

EFFECTIVE DATE OF 2007 AMENDMENT

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

EFFECTIVE DATE OF 2000 AMENDMENT

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

EFFECTIVE DATE OF 1992 AMENDMENT

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

EFFECTIVE DATE OF 1988 AMENDMENT

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

CONSTRUCTION OF 2007 AMENDMENT

Pub. L. 109-482, title I, § 102(g), Jan. 15, 2007, 120 Stat. 3685, provided that: "This Act [see Tables for classification] and the amendments made by this Act may not be construed as affecting the authorities of the national research institutes and national centers that were in effect under the Public Health Service Act [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 es-

tablish 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 opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between 2 or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning;

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

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

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

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

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

(B) 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; and

(23) shall designate a contact point or office to help innovators and physicians identify

sources of funding available for pediatric medical device development.

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)(ii)(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)(ii)(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.)

REFERENCES IN TEXT

The provisions of title 5 governing appointments in the competitive service, referred to in subsec. (b)(16), (22), are classified generally to section 3301 et seq. of Title 5, Government Organization and Employees.

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

The provisions of title 5 relating to classifications, referred to in subsec. (b)(22), are classified generally to chapter 51 (§5101 et seq.) and to subchapter III (§5331 et seq.) of chapter 53 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, as amended, which is set out in the Appendix to Title 5, Government Organization and Employees.

The provisions of title 5 relating to reimbursement for travel expenses, referred to in subsec. (d)(2)(A), are classified generally to section 5701 et seq. of Title 5, Government Organization and Employees.

The National Literacy Act of 1991, referred to in subsec. (e)(5), is Pub. L. 102-73, July 25, 1991, 105 Stat. 333, as amended, 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

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 in-

vestigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children," for "in the trial," was executed by making the substitutions in the second sentence, to reflect the probable intent of Congress.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EFFECTIVE DATE OF 2007 AMENDMENT

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

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105-115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as a note under section 321 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1992 AMENDMENT

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

RULE OF CONSTRUCTION REGARDING CONTINUATION OF PROGRAMS

Pub. L. 109-482, title I, §103(c), Jan. 15, 2007, 120 Stat. 3689, provided that: "The amendment of a program by a provision of subsection (b) [amending this section and sections 283a, 283d, 283g to 283i, 284e to 284j, 284l, 284m, 285a-9, 285a-10, 285b-7a, 285b-7b, 285c-9, 285d-6a, 285d-8, 285e-10, 285e-10a, 285f-2, 285f-3, 285g-5, 285g-9, 285g-10, 285n, 285o, 285o-2, 285o-4, 285p, 285r, 286a-1, 287a-2, 287a-3,

287a-4, 287c-11, 287c-31 to 287c-33, 288, 288-1, and 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 con-

sistent 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