

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 Research Resources.

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

(23) The National Center for Complementary and Alternative Medicine.

(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, the Office of Rare Diseases, 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) re-

garding 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 institutes 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, re-

lated 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.)

AMENDMENTS

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 subsecs. (a) to (d)(1) for former subsecs. (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 classi-

fication] 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 [this chapter] 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 [this section] (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

Section 1904 of Pub. L. 103-43 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

Section 5 of Pub. L. 99-158, 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

Section 9 of Pub. L. 99-158 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) of this section 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 information to better evaluate scientific opportunity, public health burdens, and progress in reducing minority and other health disparities;

(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;

(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 opportuni-

ties, 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) 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

(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; and

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

(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; and

(24) implement the Cures Acceleration Network described in section 282d of this title.

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 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 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) Enhancing competitiveness of certain entities in obtaining research funds

(1)(A) In the case of entities described in subparagraph (B), the Director of NIH, acting through the Director of the National Center for Research Resources, 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.

(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 National 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 of¹ 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; 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.

(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

¹ So in original. The word “of” probably should not appear.

(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 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 re-

quired 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 (i) 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);² 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 information 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

²So in original. The second closing parenthesis probably should not appear.

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 by³ paragraph (2)(C) and paragraph (3)(D)(i)(II).⁴

(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 (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

³So in original.

⁴So in original. The second closing parenthesis probably should not appear.

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)(i)(I)(II),⁵ 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 accord-

ance 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

⁵So in original. Probably should be “paragraph (2)(A)(i)(I)(II).”.

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.

(I) 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 public 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.

(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.)

REFERENCES IN TEXT

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

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 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

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: “an-

nually 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 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.”

DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY

Pub. L. 110-85, title III, §305, Sept. 27, 2007, 121 Stat. 863, 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 [subsec. (b)(23) of this section], 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 \$6,000,000 for each of fiscal years 2008 through 2012.”

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 [subsec. (j) of this section], as added by this section, apply to a pediatric postmarket 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 [subsec. (j)(3)(D) of this section], 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

Section 902(c) of Pub. L. 103–43 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

Section 1901(a) of Pub. L. 103–43 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

Section 1905 of Pub. L. 103-43 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

Section 1907 of Pub. L. 103-43 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

Section 1912 of Pub. L. 103-43 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

Section 2002 of Pub. L. 103-43 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

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

- (1) \$30,331,309,000 for fiscal year 2007;
- (2) \$32,831,309,000 for fiscal year 2008; and
- (3) such sums as may be necessary for fiscal year 2009.

(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) 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) 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) for such preceding fiscal year, subject to any applicable provisions in appropriations Acts.

(C) Common Fund strategic planning report

Not later than June 1, 2007, and every 2 years thereafter, 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) 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 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).

(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)(i), 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)(i) is inconsistent with the mission of such institute or center.

(d) Transfer authority

Of the total amount appropriated under subsection (a) 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) 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.)

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.

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

§ 282d. 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 21,¹ biological product (as that term is defined by section 262(i)² 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 NIH—

(A) is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and

(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 Office of the Director of NIH 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 NIH, 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 NIH 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 distin-

¹ So in original. A closing parenthesis probably should precede the comma.

² See References in Text note below.

guished 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 NIH

(A) Responsibilities of the Board

(i) In general

The Board shall advise, and provide recommendations to, the Director of NIH with respect to—

- (I) policies, programs, and procedures for carrying out the duties of the Director of NIH 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 NIH

With respect to each recommendation provided by the Board under subparagraph (A)(i), the Director of NIH shall respond in writing to the Board, indicating whether such Director will implement such recommendation. In the case that the Director of NIH 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)³ of title 5,

³So in original. Section 5703 of title 5 does not contain a subsec. (b).

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 NIH 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 advocacy 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 NIH 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 NIH 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 NIH 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 NIH 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 NIH determines that the goals and objectives of this section cannot adequately be carried out through a contract, grant, or cooperative agreement, the Director of NIH 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 NIH may suspend the award to any entity upon noncompliance by such en-

tity with provisions and plans under this section or diversion of funds.

(5) Audits

The Director of NIH 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 NIH 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 paragraph (1), may be allocated to the Cures Acceleration Network.

(July 1, 1944, ch. 373, title IV, §402C, as added Pub. L. 111-148, title X, §10409(d), Mar. 23, 2010, 124 Stat. 978.)

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.

§ 283. Biennial reports of Director of NIH

(a) In general

The Director of NIH shall submit to the Congress on a biennial 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) 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.

(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 and other variables 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 clearinghouses, 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 and such other information as may be necessary to demonstrate compliance with section 289a-2 of this title (regarding inclusion of women and minorities in clinical research).

(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.

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

(C) Recommendations for improving the effectiveness, efficiency, and outcomes of 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.

(b) Requirement regarding disease-specific research activities

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

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

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 submitted 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) Experts and consultants

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 that—

- (1) identifies the number of experts and consultants, including any special consultants, whose services are obtained by the National Institutes of Health or its agencies;
- (2) specifies whether such services were obtained under section 209(f) of this title, section 282(d) of this title, or other authority;
- (3) describes the qualifications of such experts and consultants;
- (4) describes the need for hiring such experts and consultants; and
- (5) if such experts and consultants make financial disclosures to the National Institutes of Health or any of its agencies, specifies the income, gifts, assets, and liabilities so disclosed.

(c) First report

The first report under subsections (a) and (b) 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.)

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 (not including any leaves of absence) between the beginning of graduate study and the receipt of a doctoral degree.

(3)¹ 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.)

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

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).

¹ So in original. Probably should be “(b)”.

(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 neuro-

biological 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

Section 203(c) of Pub. L. 103-43 provided that: “The amendment described in subsection (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

(a) Development of new vaccines

The Secretary, in consultation with the Director of the National Vaccine Program under subchapter XIX of this chapter 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.

(b) Report

In the report required in section 300aa-4¹ of this title, the Secretary, acting through the Director of the National Vaccine Program under subchapter XIX of this chapter, shall include information with respect to activities and the progress made in implementing the provisions of this section and achieving its goals.

(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.)

REFERENCES IN TEXT

Section 300aa-4 of this title, referred to in subsec. (b), was repealed by Pub. L. 105-362, title VI, § 601(a)(1)(H), Nov. 10, 1998, 112 Stat. 3285.

AMENDMENTS

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

¹ See References in Text note below.

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) of this section, 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) of this section 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) of this section. 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) of this section.

(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) of this section.

(3) The Committee shall be composed of—

(A) the Directors of each of the national research institutes and the Director of the Center for Research Resources (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.)

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

Section 2015 of Pub. L. 103-43 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, 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.¹

(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) of this section 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, genetics, 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 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) of this section 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 15 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 and the Food and Drug Administration and representatives of other governmental agencies that serve children with muscular dystrophy, such as the Department of Education; 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

¹ See References in Text note below.

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 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.²

(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 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, epidemiological, psychosocial, and rehabilitative issues, including studies of the impact of such diseases in rural and underserved communities;

(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.

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

(f) Public input

The Secretary shall, under subsection (a)(1) of this section, provide for a means through which the public can obtain information on the exist-

ing 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.)

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

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), struck out 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 nec-

²So in original. Probably should be capitalized.

essary 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. Office of Rare Diseases

(a) Establishment

There is established within the Office of the Director of NIH 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 NIH.

(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 283i 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 af-

fects less than 200,000 persons in the United States.

(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.)

AMENDMENTS

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 [this chapter] 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.”

§ 283i. 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) of this section 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) of this section 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, §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.)

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.

§ 283j. Review of centers of excellence

(a) In general

Not later than April 1, 2008, and periodically thereafter, the Secretary, acting through the Director of NIH, shall conduct a review and submit a report to the appropriate committees of the Congress on the centers of excellence.

(b) Report contents

Each report under subsection (a) shall include the following:

(1) Evaluation of the performance and research outcomes of each center of excellence.

(2) Recommendations for promoting coordination of information among centers of excellence.

(3) Recommendations for improving the effectiveness, efficiency, and outcomes of the centers of excellence.

(c) Definition

In this section, the term “center of excellence” means an entity receiving funding under this subchapter in its capacity as a center of excellence.

(July 1, 1944, ch. 373, title IV, §404H, as added Pub. L. 109-416, §2(b), Dec. 19, 2006, 120 Stat. 2821.)

PART B—GENERAL PROVISIONS RESPECTING
NATIONAL RESEARCH INSTITUTES

§ 284. Directors of national research institutes

(a) Appointment

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.

(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, demonstrations, and studies referred to in subparagraph (A);

(C) 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;

(D) 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;

(E) may develop, conduct, and support public and professional education and information programs;

(F) may secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research;

(G) 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;

(H) 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;

(I) may secure for the institute consultation services and advice of persons from the United States or abroad;

(J) 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;

(K) may accept voluntary and uncompensated services; and

(L) 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.

(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) of this section, 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—