title II, §2022(c)(3)-(5), Dec. 13, 2016, 130 Stat. 1054**

Section 288-5, July 1, 1944, ch. 373, title IV, §487E, as added Pub. L. 103-43, title XVI, §1631, June 10, 1993, 107 Stat. 185; amended Pub. L. 105-392, title IV, §410(d), Nov. 13, 1998, 112 Stat. 3589; Pub. L. 106-554, §1(a)(1) [title II, §223], Dec. 21, 2000, 114 Stat. 2763, 2763A-30, related to loan repayment program regarding clinical researchers from disadvantaged backgrounds.

Section 288-5a, July 1, 1944, ch. 373, title IV, §487F, as added Pub. L. 106-505, title II, §205, Nov. 13, 2000, 114 Stat. 2329; amended Pub. L. 109-482, title I, §103(b)(49), Jan. 15, 2007, 120 Stat. 3689, related to loan repayment program regarding clinical researchers. Another section 487F of act July 1, 1944, was classified to section 288-6 of this title, prior to repeal by Pub. L. 114-255.

Section 288-6, July 1, 1944, ch. 373, title IV, §487F, as added Pub. L. 106-310, div. A, title X, §1002(b), Oct. 17, 2000, 114 Stat. 1129; amended Pub. L. 110-85, title V, §503(b), Sept. 27, 2007, 121 Stat. 890, related to pediatric research loan repayment program. Another section 487F of act July 1, 1944, was classified to section 288-5a of this title, prior to repeal by Pub. L. 114-255.

**§ 288a. Visiting Scientist Awards**

(a) The Secretary may make awards (hereafter in this section referred to as “Visiting Scientist Awards”) to outstanding scientists who agree to serve as visiting scientists at institutions of postsecondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe.

(July 1, 1944, ch. 373, title IV, §488, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 872.)

**§ 288b. Studies respecting biomedical and behavioral research personnel****(a) Scope of undertaking**

The Secretary shall, in accordance with subsection (b), arrange for the conduct of a continuing study to—

(1) establish (A) the Nation’s overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel;

(2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this chapter, at or through national research institutes under the National Institutes of Health, and (B) other current training programs available for the training of such personnel;

(3) identify the kinds of research positions available to and held by individuals completing such programs;

(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

**(b) Arrangement with National Academy of Sciences or other nonprofit private groups or associations**

(1) The Secretary shall request the National Academy of Sciences to conduct the study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of such study.

(2) If the National Academy of Sciences is unwilling to conduct such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in subsection (c).<sup>1</sup>

(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of NIH.

(July 1, 1944, ch. 373, title IV, §489, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 872; amended Pub. L. 102-321, title I, §163(b)(5), July 10, 1992, 106 Stat. 376.)

## REFERENCES IN TEXT

Subsection (c), referred to in subsec. (b)(2), was omitted from the Code. See Codification note below.

<sup>1</sup> See References in Text note below.

## CODIFICATION

Subsec. (c) of this section, which required the Secretary to submit a report on results of the study required under subsec. (a) of this section to certain committees of Congress at least once every four years, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104-66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, page 96 of House Document No. 103-7.

## AMENDMENTS

1992—Subsec. (a)(2), Pub. L. 102-321 struck out “and institutes under the Alcohol, Drug Abuse, and Mental Health Administration” after “National Institutes of Health”.

## EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102-321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as a note under section 236 of this title.

## PART H—GENERAL PROVISIONS

## AMENDMENTS

1993—Pub. L. 103-43, title I, §141(a)(2), June 10, 1993, 107 Stat. 136, redesignated part G “General Provisions” as H. Former part H “National Foundation for Biomedical Research” redesignated I.

### § 289. Institutional review boards; ethics guidance program

(a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an “Institutional Review Board”) to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such violations.

(July 1, 1944, ch. 373, title IV, § 491, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 873.)

## PROTECTION OF HUMAN RESEARCH SUBJECTS

Pub. L. 114-255, div. A, title III, §3023, Dec. 13, 2016, 130 Stat. 1098, provided that:

“(a) IN GENERAL.—In order to simplify and facilitate compliance by researchers with applicable regulations

for the protection of human subjects in research, the Secretary of Health and Human Services (referred to in this section as the ‘Secretary’) shall, to the extent practicable and consistent with other statutory provisions, harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations in accordance with subsection (b).

“(b) AVOIDING REGULATORY DUPLICATION AND UNNECESSARY DELAYS.—The Secretary shall, as appropriate—

“(1) make such modifications to the provisions of the HHS Human Subject Regulations, the FDA Human Subject Regulations, and the vulnerable populations rules as may be necessary—

“(A) to reduce regulatory duplication and unnecessary delays;

“(B) to modernize such provisions in the context of multisite and cooperative research projects; and

“(C) to protect vulnerable populations, incorporate local considerations, and support community engagement through mechanisms such as consultation with local researchers and human research protection programs, in a manner consistent with subparagraph (B); and

“(2) ensure that human subject research that is subject to the HHS Human Subject Regulations and to the FDA Human Subject Regulations may—

“(A) use joint or shared review;

“(B) rely upon the review of—

“(i) an independent institutional review board;

or

“(ii) an institutional review board of an entity other than the sponsor of the research; or

“(C) use similar arrangements to avoid duplication of effort.

“(c) CONSULTATION.—In harmonizing or modifying regulations or guidance under this section, the Secretary shall consult with stakeholders (including researchers, academic organizations, hospitals, institutional research boards, pharmaceutical, biotechnology, and medical device developers, clinical research organizations, patient groups, and others).

“(d) TIMING.—The Secretary shall complete the harmonization described in subsection (a) not later than 3 years after the date of enactment of this Act [Dec. 13, 2016].

“(e) PROGRESS REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary shall submit to Congress a report on the progress made toward completing such harmonization.

“(f) DEFINITIONS.—

“(1) HUMAN SUBJECT REGULATIONS.—In this section:

“(A) FDA HUMAN SUBJECT REGULATIONS.—The term ‘FDA Human Subject Regulations’ means the provisions of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations).

“(B) HHS HUMAN SUBJECT REGULATIONS.—The term ‘HHS Human Subject Regulations’ means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations).

“(C) VULNERABLE POPULATION RULES.—The term ‘vulnerable population rules’ means—

“(i) except in the case of research described in clause (ii), the provisions of subparts B through D of part 46, Code of Federal Regulations (or any successor regulations); and

“(ii) in the case of research that is subject to FDA Human Subject Regulations, the provisions applicable to vulnerable populations under part 56 of title 21, Code of Federal Regulations (or any successor regulations) and subpart D of part 50 of such title 21 (or any successor regulations).

“(2) INSTITUTIONAL REVIEW BOARD DEFINED.—In this section, the term ‘institutional review board’ has the meaning that applies to the term ‘institutional review board’ under the HHS Human Subject Regulations.”

## INFORMED CONSENT FOR NEWBORN SCREENING RESEARCH

Pub. L. 113-240, §12, Dec. 18, 2014, 128 Stat. 2857, provided that:

“(a) IN GENERAL.—Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f)(2) of title 45, Code of Federal Regulations, for purposes of Federally funded research conducted pursuant to the Public Health Service Act [42 U.S.C. 201 et seq.] until such time as updates to the Federal Policy for the Protection of Human Subjects (the Common Rule) are promulgated pursuant to subsection (c). For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply.

“(b) EFFECTIVE DATE.—Subsection (a) shall apply only to newborn dried blood spots used for purposes of Federally funded research that were collected not earlier than 90 days after the date of enactment of this Act [Dec. 18, 2014].

“(c) REGULATIONS.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed regulations related to the updating of the Federal Policy for the Protection of Human Subjects (the Common Rule), particularly with respect to informed consent. Not later than 2 years after such date of enactment, the Secretary shall promulgate final regulations based on such proposed regulations.”

#### STUDY CONCERNING RESEARCH INVOLVING CHILDREN

Pub. L. 107–109, §12, Jan. 4, 2002, 115 Stat. 1416, provided that:

“(a) CONTRACT WITH INSTITUTE OF MEDICINE.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine for—

“(1) the conduct, in accordance with subsection (b), of a review of—

“(A) Federal regulations in effect on the date of the enactment of this Act [Jan. 4, 2002] relating to research involving children;

“(B) federally prepared or supported reports relating to research involving children; and

“(C) federally supported evidence-based research involving children; and

“(2) the submission to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, not later than two years after the date of enactment of this Act, of a report concerning the review conducted under paragraph (1) that includes recommendations on best practices relating to research involving children.

“(b) AREAS OF REVIEW.—In conducting the review under subsection (a)(1), the Institute of Medicine shall consider the following:

“(1) The written and oral process of obtaining and defining ‘assent’, ‘permission’ and ‘informed consent’ with respect to child clinical research participants and the parents, guardians, and the individuals who may serve as the legally authorized representatives of such children (as defined in subpart A of part 46 of title 45, Code of Federal Regulations).

“(2) The expectations and comprehension of child research participants and the parents, guardians, or legally authorized representatives of such children, for the direct benefits and risks of the child’s research involvement, particularly in terms of research versus therapeutic treatment.

“(3) The definition of ‘minimal risk’ with respect to a healthy child or a child with an illness.

“(4) The appropriateness of the regulations applicable to children of differing ages and maturity levels, including regulations relating to legal status.

“(5) Whether payment (financial or otherwise) may be provided to a child or his or her parent, guardian, or legally authorized representative for the participation of the child in research, and if so, the amount and type of payment that may be made.

“(6) Compliance with the regulations referred to in subsection (a)(1)(A), the monitoring of such compliance (including the role of institutional review boards), and the enforcement actions taken for violations of such regulations.

“(7) The unique roles and responsibilities of institutional review boards in reviewing research involving children, including composition of membership on institutional review boards.

“(c) REQUIREMENTS OF EXPERTISE.—The Institute of Medicine shall conduct the review under subsection (a)(1) and make recommendations under subsection (a)(2) in conjunction with experts in pediatric medicine, pediatric research, and the ethical conduct of research involving children.”

#### REQUIREMENT FOR ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED IN RESEARCH

Pub. L. 106–310, div. A, title XXVII, §2701, Oct. 17, 2000, 114 Stat. 1167, as amended by Pub. L. 106–505, title X, §1001(a), Nov. 13, 2000, 114 Stat. 2350, provided that: “Notwithstanding any other provision of law, not later than 6 months after the date of the enactment of this Act [Oct. 17, 2000], the Secretary of Health and Human Services shall require that all research involving children that is conducted, supported, or regulated by the Department of Health and Human Services be in compliance with subpart D of part 46 of title 45, Code of Federal Regulations.”

[Pub. L. 106–505, title X, §1001(b), Nov. 13, 2000, 114 Stat. 2350, provided that: “The amendment made by subsection (a) [amending section 2701 of Pub. L. 106–310, set out above] takes effect on the date of the enactment of the Children’s Health Act of 2000 [Oct. 17, 2000].”]

#### § 289a. Peer review requirements

##### (a) Applications for biomedical and behavioral research grants, cooperative agreements, and contracts; regulations

(1) The Secretary, acting through the Director of NIH, shall by regulation require appropriate technical and scientific peer review of—

(A) applications made for grants and cooperative agreements under this chapter for biomedical and behavioral research; and

(B) applications made for biomedical and behavioral research and development contracts to be administered through the National Institutes of Health.

(2) Regulations promulgated under paragraph (1) shall require that the review of applications made for grants, contracts, and cooperative agreements required by the regulations be conducted—

(A) to the extent practical, in a manner consistent with the system for technical and scientific peer review applicable on November 20, 1985, to grants under this chapter for biomedical and behavioral research, and

(B) to the extent practical, by technical and scientific peer review groups performing such review on or before November 20, 1985,

and shall authorize such review to be conducted by groups appointed under sections 282(b)(16) and 284(c)(3) of this title.

##### (b) Periodic review of research at National Institutes of Health

The Director of NIH shall establish procedures for periodic technical and scientific peer review of research at the National Institutes of Health. Such procedures shall require that—

(1) the reviewing entity be provided a written description of the research to be reviewed, and

(2) the reviewing entity provide the advisory council of the national research institute in-

volved with such description and the results of the review by the entity, and shall authorize such review to be conducted by groups appointed under sections 282(b)(6)<sup>1</sup> and 284(c)(3) of this title.

**(c) Compliance with requirements for inclusion of women and minorities in clinical research**

(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding compliance with section 289a-2 of this title.

(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 289a-2 of this title, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.

(July 1, 1944, ch. 373, title IV, § 492, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 874; amended Pub. L. 103-43, title I, § 132, June 10, 1993, 107 Stat. 135; Pub. L. 109-482, title I, § 102(f)(1)(B), Jan. 15, 2007, 120 Stat. 3685.)

REFERENCES IN TEXT

Section 282(b)(6) of this title, referred to in subsec. (b), was redesignated section 282(b)(16) by Pub. L. 109-482, title I, § 102(a)(3), Jan. 15, 2007, 120 Stat. 3681.

AMENDMENTS

2007—Subsec. (a)(2). Pub. L. 109-482 substituted “sections 282(b)(16)” for “sections 282(b)(6)” in concluding provisions.

1993—Subsec. (c). Pub. L. 103-43 added subsec. (c).

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

**§ 289a-1. Certain provisions regarding review and approval of proposals for research**

**(a) Review as precondition to research**

**(1) Protection of human research subjects**

(A) In the case of any application submitted to the Secretary for financial assistance to conduct research, the Secretary may not approve or fund any application that is subject to review under section 289(a) of this title by an Institutional Review Board unless the application has undergone review in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting such review.

(B) In the case of research that is subject to review under procedures established by the Secretary for the protection of human subjects in clinical research conducted by the National Institutes of Health, the Secretary may not authorize the conduct of the research unless the research has, pursuant to such procedures, been recommended for approval.

**(2) Peer review**

In the case of any proposal for the National Institutes of Health to conduct or support research, the Secretary may not approve or fund any proposal that is subject to technical and scientific peer review under section 289a of this title unless the proposal has undergone such review in accordance with such section and has been recommended for approval by a majority of the members of the entity conducting such review, and unless a majority of the voting members of the appropriate advisory council under section 284a of this title, or as applicable, of the advisory council under section 282(k) of this title, has recommended the proposal for approval.

**(b) Ethical review of research**

**(1) Procedures regarding withholding of funds**

If research has been recommended for approval for purposes of subsection (a), the Secretary may not withhold funds for the research because of ethical considerations unless—

(A) the Secretary convenes an advisory board in accordance with paragraph (5) to study such considerations; and

(B)(i) the majority of the advisory board recommends that, because of such considerations, the Secretary withhold funds for the research; or

(ii) the majority of such board recommends that the Secretary not withhold funds for the research because of such considerations, but the Secretary finds, on the basis of the report submitted under paragraph (5)(B)(ii), that the recommendation is arbitrary and capricious.

**(2) Rules of construction**

Paragraph (1) may not be construed as prohibiting the Secretary from withholding funds for research on the basis of—

(A) the inadequacy of the qualifications of the entities that would be involved with the conduct of the research (including the entity that would directly receive the funds from the Secretary), subject to the condition that, with respect to the process of review through which the research was recommended for approval for purposes of subsection (a), all findings regarding such qualifications made in such process are conclusive; or

(B) the priorities established by the Secretary for the allocation of funds among projects of research that have been so recommended.

**(3) Applicability**

The limitation established in paragraph (1) regarding the authority to withhold funds because of ethical considerations shall apply without regard to whether the withholding of funds on such basis is characterized as a disapproval, a moratorium, a prohibition, or other characterization.

**(4) Preliminary matters regarding use of procedures**

(A) If the Secretary makes a determination that an advisory board should be convened for

<sup>1</sup> See References in Text note below.

purposes of paragraph (1), the Secretary shall, through a statement published in the Federal Register, announce the intention of the Secretary to convene such a board.

(B) A statement issued under subparagraph (A) shall include a request that interested individuals submit to the Secretary recommendations specifying the particular individuals who should be appointed to the advisory board involved. The Secretary shall consider such recommendations in making appointments to the board.

(C) The Secretary may not make appointments to an advisory board under paragraph (1) until the expiration of the 30-day period beginning on the date on which the statement required in subparagraph (A) is made with respect to the board.

#### (5) Ethics advisory boards

(A) Any advisory board convened for purposes of paragraph (1) shall be known as an ethics advisory board (in this paragraph referred to as an “ethics board”).

(B)(i) An ethics board shall advise, consult with, and make recommendations to the Secretary regarding the ethics of the project of biomedical or behavioral research with respect to which the board has been convened.

(ii) Not later than 180 days after the date on which the statement required in paragraph (4)(A) is made with respect to an ethics board, the board shall submit to the Secretary, and to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report describing the findings of the board regarding the project of research involved and making a recommendation under clause (i) of whether the Secretary should or should not withhold funds for the project. The report shall include the information considered in making the findings.

(C) An ethics board shall be composed of no fewer than 14, and no more than 20, individuals who are not officers or employees of the United States. The Secretary shall make appointments to the board from among individuals with special qualifications and competence to provide advice and recommendations regarding ethical matters in biomedical and behavioral research. Of the members of the board—

- (i) no fewer than 1 shall be an attorney;
- (ii) no fewer than 1 shall be an ethicist;
- (iii) no fewer than 1 shall be a practicing physician;
- (iv) no fewer than 1 shall be a theologian; and
- (v) no fewer than one-third, and no more than one-half, shall be scientists with substantial accomplishments in biomedical or behavioral research.

(D) The term of service as a member of an ethics board shall be for the life of the board. If such a member does not serve the full term of such service, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(E) A member of an ethics board shall be subject to removal from the board by the Sec-

retary for neglect of duty or malfeasance or for other good cause shown.

(F) The Secretary shall designate an individual from among the members of an ethics board to serve as the chair of the board.

(G) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall conduct inquiries and hold public hearings.

(H) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall have access to all relevant information possessed by the Department of Health and Human Services, or available to the Secretary from other agencies.

(I) Members of an ethics board shall receive compensation for each day engaged in carrying out the duties of the board, including time engaged in traveling for purposes of such duties. Such compensation may not be provided in an amount in excess of the maximum rate of basic pay payable for GS-18 of the General Schedule.

(J) The Secretary, acting through the Director of the National Institutes of Health, shall provide to each ethics board reasonable staff and assistance to carry out the duties of the board.

(K) An ethics board shall terminate 30 days after the date on which the report required in subparagraph (B)(ii) is submitted to the Secretary and the congressional committees specified in such subparagraph.

#### (6) “Ethical considerations” defined

For purposes of this subsection, the term “ethical considerations” means considerations as to whether the nature of the research involved is such that it is unethical to conduct or support the research.

(July 1, 1944, ch. 373, title IV, §492A, as added Pub. L. 103-43, title I, §101, June 10, 1993, 107 Stat. 126; amended Pub. L. 109-482, title I, §102(e), Jan. 15, 2007, 120 Stat. 3684.)

#### AMENDMENTS

2007—Subsec. (a)(2). Pub. L. 109-482 inserted before period at end “, and unless a majority of the voting members of the appropriate advisory council under section 284a of this title, or as applicable, of the advisory council under section 282(k) of this title, has recommended the proposal for approval”.

#### CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104-14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or

subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

**§ 289a-2. Inclusion of women and minorities in clinical research**

**(a) Requirement of inclusion**

**(1) In general**

In conducting or supporting clinical research for purposes of this subchapter, the Director of NIH shall, subject to subsection (b), ensure that—

- (A) women are included as subjects in each project of such research; and
- (B) members of minority groups are included as subjects in such research.

**(2) Outreach regarding participation as subjects**

The Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall conduct or support outreach programs for the recruitment of women and members of minority groups as subjects in projects of clinical research.

**(3) Strategic planning**

**(A) In general**

The directors of the national institutes and national centers shall consult at least once annually with the Director of the National Institute on Minority Health and Health Disparities and the Director of the Office of Research on Women's Health regarding objectives of the national institutes and national centers to ensure that future activities by such institutes and centers take into account women and minorities and are focused on reducing health disparities.

**(B) Strategic plans**

Any strategic plan issued by a national institute or national center shall include details on the objectives described in subparagraph (A).

**(b) Inapplicability of requirement**

The requirement established in subsection (a) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

- (1) is inappropriate with respect to the health of the subjects;
- (2) is inappropriate with respect to the purpose of the research; or
- (3) is inappropriate under such other circumstances as the Director of NIH may designate.

**(c) Design of clinical trials**

**(1) In general**

In the case of any clinical trial in which women or members of minority groups will

under subsection (a) be included as subjects, the Director of NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

**(2) Reporting requirements**

For any new and competing project of clinical research subject to the requirements under this section that receives a grant award 1 year after December 13, 2016, or any date thereafter, for which a valid analysis is provided under paragraph (1)—

(A) and which is an applicable clinical trial as defined in section 282(j) of this title, the entity conducting such clinical research shall submit the results of such valid analysis to the clinical trial registry data bank expanded under section 282(j)(3) of this title, and the Director of the National Institutes of Health shall, as appropriate, consider whether such entity has complied with the reporting requirement described in this subparagraph in awarding any future grant to such entity, including pursuant to section 282(j)(5)(A)(ii) of this title when applicable; and

(B) the Director of the National Institutes of Health shall encourage the reporting of the results of such valid analysis described in paragraph (1) through any additional means determined appropriate by the Director.

**(d) Guidelines**

**(1) In general**

Subject to paragraph (2), the Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall establish guidelines regarding the requirements of this section. The guidelines shall include guidelines regarding—

- (A) the circumstances under which the inclusion of women and minorities as subjects in projects of clinical research is inappropriate for purposes of subsection (b);
- (B) the manner in which clinical trials are required to be designed and carried out for purposes of subsection (c); and
- (C) the operation of outreach programs under subsection (a).

**(2) Certain provisions**

With respect to the circumstances under which the inclusion of women or members of minority groups (as the case may be) as subjects in a project of clinical research is inappropriate for purposes of subsection (b), the following applies to guidelines under paragraph (1):

- (A)(i) In the case of a clinical trial, the guidelines shall provide that the costs of such inclusion in the trial is not a permissible consideration in determining whether such inclusion is inappropriate.
- (ii) In the case of other projects of clinical research, the guidelines shall provide that the costs of such inclusion in the project is

not a permissible consideration in determining whether such inclusion is inappropriate unless the data regarding women or members of minority groups, respectively, that would be obtained in such project (in the event that such inclusion were required) have been or are being obtained through other means that provide data of comparable quality.

(B) In the case of a clinical trial, the guidelines may provide that such inclusion in the trial is not required if there is substantial scientific data demonstrating that there is no significant difference between—

(i) the effects that the variables to be studied in the trial have on women or members of minority groups, respectively; and

(ii) the effects that the variables have on the individuals who would serve as subjects in the trial in the event that such inclusion were not required.

**(e) Date certain for guidelines; applicability**

**(1) Date certain**

The guidelines required in subsection (d) shall be established and published in the Federal Register not later than 180 days after June 10, 1993.

**(2) Applicability**

For fiscal year 1995 and subsequent fiscal years, the Director of NIH may not approve any proposal of clinical research to be conducted or supported by any agency of the National Institutes of Health unless the proposal specifies the manner in which the research will comply with this section.

**(f) Reports by advisory councils**

**(1) In general**

The advisory council of each national research institute shall prepare triennial reports describing the manner in which the institute has complied with this section. Each such report shall be submitted to the Director of the institute involved for inclusion in the triennial report under section 283 of this title.

**(2) Contents**

Each triennial report prepared by an advisory council of each national research institute as described in paragraph (1) shall include each of the following:

(A) The number of women included as subjects, and the proportion of subjects that are women, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease, and accounting for single-sex studies.

(B) The number of members of minority groups included as subjects, and the proportion of subjects that are members of minority groups, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease and accounting for single-race and single-ethnicity studies.

(C) For the applicable reporting period, the number of projects of clinical research that

include women and members of minority groups and that—

(i) have been completed during such reporting period; and

(ii) are being carried out during such reporting period and have not been completed.

(D) The number of studies completed during the applicable reporting period for which reporting has been submitted in accordance with subsection (c)(2)(A).

**(g) Definitions**

For purposes of this section:

(1) The term “project of clinical research” includes a clinical trial.

(2) The term “minority group” includes subpopulations of minority groups. The Director of NIH shall, through the guidelines established under subsection (d), define the terms “minority group” and “subpopulation” for purposes of the preceding sentence.

(July 1, 1944, ch. 373, title IV, §492B, as added Pub. L. 103-43, title I, §131, June 10, 1993, 107 Stat. 133; amended Pub. L. 114-255, div. A, title II, §§2031(c), 2038(b), 2053, Dec. 13, 2016, 130 Stat. 1056, 1065, 1076.)

AMENDMENTS

2016—Subsec. (a)(3). Pub. L. 114-255, §2031(c), added par. (3).

Subsec. (c). Pub. L. 114-255, §2053, designated existing provisions as par. (1), inserted heading, and added par. (2).

Subsec. (f). Pub. L. 114-255, §2038(b), designated existing provisions as par. (1), inserted heading, substituted “triennial” for “biennial” in two places, and added par. (2).

CLINICAL RESEARCH

Pub. L. 114-255, div. A, title II, §2038(h), Dec. 13, 2016, 130 Stat. 1067, provided that:

“(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Dec. 13, 2016], the Director of the National Institutes of Health, in consultation with the Director of the Office of Research on Women’s Health and the Director of the National Institute on Minority Health and Health Disparities, shall update the guidelines established under section 492B(d) of [the] Public Health Service Act (42 U.S.C. 289a-2(d)) in accordance with paragraph (2).

“(2) REQUIREMENTS.—The updated guidelines described in paragraph (1) shall—

“(A) reflect the science regarding sex differences;

“(B) improve adherence to the requirements under section 492B of the Public Health Service Act (42 U.S.C. 289a-2), including the reporting requirements under subsection (f) of such section; and

“(C) clarify the circumstances under which studies should be designed to support the conduct of analyses to detect significant differences in the intervention effect due to demographic factors related to section 492B of the Public Health Service Act, including in the absence of prior studies that demonstrate a difference in study outcomes on the basis of such factors and considering the effects of the absence of such analyses on the availability of data related to demographic differences.”

TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN

Pub. L. 114-255, div. A, title II, §2041, Dec. 13, 2016, 130 Stat. 1070, provided that:

“(a) TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.—

“(1) ESTABLISHMENT.—Not later than 90 days after the date of enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services (referred to in this section as the ‘Secretary’) shall establish a task force, in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), to be known as the ‘Task Force on Research Specific to Pregnant Women and Lactating Women’ (in this section referred to as the ‘Task Force’).

“(2) DUTIES.—The Task Force shall provide advice and guidance to the Secretary regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.

“(3) MEMBERSHIP.—

“(A) FEDERAL MEMBERS.—The Task Force shall be composed of each of the following Federal members, or the designees of such members:

“(i) The Director of the Centers for Disease Control and Prevention.

“(ii) The Director of the National Institutes of Health, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the directors of such other appropriate national research institutes.

“(iii) The Commissioner of Food and Drugs.

“(iv) The Director of the Office on Women’s Health.

“(v) The Director of the National Vaccine Program Office.

“(vi) The head of any other research-related agency or department not described in clauses (i) through (v) that the Secretary determines appropriate, which may include the Department of Veterans Affairs and the Department of Defense.

“(B) NON-FEDERAL MEMBERS.—The Task Force shall be composed of each of the following non-Federal members, including—

“(i) representatives from relevant medical societies with subject matter expertise on pregnant women, lactating women, or children;

“(ii) nonprofit organizations with expertise related to the health of women and children;

“(iii) relevant industry representatives; and

“(iv) other representatives, as appropriate.

“(C) LIMITATIONS.—The non-Federal members described in subparagraph (B) shall—

“(i) compose not more than one-half, and not less than one-third, of the total membership of the Task Force; and

“(ii) be appointed by the Secretary.

“(4) TERMINATION.—

“(A) IN GENERAL.—Subject to subparagraph (B), the Task Force shall terminate on the date that is 2 years after the date on which the Task Force is established under paragraph (1).

“(B) EXTENSION.—The Secretary may extend the operation of the Task Force for one additional 2-year period following the 2-year period described in subparagraph (A), if the Secretary determines that the extension is appropriate for carrying out the purpose of this section.

“(5) MEETINGS.—The Task Force shall meet not less than 2 times each year and shall convene public meetings, as appropriate, to fulfill its duties under paragraph (2).

“(6) TASK FORCE REPORT TO CONGRESS.—Not later than 18 months after the date on which the Task Force is established under paragraph (1), the Task Force shall prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that includes each of the following:

“(A) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies.

“(B) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research.

“(C) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women.

“(D) Identification of Federal activities, including—

“(i) the state of research on pregnancy and lactation;

“(ii) recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;

“(iii) dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and

“(iv) existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities.

“(E) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.

“(b) CONFIDENTIALITY.—Nothing in this section shall authorize the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

“(c) UPDATING PROTECTIONS FOR PREGNANT WOMEN AND LACTATING WOMEN IN RESEARCH.—

“(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act [Dec. 13, 2016], the Secretary, considering any recommendations of the Task Force available at such time and in consultation with the heads of relevant agencies of the Department of Health and Human Services, shall, as appropriate, update regulations and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research.

“(2) CRITERIA FOR EXCLUDING PREGNANT OR LACTATING WOMEN.—In updating any regulations or guidance described in paragraph (1), the Secretary shall consider any appropriate criteria to be used by institutional review boards and individuals reviewing grant proposals for excluding pregnant women or lactating women as a study population requiring additional protections from participating in human subject research.”

#### INAPPLICABILITY TO CURRENT PROJECTS

Pub. L. 103-43, title I, §133, June 10, 1993, 107 Stat. 135, provided that: “Section 492B of the Public Health Service Act, as added by section 131 of this Act [42 U.S.C. 289a-2], shall not apply with respect to projects of clinical research for which initial funding was provided prior to the date of the enactment of this Act [June 10, 1993]. With respect to the inclusion of women and minorities as subjects in clinical research conducted or supported by the National Institutes of Health, any policies of the Secretary of Health and Human Services regarding such inclusion that are in effect on the day before the date of the enactment of this Act shall continue to apply to the projects referred to in the preceding sentence.”

### § 289b. Office of Research Integrity

#### (a) In general

##### (1) Establishment of Office

Not later than 90 days after June 10, 1993, the Secretary shall establish an office to be known as the Office of Research Integrity (referred to in this section as the “Office”), which shall be established as an independent entity in the Department of Health and Human Services.

**(2) Appointment of Director**

The Office shall be headed by a Director, who shall be appointed by the Secretary, be experienced and specially trained in the conduct of research, and have experience in the conduct of investigations of research misconduct. The Secretary shall carry out this section acting through the Director of the Office. The Director shall report to the Secretary.

**(3) Definitions**

(A) The Secretary shall by regulation establish a definition for the term “research misconduct” for purposes of this section.

(B) For purposes of this section, the term “financial assistance” means a grant, contract, or cooperative agreement.

**(b) Existence of administrative processes as condition of funding for research**

The Secretary shall by regulation require that each entity that applies for financial assistance under this chapter for any project or program that involves the conduct of biomedical or behavioral research submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity;

(2) an agreement that the entity will report to the Director any investigation of alleged research misconduct in connection with projects for which funds have been made available under this chapter that appears substantial; and

(3) an agreement that the entity will comply with regulations issued under this section.

**(c) Process for response of Director**

The Secretary shall by regulation establish a process to be followed by the Director for the prompt and appropriate—

(1) response to information provided to the Director respecting research misconduct in connection with projects for which funds have been made available under this chapter;

(2) receipt of reports by the Director of such information from recipients of funds under this chapter;

(3) conduct of investigations, when appropriate; and

(4) taking of other actions, including appropriate remedies, with respect to such misconduct.

**(d) Monitoring by Director**

The Secretary shall by regulation establish procedures for the Director to monitor administrative processes and investigations that have been established or carried out under this section.

**(e) Protection of whistleblowers****(1) In general**

In the case of any entity required to establish administrative processes under subsection

(b), the Secretary shall by regulation establish standards for preventing, and for responding to the occurrence of retaliation by such entity, its officials or agents, against an employee in the terms and conditions of employment in response to the employee having in good faith—

(A) made an allegation that the entity, its officials or agents, has engaged in or failed to adequately respond to an allegation of research misconduct; or

(B) cooperated with an investigation of such an allegation.

**(2) Monitoring by Secretary**

The Secretary shall by regulation establish procedures for the Director to monitor the implementation of the standards established by an entity under paragraph (1) for the purpose of determining whether the procedures have been established, and are being utilized, in accordance with the standards established under such paragraph.

**(3) Noncompliance**

The Secretary shall by regulation establish remedies for noncompliance by an entity, its officials or agents, which has engaged in retaliation in violation of the standards established under paragraph (1). Such remedies may include termination of funding provided by the Secretary for such project or recovery of funding being provided by the Secretary for such project, or other actions as appropriate.

(July 1, 1944, ch. 373, title IV, § 493, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 874; amended Pub. L. 103-43, title I, §§ 161, 163, June 10, 1993, 107 Stat. 140, 142.)

## CODIFICATION

June 10, 1993, referred to in subsec. (a)(1), was in the original “the date of enactment of this section” which was translated as meaning the date of enactment of Pub. L. 103-43, which amended this section generally, to reflect the probable intent of Congress.

## AMENDMENTS

1993—Pub. L. 103-43, § 161, amended section generally. Prior to amendment, section read as follows:

“(a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that such entity—

“(1) has established (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of scientific fraud in connection with biomedical and behavioral research conducted at or sponsored by such entity; and

“(2) will report to the Secretary any investigation of alleged scientific fraud which appears substantial.

“(b) The Director of NIH shall establish a process for the prompt and appropriate response to information provided the Director of NIH respecting scientific fraud in connection with projects for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such fraud.”

Subsec. (e). Pub. L. 103-43, § 163, added subsec. (e).

## REGULATIONS

Pub. L. 103-43, title I, §165, June 10, 1993, 107 Stat. 143, provided that:

“(a) ISSUANCE OF FINAL RULES.—

“(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act [June 10, 1993], the Secretary shall, subject to paragraph (2), issue the final rule for each regulation required in section 493 or 493A of the Public Health Service Act [42 U.S.C. 289b, 289b-1].

“(2) DEFINITION OF RESEARCH MISCONDUCT.—Not later than 90 days after the date on which the report required in section 162(e) [107 Stat. 142] is submitted to the Secretary, the Secretary shall issue the final rule for the regulations required in section 493 of the Public Health Service Act with respect to the definition of the term ‘research misconduct’.

“(b) APPLICABILITY TO ONGOING INVESTIGATIONS.—The final rule issued pursuant to subsection (a) for investigations under section 493 of the Public Health Service Act [42 U.S.C. 289b] does not apply to investigations commenced before the date of the enactment of this Act [June 10, 1993] under authority of such section as in effect before such date.

“(c) DEFINITIONS.—For purposes of this section:

“(1) The term ‘section 493 of the Public Health Service Act’ means such section [42 U.S.C. 289b] as amended by sections 161 and 163 of this Act, except as indicated otherwise in subsection (b).

“(2) The term ‘section 493A of the Public Health Service Act’ means such section [42 U.S.C. 289b-1] as added by section 164 of this Act.

“(3) The term ‘Secretary’ means the Secretary of Health and Human Services.”

#### § 289b-1. Protection against financial conflicts of interest in certain projects of research

##### (a) Issuance of regulations

The Secretary shall by regulation define the specific circumstances that constitute the existence of a financial interest in a project on the part of an entity or individual that will, or may be reasonably expected to, create a bias in favor of obtaining results in such project that are consistent with such financial interest. Such definition shall apply uniformly to each entity or individual conducting a research project under this chapter. In the case of any entity or individual receiving assistance from the Secretary for a project of research described in subsection (b), the Secretary shall by regulation establish standards for responding to, including managing, reducing, or eliminating, the existence of such a financial interest. The entity may adopt individualized procedures for implementing the standards.

##### (b) Relevant projects

A project of research referred to in subsection (a) is a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment and for which such entity is receiving assistance from the Secretary.

##### (c) Identifying and reporting to Secretary

The Secretary shall by regulation require that each entity described in subsection (a) that applies for assistance under this chapter for any project described in subsection (b) submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect an administrative process under sub-

section (a) to identify financial interests (as defined under subsection (a)) that exist regarding the project; and

(2) an agreement that the entity will report to the Secretary such interests identified by the entity and how any such interests identified by the entity will be managed or eliminated in order that the project in question will be protected from bias that may stem from such interests; and

(3) an agreement that the entity will comply with regulations issued under this section.

##### (d) Monitoring of process

The Secretary shall monitor the establishment and conduct of the administrative process established by an entity pursuant to subsection (a).

##### (e) Response

In any case in which the Secretary determines that an entity has failed to comply with subsection (c) regarding a project of research described in subsection (b), the Secretary—

(1) shall require that, as a condition of receiving assistance, the entity disclose the existence of a financial interest (as defined under subsection (a)) in each public presentation of the results of such project; and

(2) may take such other actions as the Secretary determines to be appropriate.

##### (f) Definitions

For purposes of this section:

(1) The term “financial interest” includes the receipt of consulting fees or honoraria and the ownership of stock or equity.

(2) The term “assistance”, with respect to conducting a project of research, means a grant, contract, or cooperative agreement.

(July 1, 1944, ch. 373, title IV, §493A, as added Pub. L. 103-43, title I, §164, June 10, 1993, 107 Stat. 142.)

## REGULATIONS

Final rule for regulations required in this section to be issued not later than 180 days after June 10, 1993, see section 165 of Pub. L. 103-43, set out as a note under section 289b of this title.

#### § 289c. Research on public health emergencies

If the Secretary determines, after consultation with the Director of NIH, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control and Prevention, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of NIH—

(1) shall expedite the review by advisory councils under section 284a of this title and by peer review groups under section 289a of this title of applications for grants for research on such disease or disorder or proposals for contracts for such research;

(2) shall exercise the authority in section 6101 of title 41 respecting public exigencies to waive the advertising requirements of such section in the case of proposals for contracts for such research;

(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; and

(4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatment of such disease or disorder that has been developed in research assisted under this section.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.

(July 1, 1944, ch. 373, title IV, § 494, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 875; amended Pub. L. 102-531, title III, § 312(d)(9), Oct. 27, 1992, 106 Stat. 3504; Pub. L. 109-482, title I, § 104(b)(1)(P), Jan. 15, 2007, 120 Stat. 3693.)

#### CODIFICATION

In par. (2), “section 6101 of title 41” substituted for “section 3709 of the Revised Statutes (41 U.S.C. 5)” on authority of Pub. L. 111-350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

#### AMENDMENTS

2007—Pub. L. 109-482 struck out subsec. (a) designation before “If the Secretary” and subsec. (b) which read as follows: “Not later than 90 days after the end of a fiscal year, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on actions taken under subsection (a) of this section in such fiscal year.”

1992—Subsec. (a). Pub. L. 102-531 substituted “Centers for Disease Control and Prevention” for “Centers for Disease Control”.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

### § 289c-1. Collaborative use of certain health services research funds

The Secretary shall ensure that amounts made available under subparts 14, 15 and 16 of part C for health services research relating to alcohol abuse and alcoholism, drug abuse and mental health be used collaboratively, as appropriate, and in consultation with the Agency for Healthcare Research and Quality.

(July 1, 1944, ch. 373, title IV, § 494A, as added Pub. L. 102-321, title I, § 125, July 10, 1992, 106 Stat. 366; amended Pub. L. 103-43, title XX, § 2016(c), June 10, 1993, 107 Stat. 218; Pub. L. 104-66, title I, § 1062(b), Dec. 21, 1995, 109 Stat. 720; Pub. L. 105-362, title VI, § 601(a)(1)(F), Nov. 10, 1998, 112 Stat. 3285; Pub. L. 106-129, § 2(b)(2), Dec. 6, 1999, 113 Stat. 1670.)

#### REFERENCES IN TEXT

Subparts 14, 15 and 16 of part C, referred to in text, are classified to sections 285n et seq., 285o et seq., and 285p et seq., respectively, of this title.

#### AMENDMENTS

1999—Pub. L. 106-129, which directed the substitution of “Agency for Healthcare Research and Quality” for “Agency for Health Care Policy and Research”, was executed by making the substitution for “Agency for Health Care Policy Research”, to reflect the probable intent of Congress.

1998—Pub. L. 105-362 struck out heading and designation of subsec. (a) and heading and text of subsec. (b). Text of subsec. (b) read as follows: “Not later than De-

ember 30, 1993, and each December 30 thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report concerning the activities carried out with the amounts referred to in subsection (a) of this section.”

1995—Subsec. (b). Pub. L. 104-66 substituted “December 30, 1993, and each December 30 thereafter” for “September 30, 1993, and annually thereafter”.

1993—Subsec. (b). Pub. L. 103-43 substituted “September 30, 1993” for “May 3, 1993”.

#### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

### § 289d. Animals in research

#### (a) Establishment of guidelines

The Secretary, acting through the Director of NIH, shall establish guidelines for the following:

(1) The proper care of animals to be used in biomedical and behavioral research.

(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall require—

(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

(3) The organization and operation of animal care committees in accordance with subsection (b).

#### (b) Animal care committees; establishment; membership; functions

(1) Guidelines of the Secretary under subsection (a)(3) shall require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this chapter (including the National Institutes of Health and the national research institutes) to assure compliance with the guidelines established under subsection (a).

(2) Each animal care committee shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than three members, and shall include at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

(3) Each animal care committee of a research entity shall—

(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semi-annually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment;

(B) keep appropriate records of reviews conducted under subparagraph (A); and

(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under

subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

Reports filed under subparagraph (C) shall include any minority views filed by members of the committee.

**(c) Assurances required in application or contract proposal; reasons for use of animals; notice and comment requirements for promulgation of regulations**

The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in its application or contract proposal, submitted after the expiration of the twelve-month period beginning on November 20, 1985—

(1) assurances satisfactory to the Director of NIH that—

(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress; and

(2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract.

Notwithstanding subsection (a)(2) of section 553 of title 5, regulations under this subsection shall be promulgated in accordance with the notice and comment requirements of such section.

**(d) Failure to meet guidelines; suspension or revocation of grant or contract**

If the Director of NIH determines that—

(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this subchapter do not meet applicable guidelines established under subsection (a);

(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

(3) no action has been taken by the entity to correct such conditions;

the Director of NIH shall suspend or revoke such grant or contract under such conditions as the Director determines appropriate.

**(e) Disclosure of trade secrets or privileged or confidential information**

No guideline or regulation promulgated under subsection (a) or (c) may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential.

(July 1, 1944, ch. 373, title IV, §495, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 875.)

PROHIBITION ON FUNDING OF PROJECTS INVOLVING USE OF CHIMPANZEES OBTAINED FROM THE WILD

Pub. L. 102-394, title II, §213, Oct. 6, 1992, 106 Stat. 1812, provided that: "No funds appropriated under this Act or subsequent Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts shall be used by the National Institutes of Health, or any other Federal agency, or recipient of Federal funds on any project that entails the capture or procurement of chimpanzees obtained from the wild. For purposes of this section, the term 'recipient of Federal funds' includes private citizens, corporations, or other research institutions located outside of the United States that are recipients of Federal funds."

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 102-170, title II, §213, Nov. 26, 1991, 105 Stat. 1127.

Pub. L. 101-517, title II, §211, Nov. 5, 1990, 104 Stat. 2209.

Pub. L. 101-166, title II, §214, Nov. 21, 1989, 103 Stat. 1178.

PLAN FOR RESEARCH INVOLVING ANIMALS

Section 4 of Pub. L. 99-158 directed Director of National Institutes of Health to establish, not later than Oct. 1, 1986, a plan for research into methods of biomedical research and experimentation which reduces the use of animals in research or which produce less pain and distress in animals to develop methods found to be valid and reliable, to train scientists in use of such methods, to disseminate information on such methods and to establish an Interagency Coordinating Committee to assist in development of the plan, prior to repeal by Pub. L. 103-43, title II, §205(b), June 10, 1993, 107 Stat. 148. See section 283e of this title.

**§ 289e. Use of appropriations**

(a) Appropriations to carry out the purposes of this subchapter, unless otherwise expressly provided, may be expended in the District of Columbia for—

(1) personal services;

(2) stenographic recording and translating services;

(3) travel expenses (including the expenses of attendance at meetings when specifically authorized by the Secretary);

(4) rental;

(5) supplies and equipment;

(6) purchase and exchange of medical books, books of reference, directories, periodicals, newspapers, and press clippings;

(7) purchase, operation, and maintenance of passenger motor vehicles;

(8) printing and binding (in addition to that otherwise provided by law); and

(9) all other necessary expenses in carrying out this subchapter.

Such appropriations may be expended by contract if deemed necessary, without regard to section 6101 of title 41.

(b)(1) None of the amounts appropriated under this chapter for the purposes of this subchapter may be obligated for the construction of facilities (including the acquisition of land) unless a provision of this subchapter establishes express authority for such purpose and unless the Act making appropriations under such provision specifies that the amounts appropriated are available for such purpose.

(2) Any grants, cooperative agreements, or contracts authorized in this subchapter for the construction of facilities may be awarded only on a competitive basis.

(July 1, 1944, ch. 373, title IV, § 496, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 877; amended Pub. L. 101-190, § 8, Nov. 29, 1989, 103 Stat. 1695; Pub. L. 103-43, title XX, § 2008(b)(15), June 10, 1993, 107 Stat. 211.)

#### CODIFICATION

In subsec. (a), “section 6101 of title 41” substituted for “section 3709 of the Revised Statutes (41 U.S.C. 5)” on authority of Pub. L. 111-350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

#### AMENDMENTS

1993—Subsec. (a). Pub. L. 103-43 substituted “Appropriations to carry out the purposes of this subchapter” for “Such appropriations”.

1989—Subsec. (a). Pub. L. 101-190 designated existing provisions as subsec. (a), struck out first sentence which read as follows: “Appropriations to carry out the purposes of this subchapter shall be available for the acquisition of land or the erection of buildings only if so specified.”, and added subsec. (b).

#### CONSTRUCTION OF BIOMEDICAL FACILITIES FOR DEVELOPMENT AND BREEDING OF SPECIALIZED STRAINS OF MICE

Pub. L. 101-190, §§ 1-7, Nov. 29, 1989, 103 Stat. 1691-1695, as amended by Pub. L. 101-374, § 4(a), (c)(1), Aug. 15, 1990, 104 Stat. 458, 459, authorized a reservation of funds for making a grant to construct facilities for development and breeding of specialized strains of mice for use in biomedical research, provided for a competitive grant award process, required applicant for the grant to agree to a twenty-year transferable obligation, restricted grant applicant to public or nonprofit private status, with assurances of sufficient financial resources, set forth other grant requirements, and specified consequences of failure to comply with agreements and violation of the twenty-year obligation.

#### § 289f. Gifts and donations; memorials

The Secretary may, in accordance with section 238 of this title, accept conditional gifts for the National Institutes of Health or a national research institute or for the acquisition of grounds or for the erection, equipment, or maintenance of facilities for the National Institutes of Health or a national research institute. Donations of \$50,000 or over for the National Institutes of Health or a national research institute for carrying out the purposes of this subchapter may be acknowledged by the establishment within the National Institutes of Health or a national research institute of suitable memorials to the donors.

(July 1, 1944, ch. 373, title IV, § 497, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 877; amended Pub. L. 99-660, title III, § 311(b)(1), Nov. 14, 1986, 100 Stat. 3779; Pub. L. 100-607, title II, § 204(3), Nov. 4, 1988, 102 Stat. 3079; Pub. L. 100-690, title II, § 2620(b)(2), Nov. 18, 1988, 102 Stat. 4244; Pub. L. 101-381, title I, § 102(5), Aug. 18, 1990, 104 Stat. 586; Pub. L. 103-43, title XX, § 2010(b)(6), June 10, 1993, 107 Stat. 214.)

#### AMENDMENTS

1993—Pub. L. 103-43 substituted “section 238” for “section 300aaa”.

1990—Pub. L. 101-381 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

1988—Pub. L. 100-690 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

Pub. L. 100-607 substituted “300aaa” for “300cc”.

1986—Pub. L. 99-660 substituted “section 300cc of this title” for “section 300aa of this title”.

#### EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-690 effective immediately after enactment of Pub. L. 100-607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100-690, set out as a note under section 242m of this title.

#### EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99-660 effective Dec. 22, 1987, see section 323 of Pub. L. 99-660, as amended, set out as an Effective Date note under section 300aa-1 of this title.

#### § 289g. Fetal research

##### (a) Conduct or support by Secretary; restrictions

The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—

(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

##### (b) Risk standard for fetuses intended to be aborted and fetuses intended to be carried to term to be same

In administering the regulations for the protection of human research subjects which—

(1) apply to research conducted or supported by the Secretary;

(2) involve living human fetuses in utero; and

(3) are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations;

or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

(July 1, 1944, ch. 373, title IV, § 498, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 877; amended Pub. L. 100-607, title I, §§ 156, 157(b), Nov. 4, 1988, 102 Stat. 3059; Pub. L. 103-43, title I, § 121(b)(1), June 10, 1993, 107 Stat. 133.)

#### AMENDMENTS

1993—Subsec. (c). Pub. L. 103-43 struck out subsec. (c) which directed Biomedical Ethics Advisory Committee to conduct a study of the nature, advisability, and biomedical and ethical implications of exercising any waiver of the risk standard published in section 46.102(g) of part 46 of title 45 of the Code of Federal Regulations and to report its finding to the Biomedical Ethics Board not later than 24 months after Nov. 4, 1988, which report was to be then transmitted to specified Congressional committees.

1988—Subsec. (c)(1). Pub. L. 100-607, §157(b), substituted “24 months after November 4, 1988” for “thirty months after November 20, 1985”.

Subsec. (c)(2). Pub. L. 100-607, §156(1), substituted “24-month period beginning on November 4, 1988” for “thirty-six month period beginning on November 20, 1985”.

Subsec. (c)(3). Pub. L. 100-607, §156(2), substituted “1990” for “1988”.

#### NULLIFICATION OF CERTAIN PROVISIONS

Pub. L. 103-43, title I, §121(c), June 10, 1993, 107 Stat. 133, provided that: “The provisions of Executive Order 12806 (57 Fed. Reg. 21589 (May 21, 1992)) [formerly set out below] shall not have any legal effect. The provisions of section 204(d) of part 46 of title 45 of the Code of Federal Regulations (45 CFR 46.204(d)) shall not have any legal effect.”

#### EXECUTIVE ORDER NO. 12806. ESTABLISHMENT OF FETAL TISSUE BANK

Ex. Ord. No. 12806, May 19, 1992, 57 F.R. 21589, which established a human fetal tissue bank, was nullified by Pub. L. 103-43, title I, §121(c), June 10, 1993, 107 Stat. 133, set out above.

#### FEDERAL FUNDING OF FETAL TISSUE TRANSPLANTATION RESEARCH

Memorandum of President of the United States, Jan. 22, 1993, 58 F.R. 7457, provided:

Memorandum for the Secretary of Health and Human Services

On March 22, 1988, the Assistant Secretary for Health of Health and Human Services (“HHS”) imposed a temporary moratorium on Federal funding of research involving transplantation of fetal tissue from induced abortions. Contrary to the recommendations of a National Institutes of Health advisory panel, on November 2, 1989, the Secretary of Health and Human Services extended the moratorium indefinitely. This moratorium has significantly hampered the development of possible treatments for individuals afflicted with serious diseases and disorders, such as Parkinson’s disease, Alzheimer’s disease, diabetes, and leukemia. Accordingly, I hereby direct that you immediately lift the moratorium.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

WILLIAM J. CLINTON.

### § 289g-1. Research on transplantation of fetal tissue

#### (a) Establishment of program

##### (1) In general

The Secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes.

##### (2) Source of tissue

Human fetal tissue may be used in research carried out under paragraph (1) regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.

#### (b) Informed consent of donor

##### (1) In general

In research carried out under subsection (a), human fetal tissue may be used only if the woman providing the tissue makes a statement, made in writing and signed by the woman, declaring that—

(A) the woman donates the fetal tissue for use in research described in subsection (a);

(B) the donation is made without any restriction regarding the identity of individ-

uals who may be the recipients of transplantations of the tissue; and

(C) the woman has not been informed of the identity of any such individuals.

#### (2) Additional statement

In research carried out under subsection (a), human fetal tissue may be used only if the attending physician with respect to obtaining the tissue from the woman involved makes a statement, made in writing and signed by the physician, declaring that—

(A) in the case of tissue obtained pursuant to an induced abortion—

(i) the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for a donation of the tissue for use in such research;

(ii) no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; and

(iii) the abortion was performed in accordance with applicable State law;

(B) the tissue has been donated by the woman in accordance with paragraph (1); and

(C) full disclosure has been provided to the woman with regard to—

(i) such physician’s interest, if any, in the research to be conducted with the tissue; and

(ii) any known medical risks to the woman or risks to her privacy that might be associated with the donation of the tissue and that are in addition to risks of such type that are associated with the woman’s medical care.

#### (c) Informed consent of researcher and donee

In research carried out under subsection (a), human fetal tissue may be used only if the individual with the principal responsibility for conducting the research involved makes a statement, made in writing and signed by the individual, declaring that the individual—

(1) is aware that—

(A) the tissue is human fetal tissue;

(B) the tissue may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and

(C) the tissue was donated for research purposes;

(2) has provided such information to other individuals with responsibilities regarding the research;

(3) will require, prior to obtaining the consent of an individual to be a recipient of a transplantation of the tissue, written acknowledgment of receipt of such information by such recipient; and

(4) has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy made solely for the purposes of the research.

#### (d) Availability of statements for audit

##### (1) In general

In research carried out under subsection (a), human fetal tissue may be used only if the head of the agency or other entity conducting

the research involved certifies to the Secretary that the statements required under subsections (b)(2) and (c) will be available for audit by the Secretary.

**(2) Confidentiality of audit**

Any audit conducted by the Secretary pursuant to paragraph (1) shall be conducted in a confidential manner to protect the privacy rights of the individuals and entities involved in such research, including such individuals and entities involved in the donation, transfer, receipt, or transplantation of human fetal tissue. With respect to any material or information obtained pursuant to such audit, the Secretary shall—

(A) use such material or information only for the purposes of verifying compliance with the requirements of this section;

(B) not disclose or publish such material or information, except where required by Federal law, in which case such material or information shall be coded in a manner such that the identities of such individuals and entities are protected; and

(C) not maintain such material or information after completion of such audit, except where necessary for the purposes of such audit.

**(e) Applicability of State and local law**

**(1) Research conducted by recipients of assistance**

The Secretary may not provide support for research under subsection (a) unless the applicant for the financial assistance involved agrees to conduct the research in accordance with applicable State law.

**(2) Research conducted by Secretary**

The Secretary may conduct research under subsection (a) only in accordance with applicable State and local law.

**(f) Report**

The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this section during the preceding fiscal year, including a description of whether and to what extent research under subsection (a) has been conducted in accordance with this section.

**(g) "Human fetal tissue" defined**

For purposes of this section, the term "human fetal tissue" means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.

(July 1, 1944, ch. 373, title IV, § 498A, as added Pub. L. 103-43, title I, § 111, June 10, 1993, 107 Stat. 129.)

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104-14, set out as a note preceding section 21

of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

NULLIFICATION OF MORATORIUM

Pub. L. 103-43, title I, § 113, June 10, 1993, 107 Stat. 132, provided that:

"(a) IN GENERAL.—Except as provided in subsection (c), no official of the executive branch may impose a policy that the Department of Health and Human Services is prohibited from conducting or supporting any research on the transplantation of human fetal tissue for therapeutic purposes. Such research shall be carried out in accordance with section 498A of the Public Health Service Act [42 U.S.C. 289g-1] (as added by section 111 of this Act), without regard to any such policy that may have been in effect prior to the date of the enactment of this Act [June 10, 1993].

"(b) PROHIBITION AGAINST WITHHOLDING OF FUNDS IN CASES OF TECHNICAL AND SCIENTIFIC MERIT.—

"(1) IN GENERAL.—Subject to subsection (b)(2) of section 492A of the Public Health Service Act [42 U.S.C. 289a-1(b)(2)] (as added by section 101 of this Act), in the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may not withhold funds for the research if—

"(A) the research has been approved for purposes of subsection (a) of such section 492A;

"(B) the research will be carried out in accordance with section 498A of such Act [42 U.S.C. 289g-1] (as added by section 111 of this Act); and

"(C) there are reasonable assurances that the research will not utilize any human fetal tissue that has been obtained in violation of section 498B(a) of such Act [42 U.S.C. 289g-2(a)] (as added by section 112 of this Act).

"(2) STANDING APPROVAL REGARDING ETHICAL STATUS.—In the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the issuance in December 1988 of the Report of the Human Fetal Tissue Transplantation Research Panel shall be deemed to be a report—

"(A) issued by an ethics advisory board pursuant to section 492A(b)(5)(B)(ii) of the Public Health Service Act [42 U.S.C. 289a-1(b)(5)(B)(ii)] (as added by section 101 of this Act); and

"(B) finding, on a basis that is neither arbitrary nor capricious, that the nature of the research is such that it is not unethical to conduct or support the research.

"(c) AUTHORITY FOR WITHHOLDING FUNDS FROM RESEARCH.—In the case of any research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may withhold funds for the research if any of the conditions specified in any of subparagraphs (A) through (C) of subsection (b)(1) are not met with respect to the research.

"(d) DEFINITION.—For purposes of this section, the term 'human fetal tissue' has the meaning given such term in section 498A(f) of the Public Health Service Act [42 U.S.C. 289g-1(f)] (as added by section 111 of this Act)."

REPORT BY GENERAL ACCOUNTING OFFICE ON ADEQUACY OF REQUIREMENTS

Pub. L. 103-43, title I, § 114, June 10, 1993, 107 Stat. 132, provided that, with respect to research on the transplantation of human fetal tissue for therapeutic purposes, the Comptroller General of the United States was to conduct an audit for the purpose of determining whether and to what extent such research conducted or supported by Secretary of Health and Human Services

had been conducted in accordance with this section and whether and to what extent there have been violations of section 289g-2 of this title and directed the Comptroller General to complete the audit and report the findings to Congress, not later than May 19, 1995.

**§ 289g-2. Prohibitions regarding human fetal tissue**

**(a) Purchase of tissue**

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.

**(b) Solicitation or acceptance of tissue as directed donation for use in transplantation**

It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, the tissue will be or is obtained pursuant to an induced abortion, and—

- (1) the donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual;
- (2) the donated tissue will be transplanted into a relative of the donating individual; or
- (3) the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.

**(c) Solicitation or acceptance of tissue from fetuses gestated for research purposes**

It shall be unlawful for any person or entity involved or engaged in interstate commerce to—

- (1) solicit or knowingly acquire, receive, or accept a donation of human fetal tissue knowing that a human pregnancy was deliberately initiated to provide such tissue; or
- (2) knowingly acquire, receive, or accept tissue or cells obtained from a human embryo or fetus that was gestated in the uterus of a nonhuman animal.

**(d) Criminal penalties for violations**

**(1) In general**

Any person who violates subsection (a), (b), or (c) shall be fined in accordance with title 18, subject to paragraph (2), or imprisoned for not more than 10 years, or both.

**(2) Penalties applicable to persons receiving consideration**

With respect to the imposition of a fine under paragraph (1), if the person involved violates subsection (a) or (b)(3), a fine shall be imposed in an amount not less than twice the amount of the valuable consideration received.

**(e) Definitions**

For purposes of this section:

- (1) The term “human fetal tissue” has the meaning given such term in section 289g-1(g) of this title.
- (2) The term “interstate commerce” has the meaning given such term in section 321(b) of title 21.
- (3) The term “valuable consideration” does not include reasonable payments associated

with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

(July 1, 1944, ch. 373, title IV, §498B, as added Pub. L. 103-43, title I, §112, June 10, 1993, 107 Stat. 131; amended Pub. L. 109-242, §2, July 19, 2006, 120 Stat. 570.)

AMENDMENTS

2006—Subsec. (c). Pub. L. 109-242, §2(2), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 109-242, §2(1), (3), redesignated subsec. (c) as (d) and substituted “(a), (b), or (c)” for “(a) or (b)” in par. (1). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 109-242, §2(1), (4), redesignated subsec. (d) as (e) and substituted “section 289g-1(g)” for “section 289g-1(f)” in par. (1).

**§ 289g-3. Breast implant research**

**(a) In general**

The Director of NIH may conduct or support research to examine the long-term health implications of silicone breast implants, both gel and saline filled. Such research studies may include the following:

- (1) Developing and examining techniques to measure concentrations of silicone in body fluids and tissues.
- (2) Surveillance of recipients of silicone breast implants, including long-term outcomes and local complications.

**(b) Definition**

For purposes of this section, the term “breast implant” means a breast prosthesis that is implanted to augment or reconstruct the female breast.

(July 1, 1944, ch. 373, title IV, §498C, as added Pub. L. 107-250, title II, §215(b), Oct. 26, 2002, 116 Stat. 1615.)

BREAST IMPLANTS; STUDY BY COMPTROLLER GENERAL

Pub. L. 107-250, title II, §214, Oct. 26, 2002, 116 Stat. 1615, which provided that the Comptroller General was to conduct a study of information typically provided by health professionals to women on breast implant surgery and to report the findings of the study to Congress, was repealed by Pub. L. 111-8, div. G, title I, §1301(g), Mar. 11, 2009, 123 Stat. 829.

**§ 289g-4. Support for emergency medicine research**

**(a) Emergency medical research**

The Secretary shall support Federal programs administered by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and other agencies involved in improving the emergency care system to expand and accelerate research in emergency medical care systems and emergency medicine, including—

- (1) the basic science of emergency medicine;
- (2) the model of service delivery and the components of such models that contribute to enhanced patient health outcomes;
- (3) the translation of basic scientific research into improved practice; and
- (4) the development of timely and efficient delivery of health services.

**(b) Pediatric emergency medical research**

The Secretary shall support Federal programs administered by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and other agencies to coordinate and expand research in pediatric emergency medical care systems and pediatric emergency medicine, including—

- (1) an examination of the gaps and opportunities in pediatric emergency care research and a strategy for the optimal organization and funding of such research;
- (2) the role of pediatric emergency services as an integrated component of the overall health system;
- (3) system-wide pediatric emergency care planning, preparedness, coordination, and funding;
- (4) pediatric training in professional education; and
- (5) research in pediatric emergency care, specifically on the efficacy, safety, and health outcomes of medications used for infants, children, and adolescents in emergency care settings in order to improve patient safety.

**(c) Impact research**

The Secretary shall support research to determine the estimated economic impact of, and savings that result from, the implementation of coordinated emergency care systems.

**(d) Authorization of appropriations**

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014. (July 1, 1944, ch. 373, title IV, §498D, as added Pub. L. 111-148, title III, §3504(b), Mar. 23, 2010, 124 Stat. 521.)

**§ 289g-5. Precision medicine initiative****(a) In general**

The Secretary is encouraged to establish and carry out an initiative, to be known as the “Precision Medicine Initiative” (in this section referred to as the “Initiative”), to augment efforts to address disease prevention, diagnosis, and treatment.

**(b) Components**

The Initiative described under subsection (a) may include—

- (1) developing a network of scientists to assist in carrying out the purposes of the Initiative;
- (2) developing new approaches for addressing scientific, medical, public health, and regulatory science issues;
- (3) applying genomic technologies, such as whole genomic sequencing, to provide data on the molecular basis of disease;
- (4) collecting information voluntarily provided by a diverse cohort of individuals that can be used to better understand health and disease; and
- (5) other activities to advance the goals of the Initiative, as the Secretary determines appropriate.

**(c) Authority of the Secretary**

In carrying out this section, the Secretary may—

- (1) coordinate with the Secretary of Energy, private industry, and others, as the Secretary determines appropriate, to identify and address the advanced supercomputing and other advanced technology needs for the Initiative;
- (2) develop and utilize public-private partnerships; and
- (3) leverage existing data sources.

**(d) Requirements**

In the implementation of the Initiative under subsection (a), the Secretary shall—

- (1) ensure the collaboration of the National Institutes of Health, the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology, and the Office for Civil Rights of the Department of Health and Human Services;
- (2) comply with existing laws and regulations for the protection of human subjects involved in research, including the protection of participant privacy;
- (3) implement policies and mechanisms for appropriate secure data sharing across systems that include protections for privacy and security of data;
- (4) consider the diversity of the cohort to ensure inclusion of a broad range of participants, including consideration of biological, social, and other determinants of health that contribute to health disparities;
- (5) ensure that only authorized individuals may access controlled or sensitive, identifiable biological material and associated information collected or stored in connection with the Initiative; and
- (6) on the appropriate Internet website of the Department of Health and Human Services, identify any entities with access to such information and provide information with respect to the purpose of such access, a summary of the research project for which such access is granted, as applicable, and a description of the biological material and associated information to which the entity has access.

**(e) Report**

Not later than 1 year after December 13, 2016, the Secretary shall submit a report on the relevant data access policies and procedures to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Such report shall include steps the Secretary has taken to consult with experts or other heads of departments or agencies of the Federal Government in the development of such policies.

(July 1, 1944, ch. 373, title IV, §498E, as added Pub. L. 114-255, div. A, title II, §2011, Dec. 13, 2016, 130 Stat. 1047.)

**§ 289h. Repealed. Pub. L. 103-43, title I, § 121(b)(2), June 10, 1993, 107 Stat. 133**

Section, act July 1, 1944, ch. 373, title IV, §499, as added Nov. 20, 1985, Pub. L. 99-158, §2, 99 Stat. 878, related to construction of subchapter.

**§ 290. National Institutes of Health Management Fund; establishment; advancements; availability; final adjustments of advances**

For the purpose of facilitating the economical and efficient conduct of operations in the Na-

tional Institutes of Health which are financed by two or more appropriations where the costs of operation are not readily susceptible of distribution as charges to such appropriations, there is established the National Institutes of Health Management Fund. Such amounts as the Director of the National Institutes of Health may determine to represent a reasonable distribution of estimated costs among the various appropriations involved may be advanced each year to this fund and shall be available for expenditure for such costs under such regulations as may be prescribed by said Director, including the operation of facilities for the sale of meals to employees and others at rates to be determined by said Director to be sufficient to cover the reasonable value of the meals served and the proceeds thereof shall be deposited to the credit of this fund: *Provided*, That funds advanced to this fund shall be available only in the fiscal year in which they are advanced: *Provided further*, That final adjustments of advances in accordance with actual costs shall be effected wherever practicable with the appropriations from which such funds are advanced.

(Pub. L. 85-67, title II, §201, June 29, 1957, 71 Stat. 220; Pub. L. 87-290, title II, §201, Sept. 22, 1961, 75 Stat. 603.)

#### CODIFICATION

Section was enacted as a part of the Department of Health, Education, and Welfare Appropriation Act, 1958, and not as a part of the Public Health Service Act which comprises this chapter.

#### AMENDMENTS

1961—Pub. L. 87-290 substituted “reasonable value of the meals served” for “cost of such operation”.

### § 290a. Victims of fire

#### (a) Research on burns, burn injuries, and rehabilitation

The Secretary of Health and Human Services shall establish, within the National Institutes of Health and in cooperation with the Administrator of FEMA, an expanded program of research on burns, treatment of burn injuries, and rehabilitation of victims of fires. The National Institutes of Health shall—

- (1) sponsor and encourage the establishment throughout the Nation of twenty-five additional burn centers, which shall comprise separate hospital facilities providing specialized burn treatment and including research and teaching programs and twenty-five additional burn units, which shall comprise specialized facilities in general hospitals used only for burn victims;
- (2) provide training and continuing support of specialists to staff the new burn centers and burn units;
- (3) sponsor and encourage the establishment of ninety burn programs in general hospitals which comprise staffs of burn injury specialists;
- (4) provide special training in emergency care for burn victims;
- (5) augment sponsorship of research on burns and burn treatment;
- (6) administer and support a systematic program of research concerning smoke inhalation injuries; and

(7) sponsor and support other research and training programs in the treatment and rehabilitation of burn injury victims.

#### (b) Authorization of appropriations

For purposes of this section, there are authorized to be appropriated not to exceed \$5,000,000 for the fiscal year ending June 30, 1975 and not to exceed \$8,000,000 for the fiscal year ending June 30, 1976.

(Pub. L. 93-498, §19, Oct. 29, 1974, 88 Stat. 1547; Pub. L. 96-88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 106-503, title I, §110(a)(2)(B)(vii), Nov. 13, 2000, 114 Stat. 2302; Pub. L. 112-239, div. A, title XVIII, §1802(b)(1), Jan. 2, 2013, 126 Stat. 2100.)

#### CODIFICATION

Section was enacted as part of the Federal Fire Prevention and Control Act of 1974 (which is classified principally to chapter 49 (§2201 et seq.) of Title 15), and not as a part of the Public Health Service Act which comprises this chapter.

#### AMENDMENTS

2013—Subsec. (a). Pub. L. 112-239 substituted “Administrator of FEMA” for “Director” in introductory provisions.

2000—Subsec. (a). Pub. L. 106-503 substituted “in cooperation with the Director” for “in cooperation with the Secretary”.

#### CHANGE OF NAME

“Secretary of Health and Human Services” substituted for “Secretary of Health, Education, and Welfare” in subsec. (a) pursuant to section 509(b) of Pub. L. 96-88 which is classified to section 3508(b) of Title 20, Education.

#### TRANSFER OF FUNCTIONS

For transfer of all functions, personnel, assets, components, authorities, grant programs, and liabilities of the Federal Emergency Management Agency, including the functions of the Under Secretary for Federal Emergency Management relating thereto, to the Federal Emergency Management Agency, see section 315(a)(1) of Title 6, Domestic Security.

For transfer of functions, personnel, assets, and liabilities of the Federal Emergency Management Agency, including the functions of the Director of the Federal Emergency Management Agency relating thereto, to the Secretary of Homeland Security, and for treatment of related references, see former section 313(1) and sections 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

#### DEFINITIONS

For definition of terms used in this section, see section 2203 of Title 15, Commerce and Trade.

### PART I—FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

#### AMENDMENTS

1998—Pub. L. 105-392, title IV, §418(1), Nov. 13, 1998, 112 Stat. 3591, substituted “Foundation for the National Institutes of Health” for “National Foundation for Biomedical Research” in part heading.

1993—Pub. L. 103-43, title I, §141(a)(2), June 10, 1993, 107 Stat. 136, redesignated part H “National Foundation for Biomedical Research” as I.

### § 290b. Establishment and duties of Foundation

#### (a) In general

The Secretary shall, acting through the Director of NIH, establish a nonprofit corporation to

be known as the Foundation for the National Institutes of Health (hereafter in this section referred to as the “Foundation”). The Foundation shall not be an agency or instrumentality of the United States Government.

**(b) Purpose of Foundation**

The purpose of the Foundation shall be to support the National Institutes of Health in its mission (including collection of funds for pediatric pharmacologic research), and to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations.

**(c) Certain activities of Foundation**

**(1) In general**

In carrying out subsection (b), the Foundation may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of the following activities with respect to the purpose described in such subsection:

(A) A program to provide and administer endowed positions that are associated with the research program of the National Institutes of Health. Such endowments may be expended for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the endowed positions.

(B) A program to provide and administer fellowships and grants to research personnel in order to work and study in association with the National Institutes of Health. Such fellowships and grants may include stipends, travel, health insurance benefits and other appropriate expenses. The recipients of fellowships shall be selected by the donors and the Foundation upon the recommendation of the National Institutes of Health employees in the laboratory where the fellow would serve, and shall be subject to the agreement of the Director of the National Institutes of Health and the Executive Director of the Foundation.

(C) A program to collect funds for pediatric pharmacologic research and studies.

(D) Supplementary programs to provide for—

(i) scientists of other countries to serve in research capacities in the United States in association with the National Institutes of Health or elsewhere, or opportunities for employees of the National Institutes of Health or other public health officials in the United States to serve in such capacities in other countries, or both;

(ii) the conduct and support of studies, projects, and research, which may include stipends, travel and other support for personnel in collaboration with national and international non-profit and for-profit organizations;

(iii) the conduct and support of forums, meetings, conferences, courses, and training workshops that may include undergraduate, graduate, post-graduate, and post-doctoral accredited courses and the maintenance of accreditation of such

courses by the Foundation at the State and national level for college or continuing education credits or for degrees;

(iv) programs to support and encourage teachers and students of science at all levels of education and programs for the general public which promote the understanding of science;

(v) programs for writing, editing, printing, publishing, and vending of books and other materials; and

(vi) the conduct of other activities to carry out and support the purpose described in subsection (b).

(E) The Cures Acceleration Network described in section 287a of this title.

**(2) Fees**

The Foundation may assess fees for the provision of professional, administrative and management services by the Foundation in amounts determined reasonable and appropriate by the Executive Director.

**(3) Authority of Foundation**

The Foundation shall be the sole entity responsible for carrying out the activities described in this subsection.

**(d) Board of Directors**

**(1) Composition**

(A) The Foundation shall have a Board of Directors (hereafter referred to in this section as the “Board”), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

(B) The ex officio members of the Board shall be—

(i) the Chairman and ranking minority member of the Subcommittee on Health and the Environment (Committee on Energy and Commerce) or their designees, in the case of the House of Representatives;

(ii) the Chairman and ranking minority member of the Committee on Labor and Human Resources or their designees, in the case of the Senate;

(iii) the Director of the National Institutes of Health; and

(iv) the Commissioner of Food and Drugs.

(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board individuals from among a list of candidates to be provided by the National Academy of Science. Such appointed members shall include—

(i) representatives of the general biomedical field;

(ii) representatives of experts in pediatric medicine and research;

(iii) representatives of the general behavioral field, which may include experts in biomedical ethics; and

(iv) representatives of the general public, which may include representatives of affected industries.

(D)(i) Not later than 30 days after June 10, 1993, the Director of the National Institutes of Health shall convene a meeting of the ex officio members of the Board to—

(I) incorporate the Foundation and establish the general policies of the Foundation for carrying out the purposes of subsection (b), including the establishment of the by-laws of the Foundation; and

(II) appoint the members of the Board in accordance with subparagraph (C).

(ii) Upon the appointment of the appointed members of the Board under clause (i)(II), the terms of service as members of the Board of the ex officio members of the Board described in clauses (i) and (ii) of subparagraph (B) shall terminate. The ex officio members of the Board described in clauses (iii) and (iv) of subparagraph (B) shall continue to serve as ex officio members of the Board.

(E) The agreement of not less than three-fifths of the members of the ex officio members of the Board shall be required for the appointment of each member to the initial Board.

(F) No employee of the National Institutes of Health shall be appointed as a member of the Board.

(G) The Board may, through amendments to the bylaws of the Foundation, provide that the number of appointed members of the Board shall be greater than the number specified in subparagraph (C).

## **(2) Chair**

(A) The ex officio members of the Board under paragraph (1)(B) shall designate an individual to serve as the initial Chair of the Board.

(B) Upon the termination of the term of service of the initial Chair of the Board, the appointed members of the Board shall elect a member of the Board to serve as the Chair of the Board.

## **(3) Terms and vacancies**

(A) The term of office of each member of the Board appointed under paragraph (1)(C) shall be 5 years, except that the terms of offices for the initial appointed members of the Board shall expire as determined by the ex officio members and the Chair.

(B) Any vacancy in the membership of the appointed members of the Board shall be filled in accordance with the bylaws of the Foundation established in accordance with paragraph (6), and shall not affect the power of the remaining appointed members to execute the duties of the Board.

(C) If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(D) A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

## **(4) Compensation**

Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

## **(5) Meetings and quorum**

A majority of the appointed members of the Board shall constitute a quorum for purposes of conducting the business of the Board.

## **(6) Certain bylaws**

(A) In establishing bylaws under this subsection, the Board shall ensure that the following are provided for:

(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

(ii) Policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation. Policies with respect to ethical standards shall ensure that officers, employees and agents of the Foundation (including members of the Board) avoid encumbrances that would result in a conflict of interest, including a financial conflict of interest or a divided allegiance. Such policies shall include requirements for the provision of information concerning any ownership or controlling interest in entities related to the activities of the Foundation by such officers, employees and agents and their spouses and relatives.

(iii) Policies for the conduct of the general operations of the Foundation.

(iv) Policies for writing, editing, printing, publishing, and vending of books and other materials.

(B) In establishing bylaws under this subsection, the Board shall ensure that such bylaws (and activities carried out under the bylaws) do not—

(i) reflect unfavorably upon the ability of the Foundation or the National Institutes of Health to carry out its responsibilities or official duties in a fair and objective manner; or

(ii) compromise, or appear to compromise, the integrity of any governmental agency or program, or any officer or employee involved in such program.

## **(e) Incorporation**

The initial members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

## **(f) Nonprofit status**

The Foundation shall be considered to be a corporation under section 501(c) of title 26, and shall be subject to the provisions of such section.

## **(g) Executive Director**

### **(1) In general**

The Foundation shall have an Executive Director who shall be appointed by the Board and shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

### **(2) Compensation**

The rate of compensation of the Executive Director shall be fixed by the Board.

**(h) Powers**

In carrying out subsection (b), the Foundation may—

- (1) operate under the direction of its Board;
- (2) adopt, alter, and use a corporate seal, which shall be judicially noticed;
- (3) provide for 1 or more officers, employees, and agents, as may be necessary, define their duties, and require surety bonds or make other provisions against losses occasioned by acts of such persons;
- (4) hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees;
- (5) with the consent of any executive department or independent agency, use the information, services, staff, and facilities of such in carrying out this section;
- (6) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;
- (7) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this part;
- (8) establish a process for the selection of candidates for positions under subsection (c);
- (9) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;
- (10) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;
- (11) solicit, accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation;
- (12) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation;
- (13) appoint other groups of advisors as may be determined necessary from time to time to carry out the functions of the Foundation;
- (14) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation; and
- (15) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this part.

**(i) Administrative control**

No participant in the program established under this part shall exercise any administrative control over any Federal employee.

**(j) General provisions****(1) Foundation integrity**

The members of the Board shall be accountable for the integrity of the operations of the Foundation and shall ensure such integrity through the development and enforcement of criteria and procedures relating to standards of conduct, financial disclosure statements, conflict of interest rules, recusal and waiver rules, audits and other matter determined appropriate by the Board.

**(2) Financial conflicts of interest**

Any individual who is an officer, employee, or member of the Board of the Foundation may not (in accordance with policies and requirements developed under subsection (d)(6)) personally or substantially participate in the consideration or determination by the Foundation of any matter that would directly or predictably affect any financial interest of the individual or a relative (as such term is defined in section 109(16) of the Ethics in Government Act of 1978) of the individual, of any business organization or other entity, or of which the individual is an officer or employee, or is negotiating for employment, or in which the individual has any other financial interest.

**(3) Audits; availability of records**

The Foundation shall—

- (A) provide for annual audits of the financial condition of the Foundation; and
- (B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

**(4) Reports**

(A) Not later than 5 months following the end of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation, including an accounting of the use of amounts transferred under subsection (l).

(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts or grants to the Foundation of real or personal property, and the source and amount of all gifts or grants to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts or grants to the Foundation may be used.

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available—

- (i) for public inspection, and shall upon request provide a copy of the report to any individual for a charge that shall not exceed the cost of providing the copy; and
- (ii) to the appropriate committees of Congress.

(D) The Board shall annually hold a public meeting to summarize the activities of the Foundation and distribute written reports concerning such activities and the scientific results derived from such activities.

**(5) Service of Federal employees**

Federal employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its function, so long as the employees do not direct or control Foundation activities.

**(6) Relationship with existing entities**

The Foundation may, pursuant to appropriate agreements, merge with, acquire, or use the resources of existing nonprofit private corporations with missions similar to the purposes of the Foundation, such as the Foundation for Advanced Education in the Sciences.

**(7) Intellectual property rights**

The Board shall adopt written standards with respect to the ownership of any intellectual property rights derived from the collaborative efforts of the Foundation prior to the commencement of such efforts.

**(8) National Institutes of Health Amendments of 1990**

The activities conducted in support of the National Institutes of Health Amendments of 1990 (Public Law 101-613), and the amendments made by such Act, shall not be nullified by the enactment of this section.<sup>1</sup>

**(9) Limitation of activities****(A) In general**

The Foundation shall exist solely as an entity to work in collaboration with the research programs of the National Institutes of Health. The Foundation may not undertake activities (such as the operation of independent laboratories or competing for Federal research funds) that are independent of those of the National Institutes of Health research programs.

**(B) Gifts, grants, and other donations****(i) In general**

Gifts, grants, and other donations to the Foundation may be designated for pediatric research and studies on drugs, and funds so designated shall be used solely for grants for research and studies under subsection (c)(1)(C).

**(ii) Other gifts**

Other gifts, grants, or donations received by the Foundation and not described in clause (i) may also be used to support such pediatric research and studies.

**(iii) Report**

The recipient of a grant for research and studies shall agree to provide the Director of the National Institutes of Health and the Commissioner of Food and Drugs, at the conclusion of the research and studies—

- (I) a report describing the results of the research and studies; and
- (II) all data generated in connection with the research and studies.

**(iv) Action by the Commissioner of Food and Drugs**

The Commissioner of Food and Drugs shall take appropriate action in response to a report received under clause (iii) in accordance with paragraphs (7) through (12)<sup>2</sup> of section 284m(c) of this title, includ-

ing negotiating with the holders of approved applications for the drugs studied for any labeling changes that the Commissioner determines to be appropriate and requests the holders to make.

**(C) Applicability**

Subparagraph (A) does not apply to the program described in subsection (c)(1)(C).

**(10) Transfer of funds**

The Foundation may transfer funds to the National Institutes of Health and the National Institutes of Health may accept transfers of funds from the Foundation. Any funds transferred under this paragraph shall be subject to all Federal limitations relating to federally-funded research.

**(k) Duties of Director****(1) Applicability of certain standards to non-Federal employees**

In the case of any individual who is not an employee of the Federal Government and who serves in association with the National Institutes of Health, with respect to financial assistance received from the Foundation, the Foundation may not provide the assistance of, or otherwise permit the work at the National Institutes of Health to begin until a memorandum of understanding between the individual and the Director of the National Institutes of Health, or the designee of such Director, has been executed specifying that the individual shall be subject to such ethical and procedural standards of conduct relating to duties performed at the National Institutes of Health, as the Director of the National Institutes of Health determines is appropriate.

**(2) Support services**

The Director of the National Institutes of Health may provide facilities, utilities and support services to the Foundation if it is determined by the Director to be advantageous to the research programs of the National Institutes of Health.

**(l) Funding**

From amounts appropriated to the National Institutes of Health, for each fiscal year, the Director of NIH shall transfer not less than \$500,000 and not more than \$1,250,000 to the Foundation.

(July 1, 1944, ch. 373, title IV, §499, formerly §499A, as added Pub. L. 101-613, §2, Nov. 16, 1990, 104 Stat. 3224; amended Pub. L. 102-170, title II, §216, Nov. 26, 1991, 105 Stat. 1128; Pub. L. 102-321, title I, §163(b)(6), July 10, 1992, 106 Stat. 376; renumbered §499 and amended Pub. L. 103-43, title I, §121(b)(3), title XVII, §1701, June 10, 1993, 107 Stat. 133, 186; Pub. L. 104-316, title I, §122(b), Oct. 19, 1996, 110 Stat. 3836; Pub. L. 105-392, title IV, §418(2), Nov. 13, 1998, 112 Stat. 3591; Pub. L. 107-109, §13, Jan. 4, 2002, 115 Stat. 1417; Pub. L. 109-482, title I, §107, Jan. 15, 2007, 120 Stat. 3696; Pub. L. 110-85, title V, §502(c), Sept. 27, 2007, 121 Stat. 889; Pub. L. 111-148, title X, §10409(c), Mar. 23, 2010, 124 Stat. 978; Pub. L. 112-74, div. F, title II, §221(d)(4), Dec. 23, 2011, 125 Stat. 1090; Pub. L. 112-144, title V, §509(f), July 9, 2012, 126 Stat. 1050.)

<sup>1</sup> So in original. Probably should be "subsection".

<sup>2</sup> See References in Text note below.

## REFERENCES IN TEXT

Section 109(16) of the Ethics in Government Act of 1978, referred to in subsec. (j)(2), is section 109(16) of Pub. L. 95-521, which is set out in the Appendix to Title 5, Government Organization and Employees.

The National Institutes of Health Amendments of 1990, referred to in subsec. (j)(8), is Pub. L. 101-613, Nov. 16, 1990, 104 Stat. 3224, as amended, which enacted this section, section 285g-4 of this title, and provisions set out as notes under section 201 and 285g-4 of this title. For complete classification of this Act to the Code, see Short Title of 1990 Amendments note set out under section 201 of this title and Tables.

Section 284m of this title, referred to in subsec. (j)(9)(B)(iv), was amended generally by Pub. L. 110-85, title V, § 502(b), Sept. 27, 2007, 121 Stat. 886, and, as so amended, does not contain a par. (12) in subsec. (c).

## PRIOR PROVISIONS

A prior section 499 of act July 1, 1944, was classified to section 289h of this title prior to repeal by Pub. L. 103-43.

## AMENDMENTS

2012—Subsec. (c)(1)(C). Pub. L. 112-144 struck out “for which the Secretary issues a certification in the affirmative under section 355a(n)(1)(A) of title 21” before period at end.

2011—Subsec. (c)(1)(E). Pub. L. 112-74 substituted “section 287a” for “section 282d”.

2010—Subsec. (c)(1)(E). Pub. L. 111-148 added subpar. (E).

2007—Subsec. (c)(1)(C). Pub. L. 110-85 substituted “and studies for which the Secretary issues a certification in the affirmative under section 355a(n)(1)(A) of title 21” for “and studies listed by the Secretary pursuant to section 284m(a)(1)(A) of this title and referred under section 355a(d)(4)(C) of title 21”. Amendment, which directed striking out language ending with “section 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(a)(d)(4)(C))” in the original, was executed by striking out language ending with “section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C))” in the original to reflect the probable intent of Congress. That language had been translated as “section 355a(d)(4)(C) of title 21” for purposes of codification.

Subsec. (d)(1)(D)(ii). Pub. L. 109-482, § 107(1)(A)(i), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: “Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.”

Subsec. (d)(1)(G). Pub. L. 109-482, § 107(1)(A)(ii), inserted “appointed” after “that the number of”.

Subsec. (d)(3)(B). Pub. L. 109-482, § 107(1)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: “Any vacancy in the membership of the Board shall be filled in the manner in which the original position was made and shall not affect the power of the remaining members to execute the duties of the Board.”

Subsec. (d)(5). Pub. L. 109-482, § 107(1)(C), inserted “appointed” after “majority of the”.

Subsec. (j)(2). Pub. L. 109-482, § 107(2)(A), substituted “subsection (d)(6)” for “subsection (d)(2)(B)(i)(II)”.

Subsec. (j)(4)(A). Pub. L. 109-482, § 107(2)(B)(i), inserted “, including an accounting of the use of amounts transferred under subsection (f)” before period at end.

Subsec. (j)(4)(C). Pub. L. 109-482, § 107(2)(B)(ii), added subpar. (C) and struck out former subpar. (C) which read as follows: “The Foundation shall make copies of each report submitted under subparagraph (A) available for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.”

Subsec. (j)(10). Pub. L. 109-482, § 107(2)(C), substituted “of Health and the National Institutes of Health may accept transfers of funds from the Foundation” for “of Health”.

Subsec. (j). Pub. L. 109-482, § 107(3), added subsec. (j) and struck out former subsec. (j) which related to authorization of appropriations and limitation regarding other funds.

2002—Subsec. (b). Pub. L. 107-109, § 13(1), inserted “(including collection of funds for pediatric pharmacologic research)” after “mission”.

Subsec. (c)(1)(C), (D). Pub. L. 107-109, § 13(2), added subpar. (C) and redesignated former subpar. (C) as (D).

Subsec. (d)(1)(B)(iv). Pub. L. 107-109, § 13(3)(A)(i), added cl. (iv).

Subsec. (d)(1)(C). Pub. L. 107-109, § 13(3)(A)(ii), added subpar. (C) and struck out former subpar. (C) which read as follows: “The ex officio members of the Board under subparagraph (B) shall appoint to the Board 11 individuals from among a list of candidates to be provided by the National Academy of Science. Of such appointed members—

“(i) 4 shall be representative of the general biomedical field;

“(ii) 2 shall be representatives of the general biobehavioral field; and

“(iii) 5 shall be representatives of the general public.”

Subsec. (d)(2)(B). Pub. L. 107-109, § 13(3)(B), realigned margin.

Subsec. (e) to (g). Pub. L. 107-109, § 13(5), redesignated subsecs. (f) to (h) as (e) to (g), respectively.

Subsec. (h). Pub. L. 107-109, § 13(5), (6), redesignated subsec. (i) as (h) and substituted “solicit,” for “solicit” in par. (11). Former subsec. (h) redesignated (g).

Subsec. (i). Pub. L. 107-109, § 13(5), redesignated subsec. (j) as (i). Former subsec. (i) redesignated (h).

Subsec. (j). Pub. L. 107-109, § 13(5), redesignated subsec. (k) as (j). Former subsec. (j) redesignated (i).

Subsec. (j)(1). Pub. L. 107-109, § 13(7), struck out “(including those developed under subsection (d)(2)(B)(i)(II))” after “procedures relating to standards of conduct”.

Subsec. (j)(2). Pub. L. 107-109, § 13(7), which directed striking out “(including those developed under subsection (d)(2)(B)(i)(II))” in par. (2), could not be executed because those words do not appear in par. (2).

Subsec. (k). Pub. L. 107-109, § 13(5), redesignated subsec. (l) as (k). Former subsec. (k) redesignated (j).

Subsec. (k)(9). Pub. L. 107-109, § 13(4), designated existing provisions as subpar. (A), inserted subpar. heading, and added subpars. (B) and (C).

Subsecs. (l), (m). Pub. L. 107-109, § 13(5), redesignated subsec. (m) as (l). Former subsec. (l) redesignated (k).

1998—Subsec. (a). Pub. L. 105-392, § 418(2)(A), substituted “Foundation for the National Institutes of Health” for “National Foundation for Biomedical Research”.

Subsec. (k)(10). Pub. L. 105-392, § 418(2)(B), struck out “not” after “may” and inserted at end “Any funds transferred under this paragraph shall be subject to all Federal limitations relating to federally-funded research.”

Subsec. (m)(1). Pub. L. 105-392, § 418(2)(C), substituted “\$500,000 for each fiscal year” for “\$200,000 for the fiscal years 1994 and 1995”.

1996—Subsec. (n). Pub. L. 104-316 struck out subsec. (n) which required Comptroller General to conduct audit and prepare report to Congress on adequacy of compliance of the Foundation with guidelines established under this section.

1993—Subsec. (a). Pub. L. 103-43, § 1701(1), inserted “, acting through the Director of NIH,” after “Secretary shall” and struck out “, except for the purposes of the Ethics in Government Act and the Technology Transfer Act,” after “shall not”.

Subsec. (b). Pub. L. 103-43, § 1701(3), added subsec. (b) and struck out heading and text of former subsec. (b). Text related to duties of Foundation.

Subsec. (c). Pub. L. 103-43, § 1701(3), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 103-43, § 1701(2), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (f).

Subsec. (d)(1). Pub. L. 103-43, § 1701(4)(A), substituted “appointed members of the Board” for “members of the

Foundation” in subpar. (A), “Board” for “Council” in subpar. (B), and “appoint to the Board” for “appoint to the Council” in subpar. (C), and added subpars. (D) to (G).

Subsec. (d)(2). Pub. L. 103-43, §1701(4)(B), designated existing provisions as subpar. (A), substituted “an individual to serve as the initial Chair” for “an appointed member of the Board to serve as the Chair”, and added subpar. (B).

Subsec. (d)(3)(A). Pub. L. 103-43, §1701(4)(C), substituted “(1)(C)” for “(2)(C)”.

Subsec. (d)(5), (6). Pub. L. 103-43, §1701(4)(D), added pars. (5) and (6).

Subsec. (e). Pub. L. 103-43, §1701(2), redesignated subsec. (e) as (g).

Subsecs. (f) to (h). Pub. L. 103-43, §1701(2), redesignated subsecs. (d) to (f) as (f) to (h), respectively. Former subsecs. (g) and (h) redesignated (i) and (j), respectively.

Subsec. (i). Pub. L. 103-43, §1701(2), redesignated subsec. (g) as (i). Former subsec. (i) redesignated (m).

Subsec. (i)(4). Pub. L. 103-43, §1701(5)(A), inserted before period at end “, and define the duties of the officers and employees”.

Subsec. (i)(5), (6). Pub. L. 103-43, §1701(5)(B), (C), redesignated par. (6) as (5) and struck out former par. (5) which read as follows: “prescribe by its Board its by-laws, that shall be consistent with law, and that shall provide for the manner in which—

“(A) its officers, employees, and agents are selected;

“(B) its property is acquired, held, and transferred;

“(C) its general operations are to be conducted; and

“(D) the privileges granted by law are exercised and enjoyed;”.

Subsec. (i)(7). Pub. L. 103-43, §1701(5)(C), (D), redesignated par. (8) as (7) and substituted “part” for “sub-title”. Former par. (7) redesignated (6).

Subsec. (i)(8). Pub. L. 103-43, §1701(5)(C), (E), redesignated par. (9) as (8) and substituted “establish a process for the selection of candidates for positions under subsection (c)” for “establish a mechanism for the selection of candidates, subject to the approval of the Director of the National Institutes of Health, for the endowed scientific positions within the organizational structure of the intramural research programs of the National Institutes of Health and candidates for participation in the National Institutes of Health Scholars program”.

Subsec. (i)(9), (10). Pub. L. 103-43, §1701(5)(C), redesignated pars. (10) and (11) as (9) and (10), respectively. Former par. (9) redesignated (8).

Subsec. (i)(11). Pub. L. 103-43, §1701(5)(C), (F), redesignated par. (12) as (11) and inserted “solicit” before “accept”. Former par. (11) redesignated (10).

Subsec. (i)(12), (13). Pub. L. 103-43, §1701(5)(C), redesignated pars. (13) and (14) as (12) and (13), respectively. Former par. (12) redesignated (11).

Subsec. (i)(14). Pub. L. 103-43, §1701(5)(G), (H), added par. (14). Former par. (14) redesignated (13).

Subsec. (i)(15). Pub. L. 103-43, §1701(5)(I), substituted “part” for “subtitle”.

Subsec. (j). Pub. L. 103-43, §1701(2), redesignated subsec. (h) as (j).

Subsecs. (k), (l). Pub. L. 103-43, §1701(6), added subsecs. (k) and (l).

Subsec. (m). Pub. L. 103-43, §1701(7), amended heading and text of subsec. (m) generally. Prior to amendment, text read as follows:

“(1) AUTHORIZATION OF APPROPRIATIONS.—Subject to paragraph (2), for the purpose of carrying out this part, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1995.

“(2) LIMITATIONS.—

“(A) Amounts appropriated under paragraph (1) or made available under subparagraph (C) may not be provided to the fund established under subsection (b)(1)(A) of this section.

“(B) For the first fiscal year for which amounts are appropriated under paragraph (1), \$200,000 is authorized to be appropriated.

“(C) With respect to the first fiscal year for which amounts are appropriated under paragraph (1), the Secretary may, from amounts appropriated for such fiscal year for the programs of the Department of Health and Human Services, make available not more than \$200,000 for carrying out this part, subject to subparagraph (A).”

Pub. L. 103-43, §1701(2), redesignated subsec. (i) as (m).

Subsec. (n). Pub. L. 103-43, §1701(8), added subsec. (n). 1992—Subsec. (g)(9). Pub. L. 102-321 struck out “or the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration” after “Director of the National Institutes of Health” and “and the Alcohol, Drug Abuse, and Mental Health Administration” after “research programs of the National Institutes of Health”.

1991—Subsec. (c)(1)(C). Pub. L. 102-170, §216(1), substituted “11” for “9”.

Subsec. (c)(1)(C)(iii). Pub. L. 102-170, §216(2), substituted “5” for “3”.

#### CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104-14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

#### EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102-321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as a note under section 236 of this title.

### SUBCHAPTER III—A—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

#### PART A—ORGANIZATION AND GENERAL AUTHORITIES

#### § 290aa. Substance Abuse and Mental Health Services Administration

##### (a) Establishment

The Substance Abuse and Mental Health Services Administration (hereafter referred to in this subchapter as the “Administration”) is an agency of the Service.

##### (b) Centers

The following Centers are agencies of the Administration:

- (1) The Center for Substance Abuse Treatment.
- (2) The Center for Substance Abuse Prevention.
- (3) The Center for Mental Health Services.