

## PUBLIC HEALTH SERVICE ACT

[As Amended Through P.L. 118–228, Enacted January 4, 2025]

【Currency: This publication is a compilation of the text of title IV of Chapter 373 of the 78th Congress. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at <https://www.govinfo.gov/app/collection/comps/>】

【Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).】

【References in brackets 【】 are to title 42, United States Code】

### TITLE IV—NATIONAL RESEARCH INSTITUTES

#### PART A—NATIONAL INSTITUTES OF HEALTH

##### SEC. 401. [281] ORGANIZATION OF NATIONAL INSTITUTES OF HEALTH.

(a) RELATION TO PUBLIC HEALTH SERVICE.—The National Institutes of Health is an agency of the Service.<sup>1</sup>

(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.<sup>2</sup>
- (9) The National Eye Institute.
- (10) The National Institute of Neurological Disorders and Stroke.

<sup>1</sup> See footnote for section 202.

<sup>2</sup> Section 212 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1999 (as contained in section 101(f) of division A of Public Law 105–277; 112 Stat. 2681–359) amended subparagraph (H) to read as provided above, thereby indicating the intent of the Congress to change the designation of the Institute. (The former designation was the National Institute of Dental Research.) Conforming changes were not, however, made to section 453 or the related subpart heading, or to the reference in section 409A(a).

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

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

(13) The National Institute on Drug Abuse.

(14) The National Institute of Mental Health.

(15) The National Institute of General Medical Sciences.

(16) The National Institute of Environmental Health Sciences.

(17) The National Institute of Nursing Research.

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

(19) The National Human Genome Research Institute.

(20) The National Library of Medicine.

(21) The National Center for Advancing Translational Sciences.

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

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

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

(25) Any other national center that, as an agency separate from any national research institute, was established within the National Institutes of Health as of the day before the date of the enactment of the National Institutes of Health Reform Act of 2006.

(c) DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES.—

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

(2) OFFICES WITHIN DIVISION.—

(A) OFFICES.—The following offices are within the Division: The Office of AIDS Research, the Office of Research on Women’s Health, the Office of Behavioral and Social Sciences Research, the Office of Disease Prevention, the Office of Dietary Supplements, and any other office located within the Office of the Director of NIH as of the day before the date of the enactment of the National Institutes of Health Reform Act of 2006. 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 the date of enactment referred to in subparagraph (A); and

(ii) shall, as determined appropriate by the Director of NIH, support the Division with respect to the authorities described in section 402(b)(7).

(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 title as in effect on the day before the date of the enactment of the National Institutes of Health Reform Act of 2006.

(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 title, 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 the date of the enactment of the National Institutes of Health Reform Act of 2006, the Secretary shall establish an advisory council within the National Institutes of Health to be known as the Scientific Management Review Board (referred to in this subsection as the “Board”).

(2) DUTIES.—

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

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

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

(B) CERTAIN RESPONSIBILITIES REGARDING REPORTS.—The activities of the Board with respect to a report under subparagraph (A) shall include the following:

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

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

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

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

(II) taking into account historical funding and support for research activities at national research institutes and centers that have been established recently relative to national research 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, related to a proposal that no such changes be made; and

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

(C) AVAILABILITY OF INFORMATION FROM FORUMS.—For each meeting under subparagraph (B), the Director of NIH shall post on the Internet site of the National Institutes of Health a summary of the proceedings.

(6) COMPENSATION; TERM OF OFFICE.—The provisions of subsections (b)(4) and (c) of section 406 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 the date of the enactment of the National Institutes of Health Reform Act of 2006, 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, United States Code. 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 title:

(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 title, a reference to the National Institutes of Health includes its agencies.

## APPOINTMENT AND AUTHORITY OF DIRECTOR OF NIH

SEC. 402. [282] (a) The National Institutes of Health shall be headed by the Director of NIH who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

(b) In carrying out the purposes of section 301, the Secretary, acting through the Director of NIH—

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

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

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

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

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

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

(i) specifies the inclusion of—

(I) women;

(II) members of minority groups;

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

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

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

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

(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health, and



through the development, implementation, and updating of the strategic plan developed under subsection (m);

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

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

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

(ii) include information on such research in reports under section 403; and

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

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

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

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

(B)(i) may, with respect to funds reserved under section 402A(c)(1) for the Common Fund, allocate such funds to the national research institutes and national centers for conducting and supporting research that is identified under subparagraph (A); and

(ii) shall, with respect to funds appropriated to the Division of Program Coordination, Planning, and Strategic Initiatives pursuant to section 402A(a)(2), allocate such funds to the national research institutes and national centers for making grants for pediatric research that is identified under subparagraph (A) and shall prioritize, as appropriate, such pediatric research that does not duplicate existing research activities of the National Institutes of Health; and

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

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

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

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

- (C) foster collaboration between clinical research projects funded by the respective national research institutes and national centers that—
- (i) conduct research involving human subjects; and
  - (ii) collect similar data; and
- (D) encourage the collaboration described in subparagraph (C) to—
- (i) allow for an increase in the number of subjects studied; and
  - (ii) utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities;
- (9) shall ensure that research conducted or supported by the National Institutes of Health is subject to review in accordance with section 492 and that, after such review, the research is reviewed in accordance with section 492A(a)(2) by the appropriate advisory council under section 406 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 487; and
- (B) may conduct and support research training—
- (i) for which fellowship support is not provided under section 487; and
  - (ii) that does not consist of residency training of physicians or other health professionals;
- (12) may, from funds appropriated under section 402A(b), 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 the Act of March 3, 1877 (40 U.S.C. 34), 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, United States Code, 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 title 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 title;

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

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

(24) implement the Cures Acceleration Network described in section 480;

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

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

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

(26) shall consult with the Assistant Secretary for Preparedness and Response, the Director of the Biomedical Advanced Research and Development Authority, the Director of the Centers for Disease Control and Prevention, and the heads of other Federal agencies and offices, as appropriate, regarding research needs to advance medical countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin, including emerging infectious diseases, chemical, radiological, or nuclear agent that may cause a public

health emergency or other research needs related to emerging public health threats;

(27) shall consult with the Director of the Office of National Security within the Department of Health and Human Services, the Assistant Secretary for Preparedness and Response, the Director of National Intelligence, the Director of the Federal Bureau of Investigation, and the heads of other appropriate agencies on a regular basis, regarding biomedical research conducted or supported by the National Institutes of Health that may affect or be affected by matters of national security;

(28) shall ensure that recipients of awards from the National Institutes of Health, and, as appropriate and practicable, entities collaborating with such recipients, have in place and are adhering to appropriate technology practices and policies for the security of identifiable, sensitive information, including information collected, stored, managed, or analyzed by domestic and non-domestic entities; and

(29) shall ensure that recipients of awards from the National Institutes of Health are in compliance with the terms and conditions of such award, which may include activities to support awareness of, and compliance with, such terms and conditions by any subrecipients of the award.

Chapter 10 of title 5, United States Code, 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) 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)(1) The Director of NIH may obtain (in accordance with section 3109 of title 5, United States Code, 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, United States Code, 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) 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)<sup>3</sup>.

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

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

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

[(g) Transferred to section 461, redesignated as subsection (b) of such section, and amended (as so redesignated) by section 221(b)(5) of division F of Public Law 112–74.]

(h) 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)(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

<sup>3</sup>So in law. That Act was repealed by section 251(a)(2) of Public Law 105–220 (112 Stat. 1079).

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 505(i) of the Federal Food, Drug, and Cosmetic Act, 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, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public.<sup>4</sup> 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 561(c) of the Federal Food, Drug, and Cosmetic Act; 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.

<sup>4</sup>Section 15(c)(2) of Public Law 107–109 (115 Stat. 1420) attempted to make amendments to the first sentence of subparagraph (A), but the amendments cannot be executed because the terms to be amended appear in the second sentence, not the first. The following shows the second sentence as it would appear if the amendments were executed to the second sentence: “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.”

(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 736 of the Federal Food, Drug, and Cosmetic Act 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 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act 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 522 of the Federal Food, Drug, and Cosmetic Act.

(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 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

(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 201(h) of the Federal Food, Drug, and Cosmetic Act.

(vii) **DRUG.**—The term “drug” means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product as defined in section 351 of this Act.

(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 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act, specify whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act 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 the date of the enactment of the Food and Drug Administration Amendments Act of 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, the date of the enactment of the Food and

Drug Administration Amendments Act of 2007, shall submit to the Director of NIH for inclusion in the registry data bank the clinical trial information described in of subparagraph (A)(ii) not later than the later of—

- (i) 90 days after such date of enactment;
- (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 such date of enactment, 1 year after such date of enactment.

(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 510(k) of the Federal Food, Drug, and Cosmetic Act, or approval under section 515 or 520(m) of such Act, as applicable, for a device that was not previously cleared or approved, and not later than 30 days after such date, unless the responsible party affirmatively requests that the Director of the National Institutes of Health publicly post such clinical trial information for an applicable device clinical trial prior to such date of clearance or approval; or

(II) for a device that was previously cleared or approved, not later than 30 days after the clinical trial information under paragraph (3)(C) is required to be posted by the Secretary.

(iii) OPTION TO MAKE CERTAIN CLINICAL TRIAL INFORMATION AVAILABLE EARLIER.—The Director of the National Institutes of Health shall inform responsible parties of the option to request that clinical trial information for an applicable device clinical trial be publicly posted prior to the date of clearance or approval, in accordance with clause (ii)(I).

(iv) COMBINATION PRODUCTS.—An applicable clinical trial for a product that is a combination of drug, device, or biological product shall be considered—

(I) an applicable drug clinical trial, if the Secretary determines under section 503(g) of the Federal Food, Drug, and Cosmetic Act that the primary mode of action of such product is that of a drug or biological product; or

(II) an applicable device clinical trial, if the Secretary determines under such section that the primary mode of action of such product is that of a device.

(3) EXPANSION OF REGISTRY DATA BANK TO INCLUDE RESULTS OF CLINICAL TRIALS.—

(A) LINKING REGISTRY DATA BANK TO EXISTING RESULTS.—

(i) IN GENERAL.—Beginning not later than 90 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved, the Secretary shall ensure that the registry data bank includes links to results information as described in clause (ii) for such clinical trial—

(I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

(II) not later than 30 days after the results information described in clause (ii) becomes publicly available.

(ii) REQUIRED INFORMATION.—

(I) FDA INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

(aa) If an advisory committee considered at a meeting an applicable clinical trial, any posted Food and Drug Administration summary document regarding such applicable clinical trial.

(bb) If an applicable drug clinical trial was conducted under section 505A or 505B of the Federal Food, Drug, and Cosmetic Act, 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 505(l)(2) of the Federal Food, Drug, and Cosmetic Act.

(ee) For an applicable device clinical trial, in the case of a premarket application under section 515 of the Federal Food, Drug, and Cosmetic Act, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of such Act, or, in the case of a report under section 510(k) of such Act, the section 510(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 enactment of the Food and Drug Administration Amendments Act of 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 the date of the enactment of the Food and Drug Administration Amendments Act of 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 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act, 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 the date of the enactment of the Food and Drug Administration Amendments Act of 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 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; and

(bb) each applicable device clinical trial for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act.

(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 505 of the Federal Food, Drug, and Cosmetic Act and not licensed under section 351 of this Act (whether approval or licensure was sought or not); and

(bb) an applicable device clinical trial for a device that is not cleared under section

510(k) of the Federal Food, Drug, and Cosmetic Act and not approved under section 515 or section 520(m) of such Act (whether clearance or approval was sought or not).

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

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

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

(III) The full protocol or such information on the protocol for the trial as may be necessary to help to evaluate the results of the trial.

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

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

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

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

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

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

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

(v) **ADDITIONAL PROVISIONS.**—The regulations under this subparagraph shall also establish—

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

(II) additional information on clinical trials and results that is written in nontechnical, 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 the date of the enactment of the Food and Drug Administration Amendments Act of 2007 to provide an opportunity for input from interested parties with regard to the regulations to be issued under this subparagraph.

(E) SUBMISSION OF RESULTS INFORMATION.—

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

(I) the estimated completion date of the trial as described in paragraph (2)(A)(ii)(I)(jj); 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 505 of the Federal Food, Drug, and Cosmetic Act or initially licensed under section 351 of this Act, or the device is initially cleared under section 510(k) or initially approved under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act, 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 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(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 505 of the Federal Food, Drug, and Cosmetic Act, licensing under section 351 of this Act, or clearance under section 510(k), or approval under section 515 or 520(m), of the Federal Food, Drug, and Cosmetic Act 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 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(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 505, 351, 510(k), 515, or 520(m); or

(cc) except as provided in subclause (III), the application or premarket notification under such section 505, 351, 510(k), 515, or 520(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 351 of this Act or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act, as applicable) of the use studied in the clinical trial.

(III) TWO-YEAR LIMITATION.—The responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information subject to subclause (I) on the date that is 2 years after the date a certification under clause (iii) was made to the Director of NIH, if an action referred to in item (aa), (bb), or (cc) of subclause (I) has not occurred by such date.

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

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

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

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

(I) **ADVERSE EVENTS.**—

(i) **REGULATIONS.**—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 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 the date of the enactment of the Food and Drug Administration Amendments Act of 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 351 or under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act 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 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or section 520(m) of such Act, whose completion date is on or after the date 10 years before the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

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

(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 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act, or section 351 of this Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

(C) QUALITY CONTROL.—

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

(ii) NOTICE OF COMPLIANCE.—If the Secretary determines that any clinical trial information was not submitted as required under this subsection, or was

submitted but is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such non-compliance 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 Act 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), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice that the responsible party is not in compliance by failing to register the primary and secondary outcomes in accordance with this act, 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, United States Code) 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, United States Code.

(7) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection \$10,000,000 for each fiscal year.

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

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

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

(l) COUNCIL OF COUNCILS.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of the enactment of the National Institutes of Health Reform Act of 2006, the Director of NIH shall establish within the Of-



fice 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.

## (m) NATIONAL INSTITUTES OF HEALTH STRATEGIC PLAN.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures Act, and at least every 6 years thereafter, the Director of the National Institutes of Health shall develop and submit to the appropriate committees of Congress and post on the Internet website of the National Institutes of Health, a coordinated strategy (to be known as the “National Institutes of Health Strategic Plan”) to provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine.

(2) REQUIREMENTS.—The strategy under paragraph (1) shall—

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

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

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

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

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

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

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

(ii) rare diseases and conditions;

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

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

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

(D) include strategic priorities for funding research through the Common Fund, in accordance with section 402A(c)(1)(C);

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

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

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

(4) CONSULTATION.—The Director of National Institutes of Health shall develop the strategic plan under paragraph (1) in

consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders.

(n) UNIQUE RESEARCH INITIATIVES.—

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

(A) the Precision Medicine Initiative under section 498E;

(B) section 402(b)(7), except that not more than 50 percent of the funds available for a fiscal year through the Common Fund under section 402A(c)(1) for purposes of carrying out such section 402(b)(7) may be used to engage in such other transactions; or

(C) high impact cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, or treatment of diseases and disorders, or research urgently required to respond to a public health threat.

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

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

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

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

(o) REGENERATIVE MEDICINE.—The Director of NIH shall, as appropriate, continue to consult with the directors of relevant institutes and centers of the National Institutes of Health, other relevant experts from such institutes and centers, and relevant experts within the Food and Drug Administration, to further the field of regenerative medicine using adult stem cells, including autologous stem cells, therapeutic tissue engineering products, human cell and tissue products, human gene therapies, and genetically modified cells.

#### **SEC. 402A. [282a] AUTHORIZATION OF APPROPRIATIONS.**

(a) IN GENERAL.—

(1) THIS TITLE.—For purposes of carrying out this title, there are authorized to be appropriated—

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

(B) \$32,831,309,000 for fiscal year 2008;

(C) such sums as may be necessary for fiscal year 2009;

(D) \$34,851,000,000 for fiscal year 2018;

(E) \$35,585,871,000 for fiscal year 2019; and

(F) \$36,472,442,775 for fiscal year 2020.

(2) FUNDING FOR PEDIATRIC RESEARCH INITIATIVE.—For the purpose of carrying out section 402(b)(7)(B)(ii), there is authorized to be appropriated to the Division of Program Coordination, Planning, and Strategic Initiatives, out of the Pediatric Research Initiative Fund described in section 9008 of the Internal Revenue Code of 1986, and in addition to amounts otherwise made available under paragraph (1) of this subsection, \$12,600,000 for each of fiscal years 2024 through 2028.

(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 title 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 402(b)(7)(B)(i) (relating to research identified by the Division of Program Coordination, Planning, and Strategic Initiatives), there is established an account to be known as the Common Fund.

(B) RESERVATION.—

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

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

(C) COMMON FUND STRATEGIC PLANNING REPORT.—As part of the National Institutes of Health Strategic Plan required under section 402(m), 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 402(b)(7)(A)(i) (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 402(b)(7)(A)(i)—

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

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

(D) EVALUATION.—During the 6-month period following the end of the first fiscal year for which the total amount reserved under subparagraph (B) is equal to 5 percent of the total amount appropriated under subsection (a)(1) for such fiscal year, the Secretary, acting through the Director of NIH, in consultation with the advisory council established under section 402(k), shall submit recommendations to the Congress for changes regarding amounts for the Common Fund.

(2) TRANS-NIH RESEARCH REPORTING.—

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

(B) REPORTING.—Not later than 2 years after the date of enactment of 21st Century Cures Act, the head of each national research institute or national center shall submit to the Director of the National Institutes of Health a report, to be included in the triennial report under section 403, on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers.

(C) DETERMINATION.—For purposes of determining the amount or percentage of funds to be reported under subparagraph (B), any amounts made available to an institute or center under section 402(b)(7)(B)(i) shall be included.

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

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

(d) TRANSFER AUTHORITY.—Of the total amount appropriated under subsection (a)(1) for a fiscal year, the Director of NIH may (in addition to the reservation under subsection (c)(1) for such year)

transfer not more than 1 percent for programs or activities that are authorized in this title and identified by the Director to receive funds pursuant to this subsection. In making such transfers, the Director may not decrease any appropriation account under subsection (a)(1) by more than 1 percent.

(e) **RULE OF CONSTRUCTION.**—This section may not be construed as affecting the authorities of the Director of NIH under section 401.

**SEC. 402B. [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.

**SEC. 403. [283] TRIENNIAL REPORTS OF DIRECTOR OF NIH.**

(a) **IN GENERAL.**—The Director of NIH shall submit to the Congress on a triennial basis a report in accordance with this section. The first report shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006. Each such report shall include the following information:

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

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

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

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

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

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

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

(i) identify the agency or agencies involved;

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

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

(B) In the case of clinical research, the catalog shall, as appropriate, identify study populations by demographic

variables, including biological and social variables and relevant age categories (such as pediatric subgroups), and determinants of health, that contribute to research on minority health and health disparities.

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

(i) Epidemiological studies and longitudinal studies.

(ii) Disease registries, information 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 title;

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

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

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

(v) Clinical trials, including a breakdown of participation by study populations and demographic variables, including relevant age categories (such as pediatric subgroups), information submitted by each national research institute and national center to the Director of National Institutes of Health under section 492B(f), and such other information as may be necessary to demonstrate compliance with section 492B and other applicable requirements regarding inclusion of demographic groups.

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

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

(A) Cancer.

(B) Neurosciences.

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

(D) Organ systems.

(E) Autoimmune diseases.

(F) Genomics.

(G) Molecular biology and basic science.

(H) Technology development.

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

(J) Infectious diseases and bioterrorism.

(K) Minority health and health disparities.

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

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

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

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

(b) REQUIREMENT REGARDING DISEASE-SPECIFIC RESEARCH ACTIVITIES.—In a report under subsection (a), the Director of NIH, when reporting on research activities 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.

**SEC. 403A. [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 402(i).

(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 the date of the enactment of the National Institutes of Health Reform Act of 2006.

**SEC. 403B. [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) FIRST REPORT.—The first report under subsection (a) shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006.

**SEC. 403C. [283a–2] ANNUAL REPORTING REGARDING TRAINING OF GRADUATE STUDENTS FOR DOCTORAL DEGREES.**

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

(1) the percentage of such students admitted for study who successfully attain a doctoral degree; and

(2) for students described in paragraph (1), the average time between the beginning of graduate study and the receipt of a doctoral degree.

(3)<sup>5</sup> PROVISION OF INFORMATION TO APPLICANTS.—Each institution described in subsection (a) shall provide to each student submitting an application for a program of graduate study at such institution the information described in paragraphs (1) and (2) of such subsection with respect to the program or programs to which such student has applied.

DES

SEC. 403D. [283a–3] (a) 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) 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) 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) con-

<sup>5</sup> So in law. Paragraph (3) probably should be subsection (b).

duct or support one or more longitudinal studies to determine the incidence of the following diseases or disorders in the indicated populations and the relationship of DES to the diseases or disorders:

(1) In the case of women to whom (on or after January 1, 1938) DES was administered while the women were pregnant, the incidence of all diseases and disorders (including breast cancer, gynecological cancers, and impairments of the immune system, including autoimmune disease).

(2) In the case of women exposed to DES in utero, the incidence of clear cell cancer (including recurrences), the long-term health effects of such cancer, and the effects of treatments for such cancer.

(3) In the case of men and women exposed to DES in utero, the incidence of all diseases and disorders (including impairments of the reproductive and autoimmune systems).

(4) In the case of children of men or women exposed to DES in utero, the incidence of all diseases and disorders.

(d) 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.

#### OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH

SEC. 404A. <sup>6</sup> [283c] (a) There is established within the Office of the Director of NIH an office to be known as the Office of Behavioral and Social Sciences Research (in this section referred to as the "Office"). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

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

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

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

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

#### CHILDREN'S VACCINE INITIATIVE

##### SEC. 404B. [283d]

The Secretary, in consultation with the Director of the National Vaccine Program under title XXI and acting through the Directors of the National Institute for Allergy and Infectious Dis-

<sup>6</sup> Section 404 was struck by section 101(b)(2) of Public Law 106-525 (114 Stat. 2501).

eases, 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.

#### PLAN FOR USE OF ANIMALS IN RESEARCH

SEC. 404C. [283e] (a) The Director of NIH, after consultation with the committee established under subsection (e), shall prepare a plan—

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

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

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

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

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

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

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

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

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

(c) The Director of NIH shall periodically review, and as appropriate, make revisions in the plan required under subsection (a). A description of any revision made in the plan shall be included in the first biennial report under section 403 that is submitted after the revision is made.

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

(e)(1) The Director of NIH shall establish within the National Institutes of Health a committee to be known as the Interagency

Coordinating Committee on the Use of Animals in Research (in this subsection referred to as the “Committee”).

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

(3) The Committee shall be composed of—

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

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

#### REQUIREMENTS REGARDING SURVEYS OF SEXUAL BEHAVIOR

SEC. 404D. [283f] 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 491 and 492; and

(2) the Secretary, in accordance with section 492A, 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.

#### SEC. 404E. [283g] MUSCULAR DYSTROPHY; INITIATIVE THROUGH DIRECTOR OF NATIONAL INSTITUTES OF HEALTH.

(a) EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES.—

(1) IN GENERAL.—The Director of NIH, in coordination with the Directors of the National Institute of Neurological Disorders and Stroke, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Heart, Lung, and Blood Institute, and the other national research institutes as appropriate, shall expand and intensify programs of such Institutes with respect to research and related activities concerning various forms of muscular dystrophy, including Duchenne, Becker, congenital muscular dystrophy, limb-girdle muscular dystrophy, myotonic, facioscapulohumeral muscular dystrophy (referred to in this section as “FSHD”) and other forms of muscular dystrophy.

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

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

(b) CENTERS OF EXCELLENCE.—

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

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

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

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

(5) DURATION OF SUPPORT.—Support for a center established under paragraph (1) may be provided under this section for a period of not to exceed 5 years. Such period may be extended for 1 or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director of NIH and if such group has recommended to the Director that such period should be extended.

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

(d) COORDINATING COMMITTEE.—

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

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

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

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

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

(3) CHAIR.—

(A) IN GENERAL.—With respect to muscular dystrophy, the Chair of the Coordinating Committee shall serve as the principal advisor to the Secretary, the Assistant Secretary for Health, and the Director of NIH, and shall provide advice to the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and to the heads of other relevant agencies. The Coordinating 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, but shall meet no fewer than two times per calendar year.

(e) PLAN FOR HHS ACTIVITIES.—

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

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

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

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

(2) CERTAIN ELEMENTS OF PLAN.—The plan under paragraph (1) shall, with respect to each form of muscular dystrophy, provide for the following as appropriate:

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

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

(C) The development of improved screening techniques.

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

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

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

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

【Section 404F was transferred and redesignated as section 481 by section 221(c)(2)(A)(i) of Public Law 112–74.】

【Section 404G was transferred and redesignated as section 481A by section 221(c)(3) of Public Law 112–74.】

【Section 404H was repealed by section 2042(f)(1) of Public Law 114–255.】

#### **SEC. 404I. [283k] BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.**

(a) MODERNIZATION AND CONSTRUCTION OF FACILITIES.—

(1) IN GENERAL.—The Director of NIH, acting through the Office of the Director of NIH or the Director of the National Institute of Allergy and Infectious Diseases, may make grants or contracts to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities, subject to the provisions of this section.

(2) CONSTRUCTION AND COST OF CONSTRUCTION.—For purposes of this section, the terms “construction” and “cost of construction” include the construction of new buildings and the expansion, renovation, remodeling, and alteration of existing buildings, including architects’ fees, but do not include the cost of acquisition of land or off-site improvements.

(b) SCIENTIFIC AND TECHNICAL REVIEW BOARDS FOR MERIT-BASED REVIEW OF PROPOSALS.—

(1) IN GENERAL: APPROVAL AS PRECONDITION TO GRANTS.—

(A) ESTABLISHMENT.—There is established a Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities (referred to in this section as the “Board”).

(B) REQUIREMENT.—The Director of NIH, acting through the Office of the Director of NIH, may approve an application for a grant under subsection (a) only if the Board has under paragraph (2) recommended the application for approval.

(2) DUTIES.—

(A) ADVICE.—The Board shall provide advice to the Director of NIH and the Council of Councils established under section 402(l) (in this section referred to as the “Council”) in carrying out this section.

(B) DETERMINATION OF MERIT.—In carrying out subparagraph (A), the Board shall make a determination of the merit of each application submitted for a grant under subsection (a), after consideration of the requirements established in subsection (c), and shall report the results of the determination to the Director of NIH and the Council. Such determinations shall be conducted in a manner consistent with procedures established under section 492.

(C) AMOUNT.—In carrying out subparagraph (A), the Board shall, in the case of applications recommended for approval, make recommendations to the Director and the Council on the amount that should be provided under the grant.

(D) ANNUAL REPORT.—In carrying out subparagraph (A), the Board shall prepare an annual report for the Director of NIH and the Council describing the activities of the Board in the fiscal year for which the report is made. Each such report shall be available to the public, and shall—

(i) summarize and analyze expenditures made under this section;

(ii) provide a summary of the types, numbers, and amounts of applications that were recommended for



grants under subsection (a) but that were not approved by the Director of NIH; and

(iii) contain the recommendations of the Board for any changes in the administration of this section.

(3) MEMBERSHIP.—

(A) IN GENERAL.—Subject to subparagraph (B), the Board shall be composed of 15 members to be appointed by the Director of NIH, acting through the Office of the Director of NIH, and such ad-hoc or temporary members as the Director of NIH, acting through the Office of the Director of NIH, determines to be appropriate. All members of the Board, including temporary and ad-hoc members, shall be voting members.

(B) LIMITATION.—Not more than three individuals who are officers or employees of the Federal Government may serve as members of the Board.

(4) CERTAIN REQUIREMENTS REGARDING MEMBERSHIP.—In selecting individuals for membership on the Board, the Director of NIH, acting through the Office of the Director of NIH, shall ensure that the members are individuals who, by virtue of their training or experience, are eminently qualified to perform peer review functions. In selecting such individuals for such membership, the Director of NIH, acting through the Office of the Director of NIH, shall ensure that the members of the Board collectively—

(A) are experienced in the planning, construction, financing, and administration of entities that conduct biomedical or behavioral research sciences;

(B) are knowledgeable in making determinations of the need of entities for biomedical or behavioral research facilities, including such facilities for the dentistry, nursing, pharmacy, and allied health professions;

(C) are knowledgeable in evaluating the relative priorities for applications for grants under subsection (a) in view of the overall research needs of the United States; and

(D) are experienced with emerging centers of excellence, as described in subsection (c)(2).

(5) CERTAIN AUTHORITIES.—

(A) WORKSHOPS AND CONFERENCES.—In carrying out paragraph (2), the Board may convene workshops and conferences, and collect data as the Board considers appropriate.

(B) SUBCOMMITTEES.—In carrying out paragraph (2), the Board may establish subcommittees within the Board. Such subcommittees may hold meetings as determined necessary to enable the subcommittee to carry out its duties.

(6) TERMS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), each appointed member of the Board shall hold office for a term of 4 years. Any member appointed to fill a vacancy occurring prior to the expiration of the term for

which such member's predecessor was appointed shall be appointed for the remainder of the term of the predecessor.

(B) STAGGERED TERMS.—Members appointed to the Board shall serve staggered terms as specified by the Director of NIH, acting through the Office of the Director of NIH, when making the appointments.

(C) REAPPOINTMENT.—No member of the Board shall be eligible for reappointment to the Board until 1 year has elapsed after the end of the most recent term of the member.

(7) COMPENSATION.—Members of the Board who are not officers or employees of the United States shall receive for each day the members are engaged in the performance of the functions of the Board compensation at the same rate received by members of other national advisory councils established under this title.

(c) REQUIREMENTS FOR GRANTS.—

(1) IN GENERAL.—The Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, may make a grant under subsection (a) only if the applicant for the grant meets the following conditions:

(A) The applicant is determined by such Director to be competent to engage in the type of research for which the proposed facility is to be constructed.

(B) The applicant provides assurances satisfactory to the Director that—

(i) for not less than 20 years after completion of the construction involved, the facility will be used for the purposes of the research for which it is to be constructed;

(ii) sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility;

(iii) sufficient funds will be available, when construction is completed, for the effective use of the facility for the research for which it is being constructed; and

(iv) the proposed construction will expand the applicant's capacity for research, or is necessary to improve or maintain the quality of the applicant's research.

(C) The applicant meets reasonable qualifications established by the Director with respect to—

(i) the relative scientific and technical merit of the applications, and the relative effectiveness of the proposed facilities, in expanding the capacity for biomedical or behavioral research and in improving the quality of such research;

(ii) the quality of the research or training, or both, to be carried out in the facilities involved;

(iii) the congruence of the research activities to be carried out within the facility with the research and

investigator manpower needs of the United States; and

(iv) the age and condition of existing research facilities.

(D) The applicant has demonstrated a commitment to enhancing and expanding the research productivity of the applicant.

(2) INSTITUTIONS OF EMERGING EXCELLENCE.—From the amount appropriated to carry out this section for a fiscal year up to \$50,000,000, the Director of NIH, acting through the Office of the Director of NIH, shall make available 25 percent of such amount, and from the amount appropriated to carry out this section for a fiscal year that is over \$50,000,000, the Director of NIH, acting through the Office of the Director of NIH, shall make available up to 25 percent of such amount, for grants under subsection (a) to applicants that in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:

(A) The applicant has a plan for research or training advancement and possesses the ability to carry out the plan.

(B) The applicant carries out research and research training programs that have a special relevance to a problem, concern, or unmet health need of the United States.

(C) The applicant has been productive in research or research development and training.

(D) The applicant—

(i) has been designated as a center of excellence under section 739;

(ii) is located in a geographic area whose population includes a significant number of individuals with health status deficit, and the applicant provides health services to such individuals; or

(iii) is located in a geographic area in which a deficit in health care technology, services, or research resources may adversely affect the health status of the population of the area in the future, and the applicant is carrying out activities with respect to protecting the health status of such population.

(d) REQUIREMENT OF APPLICATION.—The Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, may make a grant under subsection (a) only if an application for the grant is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

(e) AMOUNT OF GRANT; PAYMENTS.—

(1) AMOUNT.—The amount of any grant awarded under subsection (a) shall be determined by the Director of NIH, acting through the Office of the Director of NIH or the National

Institute of Allergy and Infectious Diseases,,<sup>7</sup> except that such amount shall not exceed—

(A) 50 percent (or, in the case of the Institute, 75 percent) of the necessary cost of the construction of a proposed facility as determined by the Director; or

(B) in the case of a multipurpose facility, 40 percent (or, in the case of the Institute, 75 percent) of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

(2) RESERVATION OF AMOUNTS.—On the approval of any application for a grant under subsection (a), the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, shall reserve, from any appropriation available for such grants, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with the construction progress, as the Director may determine appropriate. The reservation of any amount by the Director under this paragraph may be amended by the Director, either on the approval of an amendment of the application or on the revision of the estimated cost of construction of the facility.

(3) EXCLUSION OF CERTAIN COSTS.—In determining the amount of any grant under subsection (a), there shall be excluded from the cost of construction an amount equal to the sum of—

(A) the amount of any other Federal grant that the applicant has obtained, or is assured of obtaining, with respect to construction that is to be financed in part by a grant authorized under this section; and

(B) the amount of any non-Federal funds required to be expended as a condition of such other Federal grant.

(4) WAIVER OF LIMITATIONS.—The limitations imposed under paragraph (1) may be waived at the discretion of the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, for applicants meeting the conditions described in subsection (c).

(f) RECAPTURE OF PAYMENTS.—If, not later than 20 years after the completion of construction for which a grant has been awarded under subsection (a)—

(1) in the case of an award by the Director of NIH, acting through the Office of the Director of NIH, the applicant or other owner of the facility shall cease to be a public or non profit private entity; or

(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so),

<sup>7</sup>Two commas in subsection (e)(1) so in law. See amendment made by section 221(b)(1)(B)(ii) of division F of Public Law 112–74.

the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

(g) GUIDELINES.—Not later than 6 months after the date of the enactment of this section, the Director of NIH, acting through the Office of the Director of NIH, after consultation with the Council, shall issue guidelines with respect to grants under subsection (a).

#### CONSTRUCTION OF REGIONAL CENTERS FOR RESEARCH ON PRIMATES

**SEC. 404J. [283l]** (a) With respect to activities carried out by the Director of NIH, acting through the Office of the Director of NIH, to support regional centers for research on primates, the Director of NIH may, for each of the fiscal years 1994<sup>8</sup> through 1996<sup>8</sup>, reserve from the amounts appropriated to carry out section 404I up to \$2,500,000 for the purpose of making awards of grants and contracts to public or nonprofit private entities to construct, renovate, or otherwise improve such regional centers. The reservation of such amounts for any fiscal year is subject to the availability of qualified applicants for such awards.

(b) The Director of NIH may not make a grant or enter into a contract under subsection (a) unless the applicant for such assistance agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such subsection, to make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount equal to not less than \$1 for each \$4 of Federal funds provided in such assistance.

#### **SEC. 404K. [283m] SANCTUARY SYSTEM FOR SURPLUS CHIMPANZEES.**

(a) IN GENERAL.—The Secretary shall provide for the establishment and operation in accordance with this section of a system to provide for the lifetime care of chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by the National Institutes of Health, the Food and Drug Administration, or other agencies of the Federal Government, and with respect to which it has been determined by the Secretary that the chimpanzees are not needed for such research (in this section referred to as “surplus chimpanzees”).

(b) ADMINISTRATION OF SANCTUARY SYSTEM.—The Secretary shall carry out this section, including the establishment of regulations under subsection (d), in consultation with the board of directors of the nonprofit private entity that receives the contract under subsection (e) (relating to the operation of the sanctuary system).

<sup>8</sup>The probable intent of the Congress is that the authorization of appropriations be for fiscal year 2000 through 2002. Section 304 of Public Law 106–505 (114 Stat. 2335) provided that section 481B(a) “is amended by striking ‘1994’ and all that follows through ‘\$5,000,000’ and inserting ‘2000 through 2002, reserve from the amounts appropriated under section 481A(i) such sums as necessary’”. The amendment cannot be executed because a term referenced in the instructions, “\$5,000,000”, does not appear in section 481B(a). The term “2,500,000” probably should have been referenced.

(c) ACCEPTANCE OF CHIMPANZEES INTO SYSTEM.—All surplus chimpanzees owned by the Federal Government shall be accepted into the sanctuary system. Subject to standards under subsection (d)(4), any chimpanzee that is not owned by the Federal Government can be accepted into the system if the owner transfers to the sanctuary system title to the chimpanzee.

(d) STANDARDS FOR PERMANENT RETIREMENT OF SURPLUS CHIMPANZEES.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this section, the Secretary shall by regulation establish standards for operating the sanctuary system to provide for the permanent retirement of surplus chimpanzees. In establishing the standards, the Secretary shall consider the recommendations of the board of directors of the nonprofit private entity that receives the contract under subsection (e), and shall consider the recommendations of the National Research Council applicable to surplus chimpanzees that are made in the report published in 1997 and entitled “Chimpanzees in Research—Strategies for Their Ethical Care, Management, and Use”.

(2) CHIMPANZEES ACCEPTED INTO SYSTEM.—With respect to chimpanzees that are accepted into the sanctuary system, standards under paragraph (1) shall include the following:

(A) A prohibition that the chimpanzees may not be used for research, except as authorized under paragraph (3).

(B) Provisions regarding the housing of the chimpanzees.

(C) Provisions regarding the behavioral well-being of the chimpanzees.

(D) A requirement that the chimpanzees be cared for in accordance with the Animal Welfare Act.

(E) A requirement that the chimpanzees be prevented from breeding.

(F) A requirement that complete histories be maintained on the health and use in research of the chimpanzees.

(G) A requirement that the chimpanzees be monitored for the purpose of promptly detecting the presence in the chimpanzees of any condition that may be a threat to the public health or the health of other chimpanzees.

(H) A requirement that chimpanzees posing such a threat be contained in accordance with applicable recommendations of the Director of the Centers for Disease Control and Prevention.

(I) A prohibition that none of the chimpanzees may be subjected to euthanasia, except as in the best interests of the chimpanzee involved, as determined by the system and an attending veterinarian.

(J) A prohibition that the chimpanzees may not be discharged from the system.

(K) A provision that the Secretary may, in the discretion of the Secretary, accept into the system chimpanzees that are not surplus chimpanzees.

(L) Such additional standards as the Secretary determines to be appropriate.

(3) RESTRICTIONS REGARDING RESEARCH.—

(A) IN GENERAL.—For purposes of paragraph (2)(A), standards under paragraph (1) shall provide that a chimpanzee accepted into the sanctuary system may not be used for studies or research, except that the chimpanzee may be used for noninvasive behavioral studies or medical studies based on information collected during the course of normal veterinary care that is provided for the benefit of the chimpanzee, provided that any such study involves minimal physical and mental harm, pain, distress, and disturbance to the chimpanzee and the social group in which the chimpanzee lives.

(B) ADDITIONAL RESTRICTION.—For purposes of paragraph (2)(A), a condition for the use in studies or research of a chimpanzee accepted into the sanctuary system is (in addition to conditions under subparagraph (A) of this paragraph) that the applicant for such use has not been fined for, or signed a consent decree for, any violation of the Animal Welfare Act.

(4) NON-FEDERAL CHIMPANZEES OFFERED FOR ACCEPTANCE INTO SYSTEM.—With respect to a chimpanzee that is not owned by the Federal Government and is offered for acceptance into the sanctuary system, standards under paragraph (1) shall include the following:

(A) A provision that the Secretary may authorize the imposition of a fee for accepting such chimpanzee into the system, except as follows:

(i) Such a fee may not be imposed for accepting the chimpanzee if, on the day before the date of the enactment of this section, the chimpanzee was owned by the nonprofit private entity that receives the contract under subsection (e) or by any individual sanctuary facility receiving a subcontract or grant under subsection (e)(1).

(ii) Such a fee may not be imposed for accepting the chimpanzee if the chimpanzee is owned by an entity that operates a primate center, and if the chimpanzee is housed in the primate center pursuant to the program for regional centers for research on primates that is carried out by the Director of NIH, acting through the Office of the Director of NIH.<sup>9</sup>

Any fees collected under this subparagraph are available to the Secretary for the costs of operating the system. Any other fees received by the Secretary for the long-term care of chimpanzees (including any Federal fees that are collected for such purpose and are identified in the report under section 3 of the Chimpanzee Health Improvement, Maintenance, and Protection Act) are available for oper-

<sup>9</sup>A period followed by a comma in clause (ii) so in law. See amendment made by section 221(b)(3)(B) of division F of Public Law 112–74.

ating the system, in addition to availability for such other purposes as may be authorized for the use of the fees.

(B) A provision that the Secretary may deny such chimpanzee acceptance into the system if the capacity of the system is not sufficient to accept the chimpanzee, taking into account the physical capacity of the system; the financial resources of the system; the number of individuals serving as the staff of the system, including the number of professional staff; the necessity of providing for the safety of the staff and of the public; the necessity of caring for accepted chimpanzees in accordance with the standards under paragraph (1); and such other factors as may be appropriate.

(C) A provision that the Secretary may deny such chimpanzee acceptance into the system if a complete history of the health and use in research of the chimpanzee is not available to the Secretary.

(D) Such additional standards as the Secretary determines to be appropriate.

(e) AWARD OF CONTRACT FOR OPERATION OF SYSTEM.—

(1) IN GENERAL.—Subject to the availability of funds pursuant to subsection (g), the Secretary shall make an award of a contract to a nonprofit private entity under which the entity has the responsibility of operating (and establishing, as applicable) the sanctuary system and awarding subcontracts or grants to individual sanctuary facilities that meet the standards under subsection (d).

(2) REQUIREMENTS.—The Secretary may make an award under paragraph (1) to a nonprofit private entity only if the entity meets the following requirements:

(A) The entity has a governing board of directors that is composed and appointed in accordance with paragraph (3) and is satisfactory to the Secretary.

(B) The terms of service for members of such board are in accordance with paragraph (3).

(C) The members of the board serve without compensation. The members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the board.

(D) The entity has an executive director meeting such requirements as the Secretary determines to be appropriate.

(E) The entity makes the agreement described in paragraph (4) (relating to non-Federal contributions).

(F) The entity agrees to comply with standards under subsection (d).

(G) The entity agrees to make necropsy reports on chimpanzees in the sanctuary system available on a reasonable basis to persons who conduct biomedical or behavioral research, with priority given to such persons who are Federal employees or who receive financial support from the Federal Government for research.

(H) Such other requirements as the Secretary determines to be appropriate.



(3) BOARD OF DIRECTORS.—For purposes of subparagraphs (A) and (B) of paragraph (2):

(A) The governing board of directors of the nonprofit private entity involved is composed and appointed in accordance with this paragraph if the following conditions are met:

(i) Such board is composed of not more than 13 voting members.

(ii) Such members include individuals with expertise and experience in the science of managing captive chimpanzees (including primate veterinary care), appointed from among individuals endorsed by organizations that represent individuals in such field.

(iii) Such members include individuals with expertise and experience in the field of animal protection, appointed from among individuals endorsed by organizations that represent individuals in such field.

(iv) Such members include individuals with expertise and experience in the zoological field (including behavioral primatology), appointed from among individuals endorsed by organizations that represent individuals in such field.

(v) Such members include individuals with expertise and experience in the field of the business and management of nonprofit organizations, appointed from among individuals endorsed by organizations that represent individuals in such field.

(vi) Such members include representatives from entities that provide accreditation in the field of laboratory animal medicine.

(vii) Such members include individuals with expertise and experience in the field of containing biohazards.

(viii) Such members include an additional member who serves as the chair of the board, appointed from among individuals who have been endorsed for purposes of clause (ii), (iii), (iv), or (v).

(ix) None of the members of the board has been fined for, or signed a consent decree for, any violation of the Animal Welfare Act.

(B) The terms of service for members of the board of directors are in accordance with this paragraph if the following conditions are met:

(i) The term of the chair of the board is 3 years.

(ii) The initial members of the board select, by a random method, one member from each of the six fields specified in subparagraph (A) to serve a term of 2 years and (in addition to the chair) one member from each of such fields to serve a term of 3 years.

(iii) After the initial terms under clause (ii) expire, each member of the board (other than the chair) is appointed to serve a term of 2 years.

(iv) An individual whose term of service expires may be reappointed to the board.

(v) A vacancy in the membership of the board is filled in the manner in which the original appointment was made.

(vi) If a member of the board does not serve the full term applicable to the member, the individual appointed to fill the resulting vacancy is appointed for the remainder of the term of the predecessor member.

(4) REQUIREMENT OF MATCHING FUNDS.—The agreement required in paragraph (2)(E) for a nonprofit private entity (relating to the award of the contract under paragraph (1)) is an agreement that, with respect to the costs to be incurred by the entity in establishing and operating the sanctuary system, the entity will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs, in cash or in kind, in an amount not less than the following, as applicable:

(A) For expenses associated with establishing the sanctuary system (as determined by the Secretary), 10 percent of such costs (\$1 for each \$9 of Federal funds provided under the contract under paragraph (1)).

(B) For expenses associated with operating the sanctuary system (as determined by the Secretary), 25 percent of such costs (\$1 for each \$3 of Federal funds provided under such contract).

(5) ESTABLISHMENT OF CONTRACT ENTITY.—If the Secretary determines that an entity meeting the requirements of paragraph (2) does not exist, not later than 60 days after the date of the enactment of this section, the Secretary shall, for purposes of paragraph (1), make a grant for the establishment of such an entity, including paying the cost of incorporating the entity under the law of one of the States.

(f) DEFINITIONS.—For purposes of this section:

(1) PERMANENT RETIREMENT.—The term “permanent retirement”, with respect to a chimpanzee that has been accepted into the sanctuary system, means that under subsection (a) the system provides for the lifetime care of the chimpanzee, that under subsection (d)(2) the system does not permit the chimpanzee to be used in research (except as authorized under subsection (d)(3)) or to be euthanized (except as provided in subsection (d)(2)(I)), that under subsection (d)(2) the system will not discharge the chimpanzee from the system, and that under such subsection the system otherwise cares for the chimpanzee.

(2) SANCTUARY SYSTEM.—The term “sanctuary system” means the system described in subsection (a).

(3) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

(4) SURPLUS CHIMPANZEES.—The term “surplus chimpanzees” has the meaning given that term in subsection (a).

(g) FUNDING.—

(1) IN GENERAL.—Of the amount appropriated for the National Institutes of Health, there are authorized to be appropriated to carry out this section and for the care, maintenance, and transportation of all chimpanzees otherwise under the ownership or control of the National Institutes of Health, and

to enable the National Institutes of Health to operate more efficiently and economically by decreasing the overall Federal cost of providing for the care, maintenance, and transportation of chimpanzees—

- (A) for fiscal year 2014, \$12,400,000;
- (B) for fiscal year 2015, \$11,650,000;
- (C) for fiscal year 2016, \$10,900,000;
- (D) for fiscal year 2017, \$10,150,000; and
- (E) for fiscal year 2018, \$9,400,000.

(2) **USE OF FUNDS FOR OTHER COMPLIANT FACILITIES.**—With respect to amounts authorized to be appropriated by paragraph (1) for a fiscal year, the Secretary may use a portion of such amounts to make awards of grants or contracts to public or private entities operating facilities that, as determined by the Secretary in consultation with the board of directors of the nonprofit private entity that receives the contract under subsection (e), provide for the retirement of chimpanzees in accordance with the same standards that apply to the sanctuary system pursuant to regulations under subsection (d). Such an award may be expended for the expenses of operating the facilities involved.

(3) **BIENNIAL REPORT.**—Not later than 180 days after the date enactment of this Act, the Director of the National Institutes of Health shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations in the House of Representatives a report, to be updated biennially, regarding—

- (A) the care, maintenance, and transportation of the chimpanzees under the ownership or control of the National Institutes of Health;
- (B) costs related to such care, maintenance, and transportation, and any other related costs; and
- (C) the research status of such chimpanzees.

**SEC. 404L. [283n] SHARED INSTRUMENTATION GRANT PROGRAM.**

(a) **REQUIREMENTS FOR GRANTS.**—In determining whether to award a grant to an applicant under the Shared Instrumentation Grant Program, the Director of NIH, acting through the Office of the Director of NIH, shall consider—

- (1) the extent to which an award for the specific instrument involved would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited;
- (2) with respect to the instrument involved, the availability and commitment of the appropriate technical expertise within the major user group or the applicant institution for use of the instrumentation;
- (3) the adequacy of the organizational plan for the use of the instrument involved and the internal advisory committee for oversight of the applicant, including sharing arrangements if any;

(4) the applicant's commitment for continued support of the utilization and maintenance of the instrument; and

(5) the extent to which the specified instrument will be shared and the benefit of the proposed instrument to the overall research community to be served.

(b) PEER REVIEW.—In awarding grants under the program described in subsection (a), the Director of NIH, acting through the Office of the Director of NIH, shall comply with the peer review requirements in section 492.

**SEC. 404M. [283o] NEXT GENERATION OF RESEARCHERS.**

(a) NEXT GENERATION OF RESEARCHERS INITIATIVE.—There shall be established within the Office of the Director of the National Institutes of Health, the Next Generation of Researchers Initiative (referred to in this section as the “Initiative”), through which the Director shall coordinate all policies and programs within the National Institutes of Health that are focused on promoting and providing opportunities for new researchers and earlier research independence.

(b) ACTIVITIES.—The Director of the National Institutes of Health, through the Initiative shall—

(1) promote policies and programs within the National Institutes of Health that are focused on improving opportunities for new researchers and promoting earlier research independence, including existing policies and programs, as appropriate;

(2) develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity;

(3) coordinate, as appropriate, with relevant agencies, professional and academic associations, academic institutions, and others, to improve and update existing information on the biomedical research workforce in order to inform programs related to the training, recruitment, and retention of biomedical researchers; and

(4) carry out other activities, including evaluation and oversight of existing programs, as appropriate, to promote the development of the next generation of researchers and earlier research independence.

**SEC. 404N. [283p] POPULATION FOCUSED RESEARCH.**

The Director of the National Institutes of Health shall, as appropriate, encourage efforts to improve research related to the health of sexual and gender minority populations, including by—

(1) facilitating increased participation of sexual and gender minority populations in clinical research supported by the National Institutes of Health, and reporting on such participation, as applicable;

(2) facilitating the development of valid and reliable methods for research relevant to sexual and gender minority populations; and

(3) addressing methodological challenges.

**SEC. 4040. [283r] NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY.**

(a) **ESTABLISHMENT.**—The Secretary, acting through the Director of NIH, shall establish an advisory committee, to be known as the “National Science Advisory Board for Biosecurity” (referred to in this section as the “Board”).

(b) **DUTIES.**—

(1)<sup>10</sup> **IN GENERAL.**—The National Science Advisory Board for Biosecurity referred to in section 205 of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417) (referred to in this section as the “Board”) shall provide technical advice, guidance, or recommendations, to relevant Federal departments and agencies related to biosafety and biosecurity oversight of biomedical research, including—

(A) oversight of federally-conducted or federally-supported dual use biomedical research, such as the review of policies or frameworks used to assess and appropriately manage safety and security risks associated with such research, taking into consideration national security concerns, the potential benefits of such research, considerations related to the research community, transparency, and public availability of information, and international research collaboration; and

(B) continuing to carry out the activities required under section 205 of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417).

(c) **CONSIDERATIONS.**—In carrying out the duties under subsection (b), the Board may consider strategies to improve the safety and security of biomedical research, including through—

(1) leveraging or using new technologies and scientific advancements to reduce safety and security risks associated with such research and improve containment of pathogens; and

(2) outreach to, and education and training of, researchers, laboratory personnel, and other appropriate individuals with respect to safety and security risks associated with such research and mitigation of such risks.

(d) **MEMBERSHIP.**—The Board shall be composed of the following:

(1) Non-voting, ex officio members, including the following:

(A) At least one representative of each of the following:

(i) The Department of Health and Human Services.

(ii) The Department of Defense.

(iii) The Department of Agriculture.

(iv) The Department of Homeland Security.

(v) The Department of Energy.

(vi) The Department of State.

(vii) The Office of Science and Technology Policy.

(viii) The Office of the Director of National Intelligence.

<sup>10</sup>So in law. There are no subsequent paragraphs in subsection (b). See amendment made by section 2313(a) of division FF of Public Law 117–328.

(B) Representatives of such other Federal departments or agencies as the Secretary determines appropriate to carry out the requirements of this section.

(2) Individuals, appointed by the Secretary, with expertise in biology, infectious diseases, public health, ethics, national security, and other fields, as the Secretary determines appropriate, who shall serve as voting members.

#### PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

##### APPOINTMENT AND AUTHORITY OF THE DIRECTORS OF THE NATIONAL RESEARCH INSTITUTES

#### SEC. 405. [284]

##### (a) APPOINTMENT.—

(1) IN GENERAL.—The Director of the National Cancer Institute shall be appointed by the President, and the Directors of the other national research institutes and national centers shall be appointed by the Secretary, acting through the Director of National Institutes of Health. Each Director of a national research institute or national center shall report directly to the Director of National Institutes of Health.

##### (2) APPOINTMENT.—

(A) TERM.—A Director of a national research institute or national center who is appointed by the Secretary, acting through the Director of National Institutes of Health, shall be appointed for 5 years.

(B) REAPPOINTMENT.—At the end of the term of a Director of a national research institute or national center, the Director may be reappointed in accordance with standards applicable to the relevant appointment mechanism. There shall be no limit on the number of terms that a Director may serve.

(C) VACANCIES.—If the office of a Director of a national research institute or national center becomes vacant before the end of such Director's term, the Director appointed to fill the vacancy shall be appointed for a 5-year term starting on the date of such appointment.

(D) CURRENT DIRECTORS.—Each Director of a national research institute or national center who is serving on the date of enactment of the 21st Century Cures Act shall be deemed to be appointed for a 5-year term under this subsection beginning on such date of enactment.

(E) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority of the Secretary or the Director of National Institutes of Health to terminate the appointment of a director referred to in subparagraph (A) before the expiration of such director's 5-year term.

(F) NATURE OF APPOINTMENT.—Appointments and reappointments under this subsection shall be made on the basis of ability and experience as it relates to the mission of the National Institutes of Health and its components, including compliance with any legal requirement that the

Secretary or Director of National Institutes of Health determines relevant.

(3) NONAPPLICATION OF CERTAIN PROVISION.—The restrictions contained in section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note) related to consultants and individual scientists appointed for limited periods of time shall not apply to Directors appointed under this subsection.

(b)(1) In carrying out the purposes of section 301 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 492(b) and any advisory council review under section 406(a)(3)(A)(i), conduct the research, investigations, experiments, demonstrations, and studies referred to in subparagraph (A);

(C) shall, as appropriate, conduct and support research that has the potential to transform the scientific field, has inherently higher risk, and that seeks to address major current challenges;

(D) may conduct and support research training (i) for which fellowship support is not provided under section 487, and (ii) which is not residency training of physicians or other health professionals;

(E) may develop, implement, and support demonstrations and programs for the application of the results of the activities of the institute to clinical practice and disease prevention activities;

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

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

(H) may make available the facilities of the institute to appropriate entities and individuals engaged in research activities and cooperate with and assist Federal and State agencies charged with protecting the public health;

(I) may accept unconditional gifts made to the institute for its activities, and, in the case of gifts of a value in excess of \$50,000, establish suitable memorials to the donor;

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

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

(L) may accept voluntary and uncompensated services; and

(M) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute.

The indemnification provisions of section 3861, title 10, United States Code, shall apply with respect to contracts entered into under this subsection and section 402(b).

(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 492;

(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 492, 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 492 and is recommended under section 406(a)(3)(A)(ii) by the advisory council for the national research institute involved; and

(C) shall, subject to section 2353(d)(2), receive from the President and the Office of Management and Budget directly all funds appropriated by the Congress for obligation and expenditure by the Institute.

(3) Before an award is made by a national research institute or by a national center for a grant for a research program or project (commonly referred to as an “R-series grant”), other than an award constituting a noncompetitive renewal of such a grant, or a noncompetitive administrative supplement to such a grant, the Director of such national research institute or national center shall, consistent with the peer review process—

(A) review and make the final decision with respect to making the award; and

(B) take into consideration, as appropriate—



- (i) the mission of the national research institute or national center and the scientific priorities identified in the strategic plan under section 402(m);
  - (ii) programs or projects funded by other agencies on similar research topics; and
  - (iii) advice by staff and the advisory council or board of such national research institute or national center.
- (c) In carrying out subsection (b), each Director of a national research institute—
- (1) shall coordinate, as appropriate, the activities of the institute with similar programs of other public and private entities;
  - (2) shall cooperate with the Directors of the other national research institutes in the development and support of multidisciplinary research and research that involves more than one institute;
  - (3) may, in consultation with the advisory council for the Institute and with the approval of the Director of NIH—
    - (A) establish technical and scientific peer review groups in addition to those appointed under section 402(b)(16); and
    - (B) appoint the members of peer review groups established under subparagraph (A); and
  - (4) may publish, or arrange for the publication of, information with respect to the purpose of the Institute without regard to section 501 of title 44, United States Code.
- Chapter 10 of title 5, United States Code, shall not apply to the duration of a peer review group appointed under paragraph (3).

## ADVISORY COUNCILS

SEC. 406. [284a] (a)(1) Except as provided in subsection (h), the Secretary shall appoint an advisory council for each national research institute which (A) shall advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute on matters related to the activities carried out by and through the institute and the policies respecting such activities, and (B) shall carry out the special functions prescribed by part C.

(2) Each advisory council for a national research institute may recommend to the Secretary acceptance, in accordance with section 231, of conditional gifts for study, investigation, or research respecting the diseases, disorders, or other aspect of human health with respect to which the institute was established, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the institute.

(3) Each advisory council for a national research institute—

(A)(i) may on the basis of the materials provided under section 492(b)(2) respecting research conducted at the institute, make recommendations to the Director of the institute respecting such research,

(ii) may review applications for grants and cooperative agreements for research or training and for which advisory council approval is required under section 405(b)(2) and recommend for approval applications for projects which show

promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspect of human health with respect to which the institute was established and with the approval of the Director of the institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b)(1) Each advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary. The ex officio members shall be nonvoting members.

(2) The ex officio members of an advisory council shall consist of—

(A) the Secretary, the Director of NIH, the Director of the national research institute for which the council is established, the Chief Medical Director of the Department of Veterans Affairs or the Chief Dental Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of an advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including not less than two individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the national research institute for which the advisory council is established.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of an advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule.

(c) The term of office of an appointed member of an advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of

the members do not all expire in the same year. A member may serve after the expiration of the member's term for 180 days after the date of such expiration. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) The chairman of an advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the national research institute for which the advisory council is established to be the chairman of the advisory council. The term of office of the chairman shall be two years.

(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the national research institute for which it was established, but at least three times each fiscal year. The location of the meetings of each advisory council is subject to the approval of the Director of the national research institute for which the advisory council was established.

(f) The Director of the national research institute for which an advisory council is established shall designate a member of the staff of the institute to serve as the executive secretary of the advisory council. The Director of such institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of such institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

(g) Each advisory council may prepare, for inclusion in the biennial report made under section 407, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the national research institute for which it was established in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the institute. Each advisory council may prepare such additional reports as it may determine appropriate.

(h)(1) Except as provided in paragraph (2), this section does not terminate the membership of any advisory council for a national research institute which was in existence on the date of enactment of the Health Research Extension Act of 1985. After such date—

(A) the Secretary shall make appointments to each such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

(B) each advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

(C) the Director of each national research institute shall perform for such advisory council the functions prescribed by this section.

(2)(A) The National Cancer Advisory Board shall be the advisory council for the National Cancer Institute. This section applies to the National Cancer Advisory Board, except that—

(i) appointments to such Board shall be made by the President;

(ii) the term of office of an appointed member shall be 6 years;

(iii) of the members appointed to the Board—

(I) not less than 5 members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors); and

(II) not less than one member shall be an individual knowledgeable in pediatric oncology;

(iv) the chairman of the Board shall be selected by the President from the appointed members and shall serve as chairman for a term of two years;

(v) the ex officio members of the Board shall be nonvoting members and shall be the Secretary, the Director of the Office of Science and Technology Policy, the Director of NIH, the Chief Medical Director of the Department of Veterans Affairs, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Science of the Department of Energy (or the designees of such officers); and

(vi) the Board shall meet at least four times each fiscal year.

(B) This section applies to the advisory council to the National Heart, Lung, and Blood Institute, except that the advisory council shall meet at least four times each fiscal year.<sup>11</sup>

#### CERTAIN USES OF FUNDS

SEC. 408. [284c] (a)(1) Except as provided in paragraph (2), the sum of the amounts obligated in any fiscal year for administrative expenses of the National Institutes of Health may not exceed an amount which is 5.5 percent of the total amount appropriated for such fiscal year for the National Institutes of Health.

(2) Paragraph (1) does not apply to the National Library of Medicine, the National Center for Nursing Research,<sup>12</sup> the John E. Fogarty International Center for Advanced Study in the Health Sciences, the Warren G. Magnuson Clinical Center, and the Office of Medical Applications of Research.

(3) For purposes of paragraph (1), the term “administrative expenses” means expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agree-

<sup>11</sup>Section 407 of the Public Health Service Act was repealed by section 104(b)(1)(C) of Public Law 109-482 (120 Stat. 3693).

<sup>12</sup>See footnote 2 for section 403(5).

ments and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

(b) For fiscal year 1989 and subsequent fiscal years, amounts made available to the National Institutes of Health shall be available for payment of nurses and allied health professionals in accordance with payment authorities, scheduling options, benefits, and other authorities provided under chapter 73 of title 38, United States Code, for nurses of the Department of Veterans Affairs.

#### DEFINITIONS

SEC. 409. [284d] (a) HEALTH SERVICE RESEARCH.—For purposes of this title, the term “health services research” means research endeavors that study the impact of the organization, financing and management of health services on the quality, cost, access to and outcomes of care. Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions.

(b) CLINICAL RESEARCH.—As used in this title, the term “clinical research” means patient oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, or epidemiologic or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials.

#### RESEARCH ON OSTEOPOROSIS, PAGET’S DISEASE, AND RELATED BONE DISORDERS

SEC. 409A. [284e] (a) ESTABLISHMENT.—The Directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute on Aging, the National Institute of Dental Research,<sup>13</sup> and the National Institute of Diabetes and Digestive and Kidney Diseases, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning osteoporosis, Paget’s disease, and related bone disorders.

(b) COORDINATION.—The Directors referred to in subsection (a) shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and the Interagency Task Force on Aging Research.

(c) INFORMATION CLEARINGHOUSE.—

(1) IN GENERAL.—In order to assist in carrying out the purpose described in subsection (a), the Director of NIH shall provide for the establishment of an information clearinghouse on osteoporosis and related bone disorders to facilitate and enhance knowledge and understanding on the part of health pro-

<sup>13</sup> See footnote for section 401(b)(1)(H).

professionals, patients, and the public through the effective dissemination of information.

(2) ESTABLISHMENT THROUGH GRANT OR CONTRACT.—For the purpose of carrying out paragraph (1), the Director of NIH shall enter into a grant, cooperative agreement, or contract with a nonprofit private entity involved in activities regarding the prevention and control of osteoporosis and related bone disorders.

#### PARKINSON'S DISEASE

SEC. 409B. [42 U.S.C. 284f] (a) IN GENERAL.—The Director of NIH shall establish a program for the conduct and support of research and training with respect to Parkinson's disease (subject to the extent of amounts appropriated to carry out this section).

(b) INTER-INSTITUTE COORDINATION.—

(1) IN GENERAL.—The Director of NIH shall provide for the coordination of the program established under subsection (a) among all of the national research institutes conducting Parkinson's disease research.

(2) CONFERENCE.—Coordination under paragraph (1) shall include the convening of a research planning conference not less frequently than once every 2 years. Each such conference shall prepare and submit to the Committee on Appropriations and the Committee on Labor and Human Resources of the Senate and the Committee on Appropriations and the Committee on Commerce of the House of Representatives a report concerning the conference.

(c) MORRIS K. UDALL RESEARCH CENTERS.—

(1) IN GENERAL.—The Director of NIH is authorized to award Core Center Grants to encourage the development of innovative multidisciplinary research and provide training concerning Parkinson's disease. The Director is authorized to award not more than 10 Core Center Grants and designate each center funded under such grants as a Morris K. Udall Center for Research on Parkinson's Disease.

(2) REQUIREMENTS.—

(A) IN GENERAL.—With respect to Parkinson's disease, each center assisted under this subsection shall—

(i) use the facilities of a single institution or a consortium of cooperating institutions, and meet such qualifications as may be prescribed by the Director of the NIH; and

(ii) conduct basic and clinical research.

(B) DISCRETIONARY REQUIREMENTS.—With respect to Parkinson's disease, each center assisted under this subsection may—

(i) conduct training programs for scientists and health professionals;

(ii) conduct programs to provide information and continuing education to health professionals;

(iii) conduct programs for the dissemination of information to the public;

(iv) separately or in collaboration with other centers, establish a nationwide data system derived from patient populations with Parkinson's disease, and where possible, comparing relevant data involving general populations;

(v) separately or in collaboration with other centers, establish a Parkinson's Disease Information Clearinghouse to facilitate and enhance knowledge and understanding of Parkinson's disease; and

(vi) separately or in collaboration with other centers, establish a national education program that fosters a national focus on Parkinson's disease and the care of those with Parkinson's disease.

(3) STIPENDS REGARDING TRAINING PROGRAMS.—A center may use funds provided under paragraph (1) to provide stipends for scientists and health professionals enrolled in training programs under paragraph (2)(B).

(4) DURATION OF SUPPORT.—Support of a center under this subsection may be for a period not exceeding five years. Such period may be extended by the Director of NIH for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(d) MORRIS K. UDALL AWARDS FOR EXCELLENCE IN PARKINSON'S DISEASE RESEARCH.—The Director of NIH is authorized to establish a grant program to support investigators with a proven record of excellence and innovation in Parkinson's disease research and who demonstrate potential for significant future breakthroughs in the understanding of the pathogenesis, diagnosis, and treatment of Parkinson's disease. Grants under this subsection shall be available for a period of not to exceed 5 years.

EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES OF NATIONAL INSTITUTES OF HEALTH WITH RESPECT TO RESEARCH ON AUTISM SPECTRUM DISORDER<sup>14</sup>

SEC. 409C. [284g] (a) IN GENERAL.—

(1) EXPANSION OF ACTIVITIES.—The Director of NIH (in this section referred to as the "Director"), in consultation with relevant Federal departments and agencies, as appropriate, shall—

(A) subject to the availability of appropriations, expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism spectrum disorder, including basic and clinical research—

(i) in fields, such as pathology, developmental neurobiology, genetics, epigenetics, pharmacology, nu-

<sup>14</sup>Title I of Public Law 106-310 (114 Stat. 1105) established several programs regarding autism, including the program under section 409C above. Section 105 of the Public Law requires annual reports to the Congress on the implementation of such title I and the amendments made by the title.

trition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, toxicology, psychiatry, psychology, developmental behavioral pediatrics, audiology, and gerontology; and

(ii) on interventions to maximize outcomes for individuals with autism spectrum disorder; and

(B) ensure that research referred to in subparagraph

(A)—

(i) investigates the causes (including possible environmental causes), diagnosis or ruling out, early and ongoing detection, prevention, services and supports across the lifespan, intervention, and treatment of autism spectrum disorder and co-occurring conditions, including dissemination and implementation of clinical care, supports, interventions, and treatments;

(ii) examines supports for caregivers; and

(iii) reflects the entire population of individuals with autism spectrum disorder, including those individuals with co-occurring conditions and the full range of needs for supports and services, including such supports and services to ensure the safety, and promote the well-being, of such individuals.

(2) CONSOLIDATION.—The Director may consolidate program activities under this section if such consolidation would improve program efficiencies and outcomes.

(3) ADMINISTRATION OF PROGRAM; COLLABORATION AMONG AGENCIES.—The Director shall carry out this section acting through the Director of the National Institute of Mental Health and in collaboration with any other agencies that the Director determines appropriate.

(b) CENTERS OF EXCELLENCE.—

(1) IN GENERAL.—The Director shall under subsection (a)(1) make awards of grants and contracts to public or non-profit private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for centers of excellence regarding research on autism spectrum disorder.

(2) RESEARCH.—Each center under paragraph (1) shall conduct basic and clinical research into autism spectrum disorder. Such research should include investigations into the causes, diagnosis, early and ongoing detection, prevention, and treatment of autism spectrum disorder across the lifespan. The centers, as a group, shall conduct research in fields such as developmental neurobiology, genetics, genomics, psychopharmacology, developmental psychology, behavioral psychology, clinical psychology, and gerontology.

(3) SERVICES FOR PATIENTS.—

(A) IN GENERAL.—A center under paragraph (1) may expend amounts provided under such paragraph to carry out a program to make individuals aware of opportunities to participate as subjects in research conducted by the centers.



(B) REFERRALS AND COSTS.—A program under subparagraph (A) may, in accordance with such criteria as the Director may establish, provide to the subjects described in such subparagraph, referrals for health and other services, and such patient care costs as are required for research.

(C) AVAILABILITY AND ACCESS.—The extent to which a center can demonstrate availability and access to clinical services shall be considered by the Director in decisions about awarding grants to applicants which meet the scientific criteria for funding under this section.

(D) REDUCING DISPARITIES.—The Director may consider, as appropriate, the extent to which a center can demonstrate availability and access to clinical services for youth and adults from diverse racial, ethnic, geographic, or linguistic backgrounds in decisions about awarding grants to applicants which meet the scientific criteria for funding under this section.

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

(5) NUMBER OF CENTERS; DURATION OF SUPPORT.—

(A) IN GENERAL.—The Director shall provide for the establishment of not less than seven centers under paragraph (1).

(B) DURATION.—Support for a center established under paragraph (1) may be provided under this section for a period not to exceed 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

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

(d) PUBLIC INPUT.—

(1) IN GENERAL.—The Director shall under subsection (a)(1) provide for means through which the public can obtain information on the existing and planned programs and activities of the National Institutes of Health with respect to autism spectrum disorder and through which the Director can receive comments from the public regarding such programs and activities.

(2) GUIDANCE.—The Director may provide guidance to centers under subsection (b)(1) on strategies, activities, and opportunities to promote engagement with, and solicit input from, individuals with autism spectrum disorder and their family members, guardians, advocates or authorized representatives, providers, or other appropriate individuals to inform the activi-

ties of the center. Such strategies, activities, and opportunities should consider including, as appropriate, individuals, family members, and caregivers of individuals with autism spectrum disorder who represent the entire population of individuals with autism spectrum disorder, including those individuals with co-occurring conditions and the full range of needs for supports and services, including such supports and services to ensure the safety, and promote the well-being, of such individuals, to inform the activities of the center.

(e) BUDGET ESTIMATE.—For each of fiscal years 2026 through 2029, the Director shall prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate for the initiatives of the National Institutes of Health pursuant to the strategic plan developed under section 399CC(b)(5) and updated under section 399CC(b)(6)(B), after reasonable opportunity for comment (but without change) by the Secretary and the Interagency Autism Coordinating Committee established under section 399CC.

#### PEDIATRIC RESEARCH INITIATIVE

SEC. 409D. [284h] (a) ESTABLISHMENT.—The Secretary shall establish within the Office of the Director of NIH a Pediatric Research Initiative (referred to in this section as the “Initiative”) to conduct and support research that is directly related to diseases, disorders, and other conditions in children. The Initiative shall be headed by the Director of NIH.

(b) PURPOSE.—The purpose of the Initiative is to provide funds to enable the Director of NIH—

(1) to increase support for pediatric biomedical research within the National Institutes of Health to realize the expanding opportunities for advancement in scientific investigations and care for children;

(2) to enhance collaborative efforts among the Institutes to conduct and support multidisciplinary research in the areas that the Director deems most promising; and

(3) in coordination with the Food and Drug Administration, to increase the development of adequate pediatric clinical trials and pediatric use information to promote the safer and more effective use of prescription drugs in the pediatric population.

(c) DUTIES.—In carrying out subsection (b), the Director of NIH shall—

(1) consult with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the other national research institutes, in considering their requests for new or expanded pediatric research efforts, and consult with the Administrator of the Health Resources and Services Administration and other advisors as the Director determines to be appropriate;

(2) have broad discretion in the allocation of any Initiative assistance among the Institutes, among types of grants, and between basic and clinical research so long as the assistance

is directly related to the illnesses and conditions of children; and

(3) be responsible for the oversight of any newly appropriated Initiative funds and annually report to Congress and the public on the extent of the total funds obligated to conduct or support pediatric research across the National Institutes of Health, including the specific support and research awards allocated through the Initiative.

(d) NATIONAL PEDIATRIC RESEARCH NETWORK.—

(1) NETWORK.—In carrying out the Initiative, the Director of NIH, in collaboration with the national research institutes and national centers that carry out activities involving pediatric research, shall support a National Pediatric Research Network in order to more effectively support pediatric research and optimize the use of Federal resources. Such National Pediatric Research Network may be comprised of, as appropriate—

(A) the pediatric research consortia receiving awards under paragraph (2); or

(B) other consortia, centers, or networks focused on pediatric research that are recognized by the Director of NIH and established pursuant to the authorities vested in the National Institutes of Health by other sections of this Act.

(2) PEDIATRIC RESEARCH CONSORTIA.—

(A) IN GENERAL.—The Director of NIH shall award funding, including through grants, contracts, or other mechanisms, to public or private nonprofit entities for providing support for pediatric research consortia, including with respect to—

(i) basic, clinical, behavioral, or translational research to meet unmet needs for pediatric research; and

(ii) training researchers in pediatric research techniques in order to address unmet pediatric research needs.

(B) RESEARCH.—The Director of NIH shall, as appropriate, ensure that—

(i) each consortium receiving an award under subparagraph (A) conducts or supports at least one category of research described in subparagraph (A)(i) and collectively such consortia conduct or support such categories of research; and

(ii) one or more such consortia provide training described in subparagraph (A)(ii).

(C) ORGANIZATION OF CONSORTIUM.—Each consortium receiving an award under subparagraph (A) shall—

(i) be formed from a collaboration of cooperating institutions;

(ii) be coordinated by a lead institution or institutions;

(iii) agree to disseminate scientific findings, including from clinical trials, rapidly and efficiently, as appropriate, to—

(I) other consortia;

(II) the National Institutes of Health;

(III) the Food and Drug Administration;

(IV) and other relevant agencies; and

(iv) meet such requirements as may be prescribed by the Director of NIH.

(D) SUPPLEMENT, NOT SUPPLANT.—Any support received by a consortium under subparagraph (A) shall be used to supplement, and not supplant, other public or private support for activities authorized to be supported under this paragraph.

(E) DURATION OF SUPPORT.—Support of a consortium under subparagraph (A) shall be for a period of not to exceed 5 years. Such period may be extended at the discretion of the Director of NIH.

(3) COORDINATION OF CONSORTIA ACTIVITIES.—The Director of NIH shall, as appropriate—

(A) provide for the coordination of activities (including the exchange of information and regular communication) among the consortia established pursuant to paragraph (2); and

(B) require the periodic preparation and submission to the Director of reports on the activities of each such consortium.

(4) ASSISTANCE WITH REGISTRIES.—Each consortium receiving an award under paragraph (2)(A) may provide assistance, as appropriate, to the Centers for Disease Control and Prevention for activities related to patient registries and other surveillance systems upon request by the Director of the Centers for Disease Control and Prevention.

(e) RESEARCH ON PEDIATRIC RARE DISEASES OR CONDITIONS.—In making awards under subsection (d)(2) for pediatric research consortia, the Director of NIH shall ensure that an appropriate number of such awards are awarded to such consortia that agree to—

(1) consider pediatric rare diseases or conditions, or those related to birth defects; and

(2) conduct or coordinate one or more multisite clinical trials of therapies for, or approaches to, the prevention, diagnosis, or treatment of one or more pediatric rare diseases or conditions.

(f) TRANSFER OF FUNDS.—The Director of NIH may transfer amounts appropriated under this section to any of the Institutes for a fiscal year to carry out the purposes of the Initiative under this section.

#### **SEC. 409E. [284i] AUTOIMMUNE DISEASES.**

(a) EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES.—

(1) IN GENERAL.—The Director of NIH shall expand, intensify, and coordinate research and other activities of the National Institutes of Health with respect to autoimmune diseases.

(2) ALLOCATIONS BY DIRECTOR OF NIH.—With respect to amounts appropriated to carry out this section for a fiscal year,

the Director of NIH shall allocate the amounts among the national research institutes that are carrying out paragraph (1).

(3) DEFINITION.—The term “autoimmune disease” includes, for purposes of this section such diseases or disorders with evidence of autoimmune pathogenesis as the Secretary determines to be appropriate.

(b) COORDINATING COMMITTEE.—

(1) IN GENERAL.—The Secretary shall ensure that the Autoimmune Diseases Coordinating Committee (referred to in this section as the “Coordinating Committee”) coordinates activities across the National Institutes and with other Federal health programs and activities relating to such diseases.

(2) COMPOSITION.—The Coordinating Committee shall be composed of the directors or their designees of each of the national research institutes involved in research with respect to autoimmune diseases and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, including the Centers for Disease Control and Prevention and the Food and Drug Administration.

(3) CHAIR.—

(A) IN GENERAL.—With respect to autoimmune diseases, the Chair of the Committee shall serve as the principal advisor to the Secretary, the Assistant Secretary for Health, and the Director of NIH, and shall provide advice to the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and other relevant agencies.

(B) DIRECTOR OF NIH.—The Chair of the Committee shall be directly responsible to the Director of NIH.

(c) PLAN FOR NIH ACTIVITIES.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Coordinating Committee shall develop a plan for conducting and supporting research and education on autoimmune diseases through the national research institutes and shall periodically review and revise the plan. The plan shall—

(A) provide for a broad range of research and education activities relating to biomedical, psychosocial, and rehabilitative issues, including studies of the disproportionate impact of such diseases on women;

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

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

(2) CERTAIN ELEMENTS OF PLAN.—The plan under paragraph (1) shall, with respect to autoimmune diseases, provide for the following as appropriate:

(A) Research to determine the reasons underlying the incidence and prevalence of the diseases.

(B) Basic research concerning the etiology and causes of the diseases.

(C) Epidemiological studies to address the frequency and natural history of the diseases, including any differences among the sexes and among racial and ethnic groups.

(D) The development of improved screening techniques.

(E) Clinical research for the development and evaluation of new treatments, including new biological agents.

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

(3) IMPLEMENTATION OF PLAN.—The Director of NIH shall ensure that programs and activities of the National Institutes of Health regarding autoimmune diseases are implemented in accordance with the plan under paragraph (1).

#### MUSCULAR DYSTROPHY RESEARCH

SEC. 409F. [284j] (a) COORDINATION OF ACTIVITIES.—The Director of NIH shall expand and increase coordination in the activities of the National Institutes of Health with respect to research on muscular dystrophies, including Duchenne muscular dystrophy.

(b) ADMINISTRATION OF PROGRAM; COLLABORATION AMONG AGENCIES.—The Director of NIH shall carry out this section through the appropriate institutes, including the National Institute of Neurological Disorders and Stroke and in collaboration with any other agencies that the Director determines appropriate.

#### SEC. 409G. [284k] CLINICAL RESEARCH.

(a) IN GENERAL.—The Director of National Institutes of Health shall undertake activities to support and expand the involvement of the National Institutes of Health in clinical research.

(b) REQUIREMENTS.—In carrying out subsection (a), the Director of National Institutes of Health shall—

(1) consider the recommendations of the Division of Research Grants Clinical Research Study Group and other recommendations for enhancing clinical research; and

(2) establish intramural and extramural clinical research fellowship programs directed specifically at medical and dental students and a continuing education clinical research training program at the National Institutes of Health.

(c) SUPPORT FOR THE DIVERSE NEEDS OF CLINICAL RESEARCH.—The Director of National Institutes of Health, in cooperation with the Directors of the Institutes, Centers, and Divisions of the National Institutes of Health, shall support and expand the resources available for the diverse needs of the clinical research community, including inpatient, outpatient, and critical care clinical research.

(d) PEER REVIEW.—The Director of National Institutes of Health shall establish peer review mechanisms to evaluate applications for the awards and fellowships provided for in subsection (b)(2) and section 409D. Such review mechanisms shall include individuals who are exceptionally qualified to appraise the merits of potential clinical research training and research grant proposals.

**SEC. 409H. [284I] ENHANCEMENT AWARDS.**

(a) **MENTORED PATIENT-ORIENTED RESEARCH CAREER DEVELOPMENT AWARDS.**—

(1) **GRANTS.**—

(A) **IN GENERAL.**—The Director of the National Institutes of Health shall make grants (to be referred to as “Mentored Patient-Oriented Research Career Development Awards”) to support individual careers in clinical research at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research.

(B) **USE.**—Grants under subparagraph (A) shall be used to support clinical investigators in the early phases of their independent careers by providing salary and such other support for a period of supervised study.

(2) **APPLICATIONS.**—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

(b) **MID-CAREER INVESTIGATOR AWARDS IN PATIENT-ORIENTED RESEARCH.**—

(1) **GRANTS.**—

(A) **IN GENERAL.**—The Director of the National Institutes of Health shall make grants (to be referred to as “Mid-Career Investigator Awards in Patient-Oriented Research”) to support individual clinical research projects at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research.

(B) **USE.**—Grants under subparagraph (A) shall be used to provide support for mid-career level clinicians to allow such clinicians to devote time to clinical research and to act as mentors for beginning clinical investigators.

(2) **APPLICATIONS.**—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director requires.

(c) **GRADUATE TRAINING IN CLINICAL INVESTIGATION AWARD.**—

(1) **IN GENERAL.**—The Director of the National Institutes of Health shall make grants (to be referred to as “Graduate Training in Clinical Investigation Awards”) to support individuals pursuing master’s or doctoral degrees in clinical investigation.

(2) **APPLICATIONS.**—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

(3) **LIMITATIONS.**—Grants under this subsection shall be for terms of 2 years or more and shall provide stipend, tuition, and institutional support for individual advanced degree programs in clinical investigation.

(4) **DEFINITION.**—As used in this subsection, the term “advanced degree programs in clinical investigation” means programs that award a master’s or Ph.D. degree in clinical investigation after 2 or more years of training in areas such as the following:

(A) Analytical methods, biostatistics, and study design.

- (B) Principles of clinical pharmacology and pharmacokinetics.
- (C) Clinical epidemiology.
- (D) Computer data management and medical informatics.
- (E) Ethical and regulatory issues.
- (F) Biomedical writing.
- (d) CLINICAL RESEARCH CURRICULUM AWARDS.—
  - (1) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as “Clinical Research Curriculum Awards”) to institutions for the development and support of programs of core curricula for training clinical investigators, including medical students. Such core curricula may include training in areas such as the following:
    - (A) Analytical methods, biostatistics, and study design.
    - (B) Principles of clinical pharmacology and pharmacokinetics.
    - (C) Clinical epidemiology.
    - (D) Computer data management and medical informatics.
    - (E) Ethical and regulatory issues.
    - (F) Biomedical writing.
  - (2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual institution or a consortium of institutions at such time as the Director may require. An institution may submit only one such application.
  - (3) LIMITATIONS.—Grants under this subsection shall be for terms of up to 5 years and may be renewable.

**SEC. 409I. [284m] PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.<sup>15</sup>**

- (a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—
  - (1) IN GENERAL.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs, biological products, or indications that require study. The list shall be revised every three years.
  - (2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary—
    - (A) shall consider—
      - (i) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;
      - (ii) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of

<sup>15</sup> Section 16 of Public Law 107–109 (115 Stat. 1421) requires the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, to submit to Congress a report that relates to section 409I and to section 505A of the Federal Food, Drug, and Cosmetic Act. The report is required to be submitted not later than October 1, 2006.



therapeutics, including drugs and biologics, and identification of biomarkers for such diseases, disorders, or conditions, may be beneficial in pediatric populations; and

(iii) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators; and

(B) may consider the availability of qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), and qualified pandemic or epidemic products (as defined in section 319F–3) to address the needs of pediatric populations, in consultation with the Assistant Secretary for Preparedness and Response, consistent with the purposes of this section.

(b) PEDIATRIC STUDIES AND RESEARCH.—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in paragraphs (1) and (2)(A) of subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.

(c) PROCESS FOR PROPOSED PEDIATRIC STUDY REQUESTS AND LABELING CHANGES.—

(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST.—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act, or section 351(m) of this Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or section 351(k) of this Act; or

(ii) there is a submitted application that could be approved under the criteria of such section; and

(B) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, and every three-year and five-year period referred to in subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act, or applicable twelve-year period referred to in section 351(k)(7) of this Act, and any seven-year period referred to in section 527 of the Federal

Food, Drug, and Cosmetic Act has ended for at least one form of the drug; and

(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

(2) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified under subsection (a) to all holders of an approved application for the drug. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act or section 351(m) of this Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.

(3) REQUESTS FOR PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).

(4) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).

(5) CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS.—A contract, grant, or other funding may be awarded under this section only if a proposal is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(6) REPORTING OF STUDIES.—

(A) IN GENERAL.—On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study, including a written request if issued.

(B) AVAILABILITY OF REPORTS.—

(i) IN GENERAL.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act) and not later than 90 days after submission of such report, shall be—

(I) posted on the internet website of the National Institutes of Health in a manner that is accessible and consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

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

(bb) proprietary interests, confidential commercial information, and intellectual property rights; and

(II) assigned a docket number by the Commissioner of Food and Drugs and made available for the submission of public comments.

(ii) SUBMISSION OF COMMENTS.—An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the submitted comments shall become part of the docket file with respect to each of the drugs.

(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take action in a timely and appropriate manner in response to the reports submitted under subparagraph (A), and shall begin such action upon receipt of the report under subparagraph (A), in accordance with paragraph (7).

(7) REQUESTS FOR LABELING CHANGE.—Within the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

(C)(i) include in the public docket file a reference to the location of the report on the internet website of the National Institutes of Health and a copy of any requested labeling changes; and

(ii) publish through a posting on the Web site of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.

(8) DISPUTE RESOLUTION.—

(A) REFERRAL TO PEDIATRIC ADVISORY COMMITTEE.—If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Committee.

(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under

subparagraph (A), the Pediatric Advisory Committee shall—

(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

(9) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

(10) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner of Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.

(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section, \$5,753,425 for the period beginning on October 1, 2022 and ending on December 23, 2022<sup>16</sup>.

(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.

#### **SEC. 409J. [284q] PAIN RESEARCH.**

(a) RESEARCH INITIATIVES.—

(1) IN GENERAL.—The Director of NIH is encouraged to continue and expand, through the Pain Consortium, an aggressive program of basic and clinical research on the causes of and potential treatments for pain.

(2) ANNUAL RECOMMENDATIONS.—Not less than annually, the Pain Consortium, in consultation with the Division of Program Coordination, Planning, and Strategic Initiatives, shall develop and submit to the Director of NIH recommendations on appropriate pain research initiatives that could be under-

<sup>16</sup>Section 3102 of division FF of Public Law 117-328 amends paragraph (1) by striking “\$5,273,973 for the period beginning on October 1, 2022 and ending on December 23, 2022” and inserting “\$25,000,000 for each of fiscal years 2023 through 2027”. The text being struck does not appear in law.

taken with funds reserved under section 402A(c)(1) for the Common Fund or otherwise available for such initiatives.

(3) DEFINITION.—In this subsection, the term “Pain Consortium” means the Pain Consortium of the National Institutes of Health or a similar trans-National Institutes of Health coordinating entity designated by the Secretary for purposes of this subsection.

(b) INTERAGENCY PAIN RESEARCH COORDINATING COMMITTEE.—

(1) ESTABLISHMENT.—The Secretary shall establish not later than 1 year after the date of the enactment of this section and as necessary maintain a committee, to be known as the Interagency Pain Research Coordinating Committee (in this section referred to as the “Committee”), to coordinate all efforts within the Department of Health and Human Services and other Federal agencies that relate to pain research.

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Committee shall be composed of the following voting members:

(i) Not more than 7 voting Federal representatives appoint by the Secretary from agencies that conduct pain care research and treatment.

(ii) 12 additional voting members appointed under subparagraph (B).

(B) ADDITIONAL MEMBERS.—The Committee shall include additional voting members appointed by the Secretary as follows:

(i) 6 non-Federal members shall be appointed from among scientists, physicians, and other health professionals.

(ii) 6 members shall be appointed from members of the general public, who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions.

(C) NONVOTING MEMBERS.—The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

(3) CHAIRPERSON.—The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH.

(4) MEETINGS.—The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

(5) DUTIES.—The Committee shall—

(A) develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, treatment, and management of pain and diseases and disorders associated with pain, including information on best practices for the utilization of non-pharmacologic treatments, non-addictive medical products, and other drugs or devices approved or cleared by the Food and Drug Administration;

(B) identify critical gaps in basic and clinical research on—

(i) the symptoms and causes of pain, including the identification of relevant biomarkers and screening models and the epidemiology of acute and chronic pain;

(ii) the diagnosis, prevention, treatment, and management of acute and chronic pain, including with respect to non-pharmacologic treatments, non-addictive medical products, and other drugs or devices approved or cleared by the Food and Drug Administration; and

(iii) risk factors for, and early warning signs of, substance use disorders in populations with acute and chronic pain; and

(C) make recommendations to the Director of NIH—

(i) to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort;

(ii) on how best to disseminate information on pain care and epidemiological data related to acute and chronic pain; and

(iii) on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.

(6) REPORT.—The Secretary shall ensure that recommendations and actions taken by the Director with respect to the topics discussed at the meetings described in paragraph (4) are included in appropriate reports to Congress.

(7) REVIEW.—The Secretary shall review the necessity of the Committee at least once every 2 years.

#### PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

##### Subpart 1—National Cancer Institute

###### PURPOSE OF INSTITUTE

SEC. 410. [285] The general purpose of the National Cancer Institute (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

###### NATIONAL CANCER PROGRAM

SEC. 411. [285a] The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute.

## CANCER CONTROL PROGRAMS

SEC. 412. [285a-1] The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include—

(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting—

(A) the detection, diagnosis, prevention, and treatment of cancer,

(B) the continuing care of cancer patients and the families of cancer patients, and

(C) rehabilitation and counseling respecting cancer, to physicians and other health professionals who provide care to individuals who have cancer;

(2) the demonstration of and the education of students of the health professions and health professionals in—

(A) effective methods for the prevention and early detection of cancer and the identification of individuals with a high risk of developing cancer, and

(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

(3) the demonstration of new methods for the dissemination of information to the general public concerning the prevention, early detection, diagnosis, and treatment and control of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

## SPECIAL AUTHORITIES OF THE DIRECTOR

SEC. 413. [285a-2] (a)(1) The Director of the Institute shall establish an information and education program to collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to cancer patients and their families, physicians and other health professionals, and the general public, information on cancer research, diagnosis, prevention, and treatment (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer). The Director of the Institute may take such action as may be necessary to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the public and between the Institute and other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

(2) In carrying out paragraph (1), the Director of the Institute shall—

(A) provide public and patient information and education programs, providing information that will help individuals take personal steps to reduce their risk of cancer, to make them aware of early detection techniques and to motivate appropriate utilization of those techniques, to help individuals deal

with cancer if it strikes, and to provide information to improve long-term survival;

(B) continue and expand programs to provide physicians and the public with state-of-the-art information on the treatment of particular forms of cancers, and to identify those clinical trials that might benefit patients while advancing knowledge of cancer treatment;

(C) assess the incorporation of state-of-the-art cancer treatments into clinical practice and the extent to which cancer patients receive such treatments and include the results of such assessments in the biennial reports required under section 407;

(D) maintain and operate the International Cancer Research Data Bank, which shall collect, catalog, store, and disseminate insofar as feasible the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country; and

(E) to the extent practicable, in disseminating the results of such cancer research and treatment, utilize information systems available to the public.

(b) The Director of the Institute in carrying out the National Cancer Program—

(1) shall establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for cancer research and set standards of safety and care for persons using such materials;

(2) shall, in consultation with the advisory council for the Institute, support (A) research in the cancer field outside the United States by highly qualified foreign nationals which can be expected to benefit the American people, (B) collaborative research involving American and foreign participants, and (C) the training of American scientists abroad and foreign scientists in the United States;

(3) shall, in consultation with the advisory council for the Institute, support appropriate programs of education and training (including continuing education and laboratory and clinical research training);

(4) shall encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

(5) may obtain (after consultation with the advisory council for the Institute and in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

(6)(A) may, in consultation with the advisory council for the Institute, acquire, construct, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and



(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(7) may, in consultation with the advisory council for the Institute, appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments to advise the Director with respect to the Director's functions;

(8) may, subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), enter into such contracts, leases, cooperative agreements, as may be necessary in the conduct of functions of the Director, with any public agency, or with any person, firm, association, corporation, or educational institution; and

(9) shall, notwithstanding section 405(a), prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Institute's advisory council.

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (5) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (5) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

**(c) PRE-CLINICAL MODELS TO EVALUATE PROMISING PEDIATRIC CANCER THERAPIES.—**

**(1) EXPANSION AND COORDINATION OF ACTIVITIES.—**The Director of the National Cancer Institute shall expand, intensify, and coordinate the activities of the Institute with respect to research on the development of preclinical models to evaluate which therapies are likely to be effective for treating pediatric cancer.

**(2) COORDINATION WITH OTHER INSTITUTES.—**The Director of the Institute shall coordinate the activities under paragraph (1) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to

the extent that those Institutes and agencies have responsibilities that are related to pediatric cancer.

#### NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

SEC. 414. [285a–3] (a)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, control, and treatment methods for cancer.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute’s advisory council.

(b) Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) construction (notwithstanding any limitation under section 496);

(2) staffing and other basic operating costs, including such patient care costs as are required for research;

(3) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer; and

(4) demonstration purposes.

As used in this paragraph, the term “construction” does not include the acquisition of land, and the term “training” does not include research training for which National Research Service Awards<sup>17</sup> may be provided under section 487.

(c) Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(d) Research centers under this section may not be considered centers of excellence for purposes of section 402(b)(10).

#### PRESIDENT’S CANCER PANEL

SEC. 415. [285a–4] (a)(1) The President’s Cancer Panel (hereafter in this section referred to as the “Panel”) shall be composed of three persons appointed by the President who by virtue of their training, experience, and background are exceptionally qualified to appraise the National Cancer Program. At least two members of the Panel shall be distinguished scientists or physicians.

(2)(A) Members of the Panel shall be appointed for three-year terms, except that (i) any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member’s predecessor was appointed shall be appointed only for the remain-

<sup>17</sup>Now Ruth L. Kirschstein National Research Service Awards. See section 487.

der of such term, and (ii) a member may serve until the member's successor has taken office. If a vacancy occurs in the Panel, the President shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

(B) The President shall designate one of the members to serve as the chairman of the Panel for a term of one year.

(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties as members of the Panel and shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment.

(3) The Panel shall meet at the call of the chairman, but not less often than four times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and the chairman shall make such transcript available to the public.

(b) The Panel shall monitor the development and execution of the activities of the National Cancer Program, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the National Cancer Program and shall submit to the President, the Secretary, and the Congress an annual evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct.

#### ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 416. [285a-5] (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of cancer. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

#### BREAST AND GYNECOLOGICAL CANCERS

SEC. 417. [285a-6] (a) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on breast cancer, ovarian cancer, and other cancers of the reproductive system of women.

(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have respon-

sibilities that are related to breast cancer and other cancers of the reproductive system of women.

(c) PROGRAMS FOR BREAST CANCER.—

(1) IN GENERAL.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, breast cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

(A) basic research concerning the etiology and causes of breast cancer;

(B) clinical research and related activities concerning the causes, prevention, detection and treatment of breast cancer;

(C) control programs with respect to breast cancer in accordance with section 412, including community-based programs designed to assist women who are members of medically underserved populations, low-income populations, or minority groups;

(D) information and education programs with respect to breast cancer in accordance with section 413; and

(E) research and demonstration centers with respect to breast cancer in accordance with section 414, including the development and operation of centers for breast cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and treatment research and related activities on breast cancer.

Not less than six centers shall be operated under subparagraph (E). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

(2) IMPLEMENTATION OF PLAN FOR PROGRAMS.—

(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 413(9)<sup>18</sup>. The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

(B) Not later than October 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary and the Director of NIH.

(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

<sup>18</sup>So in law. See section 401 of Public Law 103–43 (107 Stat. 153). Probably should be section “413(b)(9)”.

(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

(d) OTHER CANCERS.—In carrying out subsection (a), the Director of the Institute shall conduct or support research on ovarian cancer and other cancers of the reproductive system of women. Activities under such subsection shall provide for the conduct and support of—

(1) basic research concerning the etiology and causes of ovarian cancer and other cancers of the reproductive system of women;

(2) clinical research and related activities into the causes, prevention, detection and treatment of ovarian cancer and other cancers of the reproductive system of women;

(3) control programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 412;

(4) information and education programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 413; and

(5) research and demonstration centers with respect to ovarian cancer and cancers of the reproductive system in accordance with section 414.

(e) REPORT.—The Director of the Institute shall prepare, for inclusion in the biennial report submitted under section 407, a report that describes the activities of the National Cancer Institute under the research programs referred to in subsection (a), that shall include—

(1) a description of the research plan with respect to breast cancer prepared under subsection (c);

(2) an assessment of the development, revision, and implementation of such plan;

(3) a description and evaluation of the progress made, during the period for which such report is prepared, in the research programs on breast cancer and cancers of the reproductive system of women;

(4) a summary and analysis of expenditures made, during the period for which such report is made, for activities with respect to breast cancer and cancers of the reproductive system of women conducted and supported by the National Institutes of Health; and

(5) such comments and recommendations as the Director considers appropriate.

#### PROSTATE CANCER

SEC. 417A. [285a-7] (a) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on prostate cancer.

(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to prostate cancer.

(c) PROGRAMS.—

(1) IN GENERAL.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, prostate cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

(A) basic research concerning the etiology and causes of prostate cancer;

(B) clinical research and related activities concerning the causes, prevention, detection and treatment of prostate cancer;

(C) prevention and control and early detection programs with respect to prostate cancer in accordance with section 412, particularly as it relates to intensifying research on the role of prostate specific antigen for the screening and early detection of prostate cancer;

(D) an Inter-Institute Task Force, under the direction of the Director of the Institute, to provide coordination between relevant National Institutes of Health components of research efforts on prostate cancer;

(E) control programs with respect to prostate cancer in accordance with section 412;

(F) information and education programs with respect to prostate cancer in accordance with section 413; and

(G) research and demonstration centers with respect to prostate cancer in accordance with section 414, including the development and operation of centers for prostate cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and control, treatment, research, and related activities on prostate cancer.

Not less than six centers shall be operated under subparagraph (G). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

(2) IMPLEMENTATION OF PLAN FOR PROGRAMS.—

(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget

estimate prepared in accordance with section 413(9)<sup>19</sup>. The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

(B) Not later than October 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.<sup>20</sup>

**SEC. 417C. [285a-9] GRANTS FOR EDUCATION, PREVENTION, AND EARLY DETECTION OF RADIOGENIC CANCERS AND DISEASES.**

(a) **DEFINITION.**—In this section the term “entity” means any—

- (1) National Cancer Institute-designated cancer center;
- (2) Department of Veterans Affairs hospital or medical center;
- (3) Federally Qualified Health Center, community health center, or hospital;
- (4) agency of any State or local government, including any State department of health; or
- (5) nonprofit organization.

(b) **IN GENERAL.**—The Secretary, acting through the Administrator of the Health Resources and Services Administration in consultation with the Director of the National Institutes of Health and the Director of the Indian Health Service, may make competitive grants to any entity for the purpose of carrying out programs to—

- (1) screen individuals described under section 4(a)(1)(A)(i) or 5(a)(1)(A) of the Radiation Exposure Compensation Act (42 U.S.C. 2210 note) for cancer as a preventative health measure;
- (2) provide appropriate referrals for medical treatment of individuals screened under paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services;
- (3) develop and disseminate public information and education programs for the detection, prevention, and treatment of radiogenic cancers and diseases; and
- (4) facilitate putative applicants in the documentation of claims as described in section 5(a) of the Radiation Exposure Compensation Act (42 U.S.C. 2210 note).

(c) **INDIAN HEALTH SERVICE.**—The programs under subsection (a) shall include programs provided through the Indian Health Service or through tribal contracts, compacts, grants, or cooperative agreements with the Indian Health Service and which are determined appropriate to raising the health status of Indians.

<sup>19</sup> So in law. See section 402 of Public Law 103–43 (107 Stat. 155). Probably should be “section 413(b)(9)”.

<sup>20</sup> Section 417B was repealed by section 103(b)(15) of Public Law 109–482 (120 Stat. 3687).

(d) GRANT AND CONTRACT AUTHORITY.—Entities receiving a grant under subsection (b) may expend the grant to carry out the purpose described in such subsection.

(e) HEALTH COVERAGE UNAFFECTED.—Nothing in this section shall be construed to affect any coverage obligation of a governmental or private health plan or program relating to an individual referred to under subsection (b)(1).

**SEC. 417D. [285a–10] RESEARCH, INFORMATION, AND EDUCATION WITH RESPECT TO BLOOD CANCER.**

(a) JOE MOAKLEY RESEARCH EXCELLENCE PROGRAM.—

(1) IN GENERAL.—The Director of NIH shall expand, intensify, and coordinate programs for the conduct and support of research with respect to blood cancer, and particularly with respect to leukemia, lymphoma, and multiple myeloma.

(2) ADMINISTRATION.—The Director of NIH shall carry out this subsection through the Director of the National Cancer Institute and in collaboration with any other agencies that the Director determines to be appropriate.

(b) GERALDINE FERRARO CANCER EDUCATION PROGRAM.—

(1) IN GENERAL.—The Secretary shall direct the appropriate agency within the Department of Health and Human Services, in collaboration with the Director of NIH, to establish and carry out a program to provide information and education for patients and the general public with respect to blood cancer, and particularly with respect to the treatment of leukemia, lymphoma, and multiple myeloma.

(2) ADMINISTRATION.—The Agency determined by the Secretary under paragraph (1) shall carry out this subsection in collaboration with private health organizations that have national education and patient assistance programs on blood-related cancers.

**SEC. 417E. [285a–11] PEDIATRIC CANCER RESEARCH, AWARENESS, AND SURVIVORSHIP.**

(a) CHILDREN'S CANCER BIOREPOSITORIES.—

(1) AWARD.—The Secretary, acting through the Director of NIH, may make awards to an entity or entities described in paragraph (4) to build upon existing research efforts to collect biospecimens and clinical and demographic information of children, adolescents, and young adults with selected cancer subtypes (and their recurrences) for which current treatments are least effective, in order to achieve a better understanding of the causes of such cancer subtypes (and their recurrences), and the effects and outcomes of treatments for such cancers.

(2) USE OF FUNDS.—Amounts received under an award under paragraph (1) may be used to carry out the following:

(A) Collect and store high-quality, donated biospecimens and associated clinical and demographic information on children, adolescents, and young adults diagnosed with cancer in the United States, focusing on children, adolescents, and young adults with cancer enrolled in clinical trials for whom current treatments are least effective. Activities under this subparagraph may include storage of biospecimens and associated clinical and demographic data



at existing biorepositories supported by the National Cancer Institute, such as collected samples of both solid tumor cancer and paired samples.

(B) Maintain an interoperable, secure, and searchable database on stored biospecimens and associated clinical and demographic data from children, adolescents, and young adults with cancer for the purposes of research by scientists and qualified health care professionals.

(C) Establish and implement procedures for evaluating applications for access to such biospecimens and clinical and demographic data from researchers and other qualified health care professionals.

(D) Provide access to biospecimens and clinical and demographic data from children, adolescents, and young adults with cancer to researchers and qualified health care professionals for peer-reviewed research—

(i) consistent with the procedures established pursuant to subparagraph (C);

(ii) only to the extent permitted by applicable Federal and State law; and

(iii) in a manner that protects personal privacy to the extent required by applicable Federal and State privacy law, at minimum.

(3) NO REQUIREMENT.—No child, adolescent, or young adult with cancer shall be required under this subsection to contribute a specimen to a biorepository or share clinical or demographic data.

(4) APPLICATION; CONSIDERATIONS.—

(A) APPLICATION.—To be eligible to receive an award under paragraph (1) an entity shall submit an application to the Secretary at such a time, in such manner, and containing such information as the Secretary may reasonably require.

(B) CONSIDERATIONS.—In evaluating applications submitted under subparagraph (A), the Secretary shall consider the existing infrastructure of the entity that would allow for the timely capture of biospecimens and related clinical and demographic information for children, adolescents, and young adults with cancer for whom current treatments are least effective.

(5) PRIVACY PROTECTIONS AND INFORMED CONSENT.—

(A) IN GENERAL.—The Secretary may not make an award under paragraph (1) to an entity unless the Secretary ensures that such entity—

(i) collects biospecimens and associated clinical and demographic information only from participants who have given their informed consent in accordance with Federal and State law; and

(ii) protects personal privacy to the extent required by applicable Federal and State law, at minimum.

(B) INFORMED CONSENT.—The Secretary shall ensure biospecimens and associated clinical and demographic in-

formation are collected with informed consent, as described in subparagraph (A)(i).

(6) GUIDELINES AND OVERSIGHT.—The Secretary shall develop and disseminate appropriate guidelines for the development and maintenance of the biorepositories supported under this subsection, including appropriate oversight, to facilitate further research on select cancer subtypes (and their recurrences) in children, adolescents, and young adults with such cancers (and their recurrences).

(7) COORDINATION.—To encourage the greatest possible efficiency and effectiveness of federally supported efforts with respect to the activities described in this subsection, the Secretary shall ensure the appropriate coordination of programs supported under this section with existing federally supported cancer registry programs and the activities under section 399E–1, as appropriate.

(8) SUPPLEMENT NOT SUPPLANT.—Funds provided under this subsection shall be used to supplement, and not supplant, Federal and non-Federal funds available for carrying out the activities described in this subsection.

(9) REPORT.—Not later than 4 years after the date of enactment of the Childhood Cancer Survivorship, Treatment, Access, and Research Reauthorization Act of 2022, the Secretary shall submit to Congress a report on—

(A) the number of biospecimens and corresponding clinical demographic data collected through the biospecimen research efforts supported under paragraph (1);

(B) the number of biospecimens and corresponding clinical demographic data requested for use by researchers;

(C) barriers to the collection of biospecimens and corresponding clinical demographic data;

(D) barriers experienced by researchers or health care professionals in accessing the biospecimens and corresponding clinical demographic data necessary for use in research; and

(E) recommendations with respect to improving the biospecimen and biorepository research efforts under this subsection.

(10) REPORT ON RESEARCHER ACCESS TO CHILDREN'S CANCER BIOREPOSITORY SAMPLES.—Not later than 2 years after the date of enactment of the Childhood Cancer Survivorship, Treatment, Access, and Research Reauthorization Act of 2022, the Director of NIH shall—

(A) conduct a review of the procedures established under paragraph (2)(C) and other policies or procedures related to researcher access to such biospecimens to identify any opportunities to reduce administrative burden, consistent with paragraph (2)(D), in a manner that protects personal privacy to the extent required by applicable Federal and State privacy law, at a minimum; and

(B) submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the findings of the review under subparagraph

(A) and whether the Director of NIH plans to make any changes to the policies or procedures considered in such review, based on such findings.

(11) DEFINITIONS.—For purposes of this subsection:

(A) AWARD.—The term “award” includes a grant, contract, or cooperative agreement determined by the Secretary.

(B) BIOSPECIMEN.—The term “biospecimen” includes—  
 (i) solid tumor tissue or bone marrow;  
 (ii) normal or control tissue;  
 (iii) blood and plasma;  
 (iv) DNA and RNA extractions;  
 (v) familial DNA; and  
 (vi) any other sample relevant to cancer research,  
 as required by the Secretary.

(C) CLINICAL AND DEMOGRAPHIC INFORMATION.—The term “clinical and demographic information” includes—

(i) date of diagnosis;  
 (ii) age at diagnosis;  
 (iii) the patient’s sex, race, ethnicity, and environmental exposures;  
 (iv) extent of disease at enrollment;  
 (v) site of metastases;  
 (vi) location of primary tumor coded;  
 (vii) histologic diagnosis;  
 (viii) tumor marker data when available;  
 (ix) treatment and outcome data;  
 (x) information related to specimen quality; and  
 (xi) any other applicable information required by the Secretary.

(b) IMPROVING CARE FOR PEDIATRIC CANCER SURVIVORS.—

(1) RESEARCH ON PEDIATRIC CANCER SURVIVORSHIP.—The Director of NIH, in coordination with ongoing research activities, may continue to conduct or support pediatric cancer survivorship research including in any of the following areas:

(A) Outcomes of pediatric cancer survivors, including within minority or other medically underserved populations and with respect to health disparities of such outcomes.

(B) Barriers to follow-up care for pediatric cancer survivors, including within minority or other medically underserved populations.

(C) The impact of relevant factors, which may include familial, socioeconomic, and other environmental factors, on treatment outcomes and survivorship.

(D) The development of indicators used for long-term follow-up and analysis of the late effects of cancer treatment for pediatric cancer survivors.

(E) The identification of, as applicable—

(i) risk factors associated with the late effects of cancer treatment;  
 (ii) predictors of adverse neurocognitive and psychosocial outcomes; and

(iii) the molecular basis of long-term complications.

(F) The development of targeted interventions to reduce the burden of morbidity borne by cancer survivors in order to protect such cancer survivors from the late effects of cancer.

(2) **BALANCED APPROACH.**—In conducting or supporting research under paragraph (1)(A)(i) on pediatric cancer survivors within minority or other medically underserved populations, the Director of NIH shall ensure that such research addresses both the physical and the psychological needs of such survivors, as appropriate.

(c) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed as being inconsistent with the goals and purposes of the Minority Health and Health Disparities Research and Education Act of 2000.

(d) **AUTHORIZATION OF APPROPRIATIONS.**—For purposes of carrying out this section and section 399E–1, there are authorized to be appropriated \$30,000,000 for each of fiscal years 2024 through 2028. Funds appropriated under this subsection shall remain available until expended.

**SEC. 417F. [42 U.S.C. 285a–12] INTERAGENCY BREAST CANCER AND ENVIRONMENTAL RESEARCH COORDINATING COMMITTEE.**

(a) **INTERAGENCY BREAST CANCER AND ENVIRONMENTAL RESEARCH COORDINATING COMMITTEE.**—

(1) **ESTABLISHMENT.**—Not later than 6 months after the date of the enactment of this section, the Secretary shall establish a committee, to be known as the Interagency Breast Cancer and Environmental Research Coordinating Committee (in this section referred to as the “Committee”).

(2) **DUTIES.**—The Committee shall—

(A) share and coordinate information on existing research activities, and make recommendations to the National Institutes of Health and other Federal agencies regarding how to improve existing research programs, that are related to breast cancer research;

(B) develop a comprehensive strategy and advise the National Institutes of Health and other Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research, including proposals to evaluate environmental and genomic factors that may be related to the etiology of breast cancer that would—

(i) result in innovative approaches to study emerging scientific opportunities or eliminate knowledge gaps in research to improve the research portfolio;

(ii) outline key research questions, methodologies, and knowledge gaps;

(iii) expand the number of research proposals that involve collaboration between 2 or more national research institutes or national centers, including proposals for Common Fund research described in section 402(b)(7) to improve the research portfolio; and

(iv) expand the number of collaborative, multidisciplinary, and multi-institutional research grants;

(C) develop a summary of advances in breast cancer research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and treatment of cancer and other diseases and disorders; and

(D) not later than 2 years after the date of the establishment of the Committee, make recommendations to the Secretary—

(i) regarding any appropriate changes to research activities, including recommendations to improve the research portfolio of the National Institutes of Health to ensure that scientifically-based strategic planning is implemented in support of research priorities that impact breast cancer research activities;

(ii) to ensure that the activities of the National Institutes of Health and other Federal agencies, including the Department of Defense, are free of unnecessary duplication of effort;

(iii) regarding public participation in decisions relating to breast cancer research to increase the involvement of patient advocacy and community organizations representing a broad geographical area;

(iv) on how best to disseminate information on breast cancer research progress; and

(v) on how to expand partnerships between public entities, including Federal agencies, and private entities to expand collaborative, cross-cutting research.

(3) RULE OF CONSTRUCTION.—For the purposes of the Committee, when focusing on research to evaluate environmental and genomic factors that may be related to the etiology of breast cancer, nothing in this section shall be construed to restrict the Secretary from including other forms of cancer, as appropriate, when doing so may advance research in breast cancer or advance research in other forms of cancer.

(4) MEMBERSHIP.—

(A) IN GENERAL.—The Committee shall be composed of the following voting members:

(i) Not more than 7 voting Federal representatives as follows:

(I) The Director of the Centers for Disease Control and Prevention.

(II) The Director of the National Institutes of Health and the directors of such national research institutes and national centers (which may include the National Institute of Environmental Health Sciences) as the Secretary determines appropriate.

(III) One representative from the National Cancer Institute Board of Scientific Advisors, appointed by the Director of the National Cancer Institute.

(IV) The heads of such other agencies of the Department of Health and Human Services as the Secretary determines appropriate.

(V) Representatives of other Federal agencies that conduct or support cancer research, including the Department of Defense.

(ii) 12 additional voting members appointed under subparagraph (B).

(B) **ADDITIONAL MEMBERS.**—The Committee shall include additional voting members appointed by the Secretary as follows:

(i) 6 members shall be appointed from among scientists, physicians, and other health professionals, who—

(I) are not officers or employees of the United States;

(II) represent multiple disciplines, including clinical, basic, and public health sciences;

(III) represent different geographical regions of the United States;

(IV) are from practice settings, academia, or other research settings; and

(V) are experienced in scientific peer review process.

(ii) 6 members shall be appointed from members of the general public, who represent individuals with breast cancer.

(C) **NONVOTING MEMBERS.**—The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

(5) **CHAIRPERSON.**—The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH.

(6) **MEETINGS.**—The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

(b) **REVIEW.**—The Secretary shall review the necessity of the Committee in calendar year 2011 and, thereafter, at least once every 2 years.

**SEC. 417G. [42 U.S.C. 285a-13] SCIENTIFIC FRAMEWORK FOR RECALCITRANT CANCERS.**

(a) **DEVELOPMENT OF SCIENTIFIC FRAMEWORK.**—

(1) **IN GENERAL.**—For each recalcitrant cancer identified under subsection (b), the Director of the Institute shall develop (in accordance with subsection (c)) a scientific framework for the conduct or support of research on such cancer.

(2) **CONTENTS.**—The scientific framework with respect to a recalcitrant cancer shall include the following:

(A) **CURRENT STATUS.**—

(i) **REVIEW OF LITERATURE.**—A summary of findings from the current literature in the areas of—

(I) the prevention, diagnosis, and treatment of such cancer;

(II) the fundamental biologic processes that regulate such cancer (including similarities and

differences of such processes from the biological processes that regulate other cancers); and

(III) the epidemiology of such cancer.

(ii) **SCIENTIFIC ADVANCES.**—The identification of relevant emerging scientific areas and promising scientific advances in basic, translational, and clinical science relating to the areas described in subclauses (I) and (II) of clause (i).

(iii) **RESEARCHERS.**—A description of the availability of qualified individuals to conduct scientific research in the areas described in clause (i).

(iv) **COORDINATED RESEARCH INITIATIVES.**—The identification of the types of initiatives and partnerships for the coordination of intramural and extramural research of the Institute in the areas described in clause (i) with research of the relevant national research institutes, Federal agencies, and non-Federal public and private entities in such areas.

(v) **RESEARCH RESOURCES.**—The identification of public and private resources, such as patient registries and tissue banks, that are available to facilitate research relating to each of the areas described in clause (i).

(B) **IDENTIFICATION OF RESEARCH QUESTIONS.**—The identification of research questions relating to basic, translational, and clinical science in the areas described in subclauses (I) and (II) of subparagraph (A)(i) that have not been adequately addressed with respect to such recalcitrant cancer.

(C) **RECOMMENDATIONS.**—Recommendations for appropriate actions that should be taken to advance research in the areas described in subparagraph (A)(i) and to address the research questions identified in subparagraph (B), as well as for appropriate benchmarks to measure progress on achieving such actions, including the following:

(i) **RESEARCHERS.**—Ensuring adequate availability of qualified individuals described in subparagraph (A)(iii).

(ii) **COORDINATED RESEARCH INITIATIVES.**—Promoting and developing initiatives and partnerships described in subparagraph (A)(iv).

(iii) **RESEARCH RESOURCES.**—Developing additional public and private resources described in subparagraph (A)(v) and strengthening existing resources.

(3) **TIMING.**—

(A) **INITIAL DEVELOPMENT AND SUBSEQUENT UPDATE.**—For each recalcitrant cancer identified under subsection (b)(1), the Director of the Institute shall—

(i) develop a scientific framework under this subsection not later than 18 months after the date of the enactment of this section; and

(ii) review and update the scientific framework not later than 5 years after its initial development.

(B) OTHER UPDATES.—The Director of the Institute may review and update each scientific framework developed under this subsection as necessary.

(4) PUBLIC NOTICE.—With respect to each scientific framework developed under subsection (a), not later than 30 days after the date of completion of the framework, the Director of the Institute shall—

(A) submit such framework to the Committee on Energy and Commerce and Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and Committee on Appropriations of the Senate; and

(B) make such framework publically available on the Internet website of the Department of Health and Human Services.

(b) IDENTIFICATION OF RECALCITRANT CANCER.—

(1) IN GENERAL.—Not later than 6 months after the date of the enactment of this section, the Director of the Institute shall identify two or more recalcitrant cancers that each—

(A) have a 5-year relative survival rate of less than 20 percent; and

(B) are estimated to cause the death of at least 30,000 individuals in the United States per year.

(2) ADDITIONAL CANCERS.—The Director of the Institute may, at any time, identify other recalcitrant cancers for purposes of this section. In identifying a recalcitrant cancer pursuant to the previous sentence, the Director may consider additional metrics of progress (such as incidence and mortality rates) against such type of cancer.

(c) WORKING GROUPS.—For each recalcitrant cancer identified under subsection (b), the Director of the Institute shall convene a working group comprised of representatives of appropriate Federal agencies and other non-Federal entities to provide expertise on, and assist in developing, a scientific framework under subsection (a). The Director of the Institute (or the Director's designee) shall participate in the meetings of each such working group.

(d) REPORTING.—

(1) BIENNIAL REPORTS.—The Director of NIH shall ensure that each biennial report under section 403 includes information on actions undertaken to carry out each scientific framework developed under subsection (a) with respect to a recalcitrant cancer, including the following:

(A) Information on research grants awarded by the National Institutes of Health for research relating to such cancer.

(B) An assessment of the progress made in improving outcomes (including relative survival rates) for individuals diagnosed with such cancer.

(C) An update on activities pertaining to such cancer under the authority of section 413(b)(7).

(2) ADDITIONAL ONE-TIME REPORT FOR CERTAIN FRAMEWORKS.—For each recalcitrant cancer identified under subsection (b)(1), the Director of the Institute shall, not later than 6 years after the initial development of a scientific framework



under subsection (a), submit a report to the Congress on the effectiveness of the framework (including the update required by subsection (a)(3)(A)(ii)) in improving the prevention, detection, diagnosis, and treatment of such cancer.

(e) **RECOMMENDATIONS FOR EXCEPTION FUNDING.**—The Director of the Institute shall consider each relevant scientific framework developed under subsection (a) when making recommendations for exception funding for grant applications.

(f) **DEFINITION.**—In this section, the term “recalcitrant cancer” means a cancer for which the five-year relative survival rate is below 50 percent.

### Subpart 2—National Heart, Lung, and Blood Institute

#### PURPOSE OF THE INSTITUTE

**SEC. 418. [285b]** The general purpose of the National Heart, Lung, and Blood Institute (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood products and the management of blood resources.

#### HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PREVENTION AND CONTROL PROGRAMS

**SEC. 419. [285b–1]** (a) The Director of the Institute shall conduct and support programs for the prevention and control of heart, blood vessel, lung, and blood diseases. Such programs shall include community-based and population-based programs carried out in cooperation with other Federal agencies, with public health agencies of State or local governments, with nonprofit private entities that are community-based health agencies, or with other appropriate public or nonprofit private entities.

(b) In carrying out programs under subsection (a), the Director of the Institute shall give special consideration to the prevention and control of heart, blood vessel, lung, and blood diseases in children, and in populations that are at increased risk with respect to such diseases.

#### INFORMATION AND EDUCATION

**SEC. 420. [285b–2]** The Director of the Institute shall collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to patients, families of patients, physicians and other health professionals, and the general public, information on research, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases, the maintenance of health to reduce the incidence of such diseases, and on the use of blood and blood products and the management of blood resources. In carrying out this section, the Director of the Institute shall place special emphasis upon the utilization of collaborative efforts with both the public and private sectors to—

(1) increase the awareness and knowledge of health care professionals and the public regarding the prevention of heart

and blood vessel, lung, and blood diseases and the utilization of blood resources; and

(2) develop and disseminate to health professionals, patients and patient families, and the public information designed to encourage adults and children to adopt healthful practices concerning the prevention of such diseases.

NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND  
BLOOD RESOURCES PROGRAM

SEC. 421. [285b–3] (a)(1) The National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this subpart referred to as the “Program” may provide for—

(A) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;

(B) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

(C) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including the provision of emergency medical services), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

(D) establishment of programs that will focus and apply scientific and technological efforts involving the biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on the refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of and rehabilitation from such diseases;

(E) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;

(F) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of blood resources in the United States, including the collection, preservation, fractionation, and distribution of blood and blood products;

(G) the education (including continuing education) and training of scientists, clinical investigators, and educators, in fields and specialties (including computer sciences) requisite to the conduct of clinical programs respecting heart, blood vessel, lung, and blood diseases and blood resources;

(H) public and professional education relating to all aspects of such diseases, including the prevention of such dis-

eases, and the use of blood and blood products and the management of blood resources;

(I) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, hemolytic diseases such as sickle cell anemia and Cooley's anemia, and hemophilic diseases) and for the development and demonstration of diagnostic, treatment, and preventive approaches to such diseases; and

(J) establishment of programs for study, research, development, demonstrations and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, or blood diseases.

(2) The Program shall be coordinated with other national research institutes to the extent that they have responsibilities respecting such diseases and shall give special emphasis to the continued development in the Institute of programs related to the causes of stroke and to effective coordination of such programs with related stroke programs in the National Institute of Neurological and Communicative Disorders and Stroke. The Director of the Institute, with the advice of the advisory council for the Institute, shall revise annually the plan for the Program and shall carry out the Program in accordance with such plan.

(b) In carrying out the Program, the Director of the Institute, under policies established by the Director of NIH—

(1) may, after consultation with the advisory council for the Institute, obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of such service) the services of not more than one hundred experts or consultants who have scientific or professional qualifications;

(2)(A) may, in consultation with the advisory council for the Institute, acquire and construct, improve, repair, operate, alter, renovate, and maintain, heart, blood vessel, lung, and blood disease and blood resource laboratories, research, training, and other facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(3) subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), may enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary in the conduct of the Director's functions, with any public agency, or with any person, firm, association, corporation, or educational institutions;

(4) may make grants to public and nonprofit private entities to assist in meeting the cost of the care of patients in hospitals, clinics, and related facilities who are participating in research projects; and

(5) shall, in consultation with the advisory council for the Institute, conduct appropriate intramural training and education programs, including continuing education and laboratory and clinical research training programs.

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES, SICKLE CELL ANEMIA, AND BLOOD RESOURCES

SEC. 422. [285b–4] (a)(1) The Director of the Institute may provide, in accordance with subsection (c), for the development of—

(A) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment and rehabilitation methods (including methods of providing emergency medical services) for heart and blood vessel diseases;

(B) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment and rehabilitation methods (including methods of providing emergency medical services) for lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children);

(C) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood diseases and research into blood, in the use of blood products and in the management of blood resources; and

(D) three centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment (including genetic studies, intrauterine environment studies, postnatal studies, heart arrhythmias, and acquired heart disease and preventive cardiology) for cardiovascular diseases in children.

(2) The centers developed under paragraph (1) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, pulmonary, and blood diseases:

(A) Programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular, pulmonary, and blood diseases.

(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such diseases.

(C) Programs to develop health professions and allied health professions personnel highly skilled in the prevention of such diseases.

(D) Programs to develop improved methods of providing emergency medical services for persons with such diseases.

(E) Programs of continuing education for health and allied health professionals in the diagnosis, prevention, and treatment of such diseases and the maintenance of health to reduce the incidence of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases and the maintenance of health.

(3) The research, training, and demonstration activities carried out through any such center may relate to any one or more of the diseases referred to in paragraph (1) of this subsection.

(b) The Director of the Institute shall provide, in accordance with subsection (c), for the development of ten centers for basic and clinical research into the diagnosis, treatment, and control of sickle cell anemia.

(c)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(3) Federal payments made under a cooperative agreement or grant under paragraph (1) may be used for—

(A) construction (notwithstanding any limitation under section 496);

(B) staffing and other basic operating costs, including such patient care costs as are required for research;

(C) training, including training for allied health professionals; and

(D) demonstration purposes.

As used in this subsection, the term “construction” does not include the acquisition of land, and the term “training” does not include re-

search training for which National Research Service Awards<sup>21</sup> may be provided under section 487.

(4) Support of a center under paragraph (1) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

#### ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 423. [285b–6] (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of heart, blood vessel, lung, and blood diseases. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

#### NATIONAL CENTER ON SLEEP DISORDERS RESEARCH

SEC. 424. [285b–7] (a) Not later than 1 year after the date of the enactment of the National Institutes of Health Revitalization Act of 1993, the Director of the Institute shall establish the National Center on Sleep Disorders Research (in this section referred to as the “Center”). The Center shall be headed by a director, who shall be appointed by the Director of the Institute.

(b) The general purpose of the Center is—

(1) the conduct and support of research, training, health information dissemination, and other activities with respect to sleep disorders, including biological and circadian rhythm research, basic understanding of sleep, chronobiological and other sleep related research; and

(2) to coordinate the activities of the Center with similar activities of other Federal agencies, including the other agencies of the National Institutes of Health, and similar activities of other public entities and nonprofit entities.

(c)(1) The Director of the National Institutes of Health shall establish a board to be known as the Sleep Disorders Research Advisory Board (in this section referred to as the “Advisory Board”).

(2) The Advisory Board shall advise, assist, consult with, and make recommendations to the Director of the National Institutes of Health, through the Director of the Institute, and the Director of the Center concerning matters relating to the scientific activities carried out by and through the Center and the policies respecting such activities, including recommendations with respect to the plan required in subsection (c)<sup>22</sup>.

<sup>21</sup> Now Ruth L. Kirschstein National Research Service Awards. See section 487.

<sup>22</sup> So in law. See section 503 of Public Law 103–43 (107 Stat. 159). Probably should be “subsection (d)”.

(3)(A) The Director of the National Institutes of Health shall appoint to the Advisory Board 12 appropriately qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, eight shall be representatives of health and scientific disciplines with respect to sleep disorders and four shall be individuals representing the interests of individuals with or undergoing treatment for sleep disorders.

(B) The following officials shall serve as ex officio members of the Advisory Board:

- (i) The Director of the National Institutes of Health.
- (ii) The Director of the Center.
- (iii) The Director of the National Heart, Lung and Blood Institute.
- (iv) The Director of the National Institute of Mental Health.
- (v) The Director of the National Institute on Aging.
- (vi) The Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development.
- (vii) The Director of the National Institute of Neurological Disorders and Stroke.
- (viii) The Assistant Secretary for Health.
- (ix) The Assistant Secretary of Defense (Health Affairs).
- (x) The Chief Medical Director of the Veterans' Administration.

(4) The members of the Advisory Board shall, from among the members of the Advisory Board, designate an individual to serve as the chair of the Advisory Board.

(5) Except as inconsistent with, or inapplicable to, this section, the provisions of section 406 shall apply to the advisory board<sup>23</sup> established under this section in the same manner as such provisions apply to any advisory council established under such section.

(d)(1) After consultation with the Director of the Center and the advisory board established under subsection (c), the Director of the National Institutes of Health shall develop a comprehensive plan for the conduct and support of sleep disorders research.

(2) The plan developed under paragraph (1) shall identify priorities with respect to such research and shall provide for the coordination of such research conducted or supported by the agencies of the National Institutes of Health.

(3) The Director of the National Institutes of Health (after consultation with the Director of the Center and the advisory board established under subsection (c)) shall revise the plan developed under paragraph (1) as appropriate.

(e) The Director of the Center, in cooperation with the Centers for Disease Control and Prevention, is authorized to coordinate activities with the Department of Transportation, the Department of Defense, the Department of Education, the Department of Labor, and the Department of Commerce to collect data, conduct studies, and disseminate public information concerning the impact of sleep disorders and sleep deprivation.

<sup>23</sup> So in law. See section 503 of Public Law 103-43 (107 Stat. 159). Probably should be capitalized.

## HEART ATTACK, STROKE, AND OTHER CARDIOVASCULAR DISEASES IN WOMEN

SEC. 424A. [285b–7a] (a) IN GENERAL.—The Director of the Institute shall expand, intensify, and coordinate research and related activities of the Institute with respect to heart attack, stroke, and other cardiovascular diseases in women.

(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate activities under subsection (a) with similar activities conducted by the other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to heart attack, stroke, and other cardiovascular diseases in women.

(c) CERTAIN PROGRAMS.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the causes of, and to develop methods for preventing, cardiovascular diseases in women. Activities under such subsection shall include conducting and supporting the following:

(1) Research to determine the reasons underlying the prevalence of heart attack, stroke, and other cardiovascular diseases in women, including African-American women and other women who are members of racial or ethnic minority groups.

(2) Basic research concerning the etiology and causes of cardiovascular diseases in women.

(3) Epidemiological studies to address the frequency and natural history of such diseases and the differences among men and women, and among racial and ethnic groups, with respect to such diseases.

(4) The development of safe, efficient, and cost-effective diagnostic approaches to evaluating women with suspected ischemic heart disease.

(5) Clinical research for the development and evaluation of new treatments for women, including rehabilitation.

(6) Studies to gain a better understanding of methods of preventing cardiovascular diseases in women, including applications of effective methods for the control of blood pressure, lipids, and obesity.

(7) Information and education programs for patients and health care providers on risk factors associated with heart attack, stroke, and other cardiovascular diseases in women, and on the importance of the prevention or control of such risk factors and timely referral with appropriate diagnosis and treatment. Such programs shall include information and education on health-related behaviors that can improve such important risk factors as smoking, obesity, high blood cholesterol, and lack of exercise.



## COORDINATION OF FEDERAL ASTHMA ACTIVITIES

SEC. 424B<sup>24</sup> [285b–7b] (a) IN GENERAL.—The Director of Institute shall, through the National Asthma Education Prevention Program Coordinating Committee—

(1) identify all Federal programs that carry out asthma-related activities; and

(2) develop, in consultation with appropriate Federal agencies and professional and voluntary health organizations, a Federal plan for responding to asthma.

(b) REPRESENTATION OF THE DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT.—A representative of the Department of Housing and Urban Development shall be included on the National Asthma Education Prevention Program Coordinating Committee for the purpose of performing the tasks described in subsection (a).<sup>25</sup>

## SEC. 424C. [285b–7c] TUBERCULOSIS.

(a) IN GENERAL.—The Director of the National Institutes of Health may expand, intensify, and coordinate research and development and related activities of the Institutes with respect to tuberculosis including activities toward the goal of eliminating such disease.

(b) CERTAIN ACTIVITIES.—Activities under subsection (a) may include—

(1) enhancing basic and clinical research on tuberculosis, including drug resistant tuberculosis;

(2) expanding research on the relationship between such disease and the human immunodeficiency virus; and

(3) developing new tools for the elimination of tuberculosis, including public health interventions and methods to enhance detection and response to outbreaks of tuberculosis, including multidrug resistant tuberculosis.

## SEC. 425. [285b–8] CONGENITAL HEART DISEASE.

(a) IN GENERAL.—The Director of the Institute may expand, intensify, and coordinate research and related activities of the Institute with respect to congenital heart disease, which may include congenital heart disease research with respect to—

(1) causation of congenital heart disease, including genetic causes;

(2) long-term outcomes in individuals with congenital heart disease, including infants, children, teenagers, adults, and elderly individuals;

(3) diagnosis, treatment, and prevention;

(4) studies using longitudinal data and retrospective analysis to identify effective treatments and outcomes for individuals with congenital heart disease; and

(5) identifying barriers to life-long care for individuals with congenital heart disease.

(b) COORDINATION OF RESEARCH ACTIVITIES.—The Director of the Institute may coordinate research efforts related to congenital

<sup>24</sup>So in law. The section designation lacks a period. See section 521 of Public Law 106–310 (114 Stat. 1116).

<sup>25</sup>Section 425 was repealed by section 103(b)(20) of Public Law 109–482 (120 Stat. 3688).

heart disease among multiple research institutions and may develop research networks.

(c) **MINORITY AND MEDICALLY UNDERSERVED COMMUNITIES.**—In carrying out the activities described in this section, the Director of the Institute shall consider the application of such research and other activities to minority and medically underserved communities.

### Subpart 3—National Institute of Diabetes and Digestive and Kidney Diseases

#### PURPOSE OF THE INSTITUTE

**SEC. 426. [285c]** The general purpose of the National Institute of Diabetes and Digestive and Kidney Diseases (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases.

#### DATA SYSTEMS AND INFORMATION CLEARINGHOUSES

**SEC. 427. [285c–1]** (a) The Director of the Institute shall (1) establish the National Diabetes Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with diabetes, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing diabetes, and (2) establish the National Diabetes Information Clearinghouse to facilitate and enhance knowledge and understanding of diabetes on the part of health professionals, patients, and the public through the effective dissemination of information.

(b) The Director of the Institute shall (1) establish the National Digestive Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with digestive diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing digestive diseases, and (2) establish the National Digestive Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of digestive diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

(c) The Director of the Institute shall (1) establish the National Kidney and Urologic Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with kidney and urologic diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing kidney and urologic diseases, and (2) establish the National Kidney and Urologic Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of kidney and urologic diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

DIVISION DIRECTORS FOR DIABETES, ENDOCRINOLOGY, AND METABOLIC DISEASES, DIGESTIVE DISEASES AND NUTRITION, AND KIDNEY, UROLOGIC, AND HEMATOLOGIC DISEASES

SEC. 428. [285c–2] (a)(1) In the Institute there shall be a Division Director for Diabetes, Endocrinology, and Metabolic Diseases, a Division Director for Digestive Diseases and Nutrition, and a Division Director for Kidney, Urologic, and Hematologic Diseases. Such Division Directors, under the supervision of the Director of the Institute, shall be responsible for—

(A) developing a coordinated plan (including recommendations for expenditures) for each of the national research institutes within the National Institutes of Health with respect to research and training concerning diabetes, endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases;

(B) assessing the adequacy of management approaches for the activities within such institutes concerning such diseases and nutrition and developing improved approaches if needed;

(C) monitoring and reviewing expenditures by such institutes concerning such diseases and nutrition; and

(D) identifying research opportunities concerning such diseases and nutrition and recommending ways to utilize such opportunities.

(2) The Director of the Institute shall transmit to the Director of NIH the plans, recommendations, and reviews of the Division Directors under subparagraphs (A) through (D) of paragraph (1) together with such comments and recommendations as the Director of the Institute determines appropriate.

(b) The Director of the Institute, acting through the Division Director for Diabetes, Endocrinology, and Metabolic Diseases, the Division Director for Digestive Diseases and Nutrition, and the Division Director for Kidney, Urologic, and Hematologic Diseases, shall—

(1) carry out programs of support for research and training (other than training for which National Research Service Awards<sup>26</sup> may be made under section 487) in the diagnosis, prevention, and treatment of diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

INTERAGENCY COORDINATING COMMITTEES

SEC. 429. [285c–3] (a) For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to diabetes mellitus, digestive diseases, and kidney, urologic, and hematologic diseases; and

<sup>26</sup>Now Ruth L. Kirschstein National Research Service Awards. See section 487.

(2) coordinating those aspects of all Federal health programs and activities relating to such diseases to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities;

the Secretary shall establish a Diabetes Mellitus Interagency Coordinating Committee, a Digestive Diseases Interagency Coordinating Committee, and a Kidney, Urologic, and Hematologic Diseases Coordinating Committee (hereafter in this section individually referred to as a "Committee").

(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research with respect to the diseases for which the Committee is established, the Division Director of the Institute for the diseases for which the Committee is established, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers) and shall include representation from all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

#### ADVISORY BOARDS

SEC. 430. [285c-4] (a) The Secretary shall establish in the Institute the National Diabetes Advisory Board, the National Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases Advisory Board (hereafter in this section individually referred to as an "Advisory Board").

(b) Each Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to the diseases with respect to which the Advisory Board is established; and

(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in the fields of health education, nursing, data systems, public information, and community program development.

(2)(A) The following shall be ex officio members of each Advisory Board:

(i) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Diabetes and

Digestive and Kidney Diseases, the Director of the Centers for Disease Control and Prevention, the Chief Medical Director of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs, and the Division Director of the National Institute of Diabetes and Digestive and Kidney Diseases for the diseases for which the Board is established (or the designees of such officers).

(ii) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(B) In the case of the National Diabetes Advisory Board, the following shall also be ex officio members: The Director of the National Heart, Lung, and Blood Institute, the Director of the National Eye Institute, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the Administrator of the Health Resources and Services Administration (or the designees of such officers).

(c) Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

(d) The term of office of an appointed member of an Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in an Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

(e) The members of each Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of an Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) Each Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board shall—

(1) review and evaluate the implementation of the plan (referred to in section 433) respecting the diseases with respect

to which the Advisory Board was established and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting such diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan, the coordinating committee for such diseases, and with key non-Federal entities involved in activities affecting the control of such diseases.

(i) In carrying out its functions, each Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Boards established under subsection (a) before the expiration of 90 days after such date. The members of the Boards in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Boards established under subsection (a) for diabetes and digestive diseases, except that at least one-half of the members of the National Diabetes Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall be appointed to the National Diabetes Advisory Board first established under subsection (a).

#### RESEARCH AND TRAINING CENTERS

SEC. 431. [285c-5] (a)(1) Consistent with applicable recommendations of the National Commission on Diabetes, the Director of the Institute shall provide for the development or substantial expansion of centers for research and training in diabetes mellitus and related endocrine and metabolic diseases. Each center developed or expanded under this subsection shall—

(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Secretary; and

(B) conduct—

(i) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic diseases and the complications resulting from such diseases;

(ii) training programs for physicians and allied health personnel in current methods of diagnosis and treatment

of such diseases and complications, and in research in diabetes; and

(iii) information programs for physicians and allied health personnel who provide primary care for patients with such diseases or complications.

(2) A center may use funds provided under paragraph (1) to provide stipends for nurses and allied health professionals enrolled in research training programs described in paragraph (1)(B)(ii).

(b) Consistent with applicable recommendations of the National Digestive Diseases Advisory Board, the Director shall provide for the development or substantial expansion of centers for research in digestive diseases and related functional, congenital, metabolic disorders, and normal development of the digestive tract. Each center developed or expanded under this subsection—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of digestive diseases and nutritional disorders and related functional, congenital, or metabolic complications resulting from such diseases or disorders;

(3) shall encourage research into and programs for—

(A) providing information for patients with such diseases and the families of such patients, physicians and others who care for such patients, and the general public;

(B) model programs for cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases, disorders, and complications; and

(4) may perform research and participate in epidemiological studies and data collection relevant to digestive diseases and disorders and disseminate such research, studies, and data to the health care profession and to the public.

(c) The Director shall provide for the development or substantial expansion of centers for research in kidney and urologic diseases. Each center developed or expanded under this subsection—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of kidney and urologic diseases;

(3) shall encourage research into and programs for—

(A) providing information for patients with such diseases, disorders, and complications and the families of such patients, physicians and others who care for such patients, and the general public;

(B) model programs for cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases; and

(4) may perform research and participate in epidemiological studies and data collection relevant to kidney and urologic diseases in order to disseminate such research, studies, and data to the health care profession and to the public.

(d)(1) The Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the development or substantial expansion of centers for research and training regarding nutritional disorders, including obesity.

(2) The Director of the Institute shall carry out paragraph (1) in collaboration with the Director of the National Cancer Institute and with the Directors of such other agencies of the National Institutes of Health as the Director of NIH determines to be appropriate.

(3) Each center developed or expanded under paragraph (1) shall—

(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director;

(B) conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of nutritional disorders, including obesity and the impact of nutrition and diet on child development;

(C) conduct training programs for physicians and allied health professionals in current methods of diagnosis and treatment of such diseases and complications, and in research in such disorders; and

(D) conduct information programs for physicians and allied health professionals who provide primary care for patients with such disorders or complications.

(e) Insofar as practicable, centers developed or expanded under this section should be geographically dispersed throughout the United States and in environments with proven research capabilities. Support of a center under this section may be for a period of not to exceed five years and such period may be extended by the Director of the Institute for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

#### ADVISORY COUNCIL SUBCOMMITTEES

SEC. 432. [285c-6] There are established within the advisory council for the Institute appointed under section 406 a subcommittee on diabetes and endocrine and metabolic diseases, a subcommittee on digestive diseases and nutrition, and a subcommittee on kidney, urologic, and hematologic diseases. The subcommittees shall be composed of members of the advisory council who are outstanding in the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and members of the advisory council who are leaders in the fields of education and public affairs. The subcommittees are authorized to review applications made to the Director of the Institute for grants



for research and training projects relating to the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and shall recommend to the advisory council those applications and contracts that the subcommittees determine will best carry out the purposes of the Institute. The subcommittees shall also review and evaluate the diabetes and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases programs of the Institute and recommend to the advisory council such changes in the administration of such programs as the subcommittees determine are necessary.

#### BIENNIAL REPORT

SEC. 433. [285c-7] The Director of the Institute shall prepare for inclusion in the biennial report made under section 407 a description of the Institute's activities—

(1) under the current diabetes plan under the National Diabetes Mellitus Research and Education Act; and

(2) under the current digestive diseases plan formulated under the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976.

The description submitted by the Director shall include an evaluation of the activities of the centers supported under section 431.

#### NUTRITIONAL DISORDERS PROGRAM

SEC. 434. [285c-8] (a) The Director of the Institute, in consultation with the Director of NIH, shall establish a program of conducting and supporting research, training, health information dissemination, and other activities with respect to nutritional disorders, including obesity.

(b) In carrying out the program established under subsection (a), the Director of the Institute shall conduct and support each of the activities described in such subsection.

(c) In carrying out the program established under subsection (a), the Director of the Institute shall carry out activities to facilitate and enhance knowledge and understanding of nutritional disorders, including obesity, on the part of health professionals, patients, and the public through the effective dissemination of information.

#### JUVENILE DIABETES

SEC. 434A. [285c-9] (a) LONG-TERM EPIDEMIOLOGY STUDIES.—The Director of the Institute shall conduct or support long-term epidemiology studies in which individuals with or at risk for type 1, or juvenile, diabetes are followed for 10 years or more. Such studies shall investigate the causes and characteristics of the disease and its complications.

(b) CLINICAL TRIAL INFRASTRUCTURE/INNOVATIVE TREATMENTS FOR JUVENILE DIABETES.—The Secretary, acting through the Director of the National Institutes of Health, shall support regional clinical research centers for the prevention, detection, treatment, and cure of juvenile diabetes.

(c) PREVENTION OF TYPE 1 DIABETES.—The Secretary, acting through the appropriate agencies, shall provide for a national effort

to prevent type 1 diabetes. Such effort shall provide for a combination of increased efforts in research and development of prevention strategies, including consideration of vaccine development, coupled with appropriate ability to test the effectiveness of such strategies in large clinical trials of children and young adults.

Subpart 4—National Institute of Arthritis and Musculoskeletal and Skin Diseases

PURPOSE OF THE INSTITUTE

SEC. 435. [285d] The general purpose of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research and training, the dissemination of health information, and other programs with respect to arthritis and musculoskeletal and skin diseases (including sports-related disorders), with particular attention to the effect of these diseases on children.

NATIONAL ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES PROGRAM

SEC. 436. [285d–1] (a) The Director of the Institute, with the advice of the Institute’s advisory council, shall prepare and transmit to the Director of NIH a plan for a national arthritis and musculoskeletal and skin diseases program to expand, intensify, and coordinate the activities of the Institute respecting arthritis and musculoskeletal and skin diseases. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The plan shall place particular emphasis upon expanding research into better understanding the causes and the development of effective treatments for arthritis affecting children. The Director of the Institute shall periodically review and revise such plan and shall transmit any revisions of such plan to the Director of NIH.

(b) Activities under the national arthritis and musculoskeletal and skin diseases program shall be coordinated with the other national research institutes to the extent that such institutes have responsibilities respecting arthritis and musculoskeletal and skin diseases, and shall, at least, provide for—

(1) investigation into the epidemiology, etiology, and prevention of all forms of arthritis and musculoskeletal and skin diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important knowledge to the treatment and understanding of arthritis and musculoskeletal and skin diseases;

(2) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treatment, including medical rehabilitation, and prevention of arthritis and musculoskeletal and skin diseases;

(3) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute

for damaged bone, muscle, and joints and other supporting structures;

(4) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields; and

(5) research into the causes of arthritis affecting children and the development, trial, and evaluation of techniques, drugs and devices used in the diagnosis, treatment (including medical rehabilitation), and prevention of arthritis in children.

(c) The Director of the Institute shall carry out the national arthritis and musculoskeletal and skin diseases program in accordance with the plan prepared under subsection (a) and any revisions of such plan made under such subsection.

#### RESEARCH AND TRAINING

SEC. 437. [285d–2] The Director of the Institute shall—

(1) carry out programs of support for research and training (other than training for which National Research Service Awards<sup>27</sup> may be made under section 487) in the diagnosis, prevention, and treatment of arthritis and musculoskeletal and skin diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

#### DATA SYSTEM AND INFORMATION CLEARINGHOUSE

SEC. 438. [285d–3] (a) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with arthritis and musculoskeletal and skin diseases, including where possible, data involving general populations for the purpose of detection of individuals with a risk of developing arthritis and musculoskeletal and skin diseases.

(b) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of arthritis and musculoskeletal and skin diseases, including juvenile arthritis and related conditions, by health professionals, patients, and the public.

#### INTERAGENCY COORDINATING COMMITTEES

SEC. 439. [285d–4] (a) For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to arthritis, musculoskeletal diseases, and skin diseases, including sports-related disorders; and

<sup>27</sup> Now Ruth L. Kirschstein National Research Service Awards. See section 487.

(2) coordinating the aspects of all Federal health programs and activities relating to arthritis, musculoskeletal diseases, and skin diseases in order to assure the adequacy and technical soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities,

the Secretary shall establish an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and a Skin Diseases Interagency Coordinating Committee (hereafter in this section individually referred to as a "Committee").

(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the Chief Medical Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and representatives of all other Federal departments and agencies (as determined by the Secretary) whose programs involve health functions or responsibilities relevant to arthritis and musculoskeletal diseases or skin diseases, as the case may be. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

#### ARTHRITIS AND MUSCULOSKELETAL DISEASES DEMONSTRATION PROJECTS

SEC. 440. [285d-5] (a) The Director of the Institute may make grants to public and private nonprofit entities to establish and support projects for the development and demonstration of methods for screening, detection, and referral for treatment of arthritis and musculoskeletal diseases and for the dissemination of information on such methods to the health and allied health professions. Activities under such projects shall be coordinated with Federal, State, local, and regional health agencies, centers assisted under section 441, and the data system established under subsection (c).

(b) Projects supported under this section shall include—

(1) programs which emphasize the development and demonstration of new and improved methods of screening and early detection, referral for treatment, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) programs which emphasize the development and demonstration of new and improved methods for patient referral from local hospitals and physicians to appropriate centers for early diagnosis and treatment;

(3) programs which emphasize the development and demonstration of new and improved means of standardizing patient data and recordkeeping;

(4) programs which emphasize the development and demonstration of new and improved methods of dissemination of knowledge about the programs, methods, and means referred

to in paragraphs (1), (2), and (3) of this subsection to health and allied health professionals;

(5) programs which emphasize the development and demonstration of new and improved methods for the dissemination to the general public of information—

(A) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(B) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive treatment, and control methods for arthritis and unapproved and ineffective drugs and devices for arthritis and musculoskeletal diseases; and

(6) projects for investigation into the epidemiology of all forms and aspects of arthritis and musculoskeletal diseases, including investigations into the social, environmental, behavioral, nutritional, and genetic determinants and influences involved in the epidemiology of arthritis and musculoskeletal diseases.

(c) The Director shall provide for the standardization of patient data and recordkeeping for the collection, storage, analysis, retrieval, and dissemination of such data in cooperation with projects assisted under this section, centers assisted under section 441, and other persons engaged in arthritis and musculoskeletal disease programs.

#### MULTIPURPOSE ARTHRITIS AND MUSCULOSKELETAL DISEASES CENTERS

SEC. 441. [285d–6] (a) The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including staffing and other operating costs such as the costs of patient care required for research) of new and existing centers for arthritis and musculoskeletal diseases. For purposes of this section, the term “modernization” means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

(b) Each center assisted under this section shall—

(1)(A) use the facilities of a single institution or a consortium of cooperating institutions, and (B) meet such qualifications as may be prescribed by the Secretary; and

(2) conduct—

(A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of and rehabilitation from arthritis and musculoskeletal diseases and complications resulting from arthritis and musculoskeletal diseases, including research into implantable biomaterials and biomechanical and other orthopedic procedures;

(B) training programs for physicians, scientists, and other health and allied health professionals;

(C) information and continuing education programs for physicians and other health and allied health professionals who provide care for patients with arthritis and musculoskeletal diseases; and

(D) programs for the dissemination to the general public of information—

(i) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(ii) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods and unapproved and ineffective drugs and devices.

A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in paragraph (2)(B).

(c) Each center assisted under this section may conduct programs to—

(1) establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping; and

(3) develop community consultative services to facilitate the referral of patients to centers for treatment.

(d) The Director of the Institute shall, insofar as practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of children affected by arthritis and musculoskeletal diseases.

(e) Support of a center under this section may be for a period of not to exceed five years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(f) Not later than October 1, 1993, the Director shall establish a multipurpose arthritis and musculoskeletal disease center for the purpose of expanding the level of research into the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculoskeletal diseases.

#### LUPUS

SEC. 441A. [285d–6a] (a) IN GENERAL.—The Director of the Institute shall expand and intensify research and related activities of the Institute with respect to lupus.

(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by the other national research institutes and agencies of the National Institutes of

Health to the extent that such Institutes and agencies have responsibilities that are related to lupus.

(c) PROGRAMS FOR LUPUS.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the causes of, and to find a cure for, lupus. Activities under such subsection shall include conducting and supporting the following:

(1) Research to determine the reasons underlying the elevated prevalence of lupus in women, including African-American women.

(2) Basic research concerning the etiology and causes of the disease.

(3) Epidemiological studies to address the frequency and natural history of the disease and the differences among the sexes and among racial and ethnic groups with respect to the disease.

(4) The development of improved diagnostic techniques.

(5) Clinical research for the development and evaluation of new treatments, including new biological agents.

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

#### ADVISORY BOARD

SEC. 442. [285d–7] (a) The Secretary shall establish in the Institute the National Arthritis and Musculoskeletal and Skin Diseases Advisory Board (hereafter in this section referred to as the “Advisory Board”).

(b) The Advisory Board shall be composed of twenty appointed members and nonvoting, ex officio members, as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to arthritis, musculoskeletal diseases, and skin diseases; and

(B) eight members from the general public who are knowledgeable with respect to such diseases, including one member who is a person who has such a disease, one person who is the parent of an adult with such a disease, and two members who are parents of children with arthritis.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in health education, nursing, data systems, public information, or community program development.

(2) The following shall be ex officio members of the Advisory Board:

(A) the Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Director of the Centers for Disease Control and Prevention, the Chief Medical Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(c) Members of the Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Advisory Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Advisory Board.

(d) The term of office of an appointed member of the Advisory Board is four years. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

(e) The members of the Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) The Advisory Board shall—

(1) review and evaluate the implementation of the plan prepared under section 436(a) and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting arthritis, musculoskeletal diseases and skin diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies for Federal agencies involved in the implementation of such plan, the interagency coordinating committees for such diseases established under section 439, and with key non-Federal entities involved in activities affecting the control of such diseases.

(i) In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the par-



ticular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) The National Arthritis Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Board established under subsection (a) before the expiration of 90 days after such date. The members of the Board in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Advisory Board established under subsection (a).

#### JUVENILE ARTHRITIS AND RELATED CONDITIONS

**SEC. 442A. [285d–8]** (a) **EXPANSION AND COORDINATION OF ACTIVITIES.**—The Director of the Institute, in coordination with the Director of the National Institute of Allergy and Infectious Diseases, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning juvenile arthritis and related conditions.

(b) **COORDINATION.**—The Directors referred to in subsection (a) shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Inter-agency Coordinating Committee.

#### Subpart 5—National Institute on Aging

##### PURPOSE OF THE INSTITUTE

**SEC. 443. [285e]** The general purpose of the National Institute on Aging (hereafter in this subpart referred to as the “Institute”) is the conduct and support of biomedical, social, and behavioral research, training, health information dissemination, and other programs with respect to the aging process and the diseases and other special problems and needs of the aged.

##### SPECIAL FUNCTIONS

**SEC. 444. [285e–1]** (a) In carrying out the training responsibilities under this Act or any other Act for health and allied health professions personnel, the Secretary shall take appropriate steps to insure the education and training of adequate numbers of allied health, nursing, and paramedical personnel in the field of health care for the aged.

(b) The Director of the Institute shall conduct scientific studies to measure the impact on the biological, medical, social, and psychological aspects of aging of programs and activities assisted or conducted by the Department of Health and Human Services.

(c) The Director of the Institute shall carry out public information and education programs designed to disseminate as widely as possible the findings of research sponsored by the Institute, other relevant aging research and studies, and other information about the process of aging which may assist elderly and near-elderly persons in dealing with, and all Americans in understanding, the problems and processes associated with growing older.

(d) The Director of the Institute shall make grants to public and private nonprofit institutions to conduct research relating to Alzheimer's Disease.

#### ALZHEIMER'S DISEASE CENTERS

SEC. 445. [285e-2] (a)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities (including university medical centers) to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support (including staffing) for centers for basic and clinical research (including multidisciplinary research) into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for Alzheimer's disease.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(b)(1) Federal payments made under a cooperative agreement or grant under subsection (a) may, with respect to Alzheimer's disease, be used for—

(A) diagnostic examinations, patient assessments, patient care costs, and other costs necessary for conducting research;

(B) training, including training for allied health professionals;

(C) diagnostic and treatment clinics designed to meet the special needs of minority and rural populations and other underserved populations;

(D) activities to educate the public; and

(E) the dissemination of information.

(2) For purposes of paragraph (1), the term "training" does not include research training for which National Research Service Awards<sup>28</sup> may be provided under section 487.

(c) Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

#### CLAUDE D. PEPPER OLDER AMERICANS INDEPENDENCE CENTERS

SEC. 445A. [285e-3] (a) The Director of the Institute shall enter into cooperative agreements with, and make grants to, public and private nonprofit entities for the development or expansion of not less than 10 centers of excellence in geriatric research and training of researchers. Each such center shall be known as a Claude D. Pepper Older Americans Independence Center.

(b) Each center developed or expanded under this section shall—

(1) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such re-

<sup>28</sup>Now Ruth L. Kirschstein National Research Service Awards. See section 487.

search and training qualifications as may be prescribed by the Director; and

(2) conduct—

(A) research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause, which research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals; and

(B) programs to develop individuals capable of conducting research described in subparagraph (A).

(c) In making cooperative agreements and grants under this section for the development or expansion of centers, the Director of the Institute shall ensure that, to the extent practicable, any such centers are distributed equitably among the principal geographic regions of the United States.

(d) For purposes of this section, the term “independence”, with respect to diseases, disorders, and complications of aging, means the functional ability of individuals to perform activities of daily living or instrumental activities of daily living without assistance or supervision.

#### AWARDS AUTHORIZED

SEC. 445B.<sup>29</sup> [285e-4] (a) The Director of the Institute shall make awards to senior researchers who have made distinguished achievements in biomedical research in areas relating to Alzheimer's disease and related dementias. Awards under this section shall be used by the recipients to support research in areas relating to such disease and dementias, and may be used by the recipients to train junior researchers who demonstrate exceptional promise to conduct research in such areas.

(b) The Director of the Institute may make awards under this section to researchers at centers supported under section 445 and to researchers at other public and nonprofit private entities.

(c) The Director of the Institute shall make awards under this section only to researchers who have been recommended for such awards by the National Advisory Council on Aging.

(d) The Director of the Institute shall establish procedures for the selection of the recipients of awards under this section.

(e) Awards under this section shall be made for a one-year period, and may be renewed for not more than six additional consecutive one-year periods.

#### RESEARCH PROGRAM AND PLAN

SEC. 445C. [285e-5] (a) The Director of the Institute shall conduct, or make grants for the conduct of, research relevant to appro-

<sup>29</sup> Sections 445B through 445F were originally enacted as provisions of title IX of Public Law 99-660, and were transferred to the Public Health Service Act by section 142 of Public Law 100-607. (Various provisions relating to Alzheimer's disease remain in such title IX, which is included in this compilation.)

priate services for individuals with Alzheimer's disease and related dementias and their families.

(b)(1) Within 6 months after the date of enactment of the Alzheimer's Disease and Related Dementias Services Research Act of 1986, the Director of the Institute shall prepare and transmit to the Chairman of the Council on Alzheimer's Disease (in this section referred to as the "Council") a plan for the research to be conducted under subsection (a). The plan shall—

(A) provide for research concerning—

(i) the epidemiology of, and the identification of risk factors for, Alzheimer's disease and related dementias; and

(ii) the development and evaluation of reliable and valid multidimensional diagnostic and assessment procedures and instruments; and

(B) ensure that research carried out under the plan is coordinated with, and uses, to the maximum extent feasible, resources of, other Federal programs relating to Alzheimer's disease and related dementias, including centers supported under section 445, centers supported by the National Institute of Mental Health on the psychopathology of the elderly, relevant activities of the Administration on Aging, other programs and centers involved in research on Alzheimer's disease and related dementias supported by the Department, and other programs relating to Alzheimer's disease and related dementias which are planned or conducted by Federal agencies other than the Department, State or local agencies, community organizations, or private foundations.

(2) Within one year after transmitting the plan required under paragraph (1), and annually thereafter, the Director of the Institute shall prepare and transmit to the Chairman of the Council such revisions of such plan as the Director considers appropriate.

(c) In preparing and revising the plan required by subsection (b), the Director of the Institute shall consult with the Chairman of the Council and the heads of agencies within the Department.

(d) the<sup>30</sup> Director of the Institute may develop, or make grants to develop—

(1) model techniques to—

(A) promote greater independence, including enhanced independence in performing activities of daily living and instrumental activities of daily living, for persons with Alzheimer's disease and related disorders; and

(B) prevent or reduce the severity of secondary disabilities, including confusional episodes, falls, bladder and bowel incontinence, and adverse effects of prescription and over-the-counter medications, in such persons; and

(2) model curricula for health care professionals, health care paraprofessionals, and family caregivers, for training and application in the use of such techniques.

(e) For purposes of this section, the term "Council on Alzheimer's Disease" means the council established in section 911(a)<sup>31</sup> of Public Law 99-660.

<sup>30</sup> So in law. See section 9 of Public Law 102-507 (106 Stat. 3287). Probably should be "The".

<sup>31</sup> Section 911 was repealed by section 601(a)(2)(E) of Public Law 105-362 (112 Stat. 3286).

## DISSEMINATION

SEC. 445D. [285e–6] The Director of the Institute shall disseminate the results of research conducted under section 445C and this section to appropriate professional entities and to the public.

## CLEARINGHOUSE ON ALZHEIMER’S DISEASE

SEC. 445E. [285e–7] (a) The Director of the Institute shall establish the Clearinghouse on Alzheimer’s Disease (hereinafter referred to as the “Clearinghouse”). The purpose of the Clearinghouse is the dissemination of information concerning services available for individuals with Alzheimer’s disease and related dementias and their families. The Clearinghouse shall—

(1) compile, archive, and disseminate information concerning research, demonstration, evaluation, and training programs and projects concerning Alzheimer’s disease and related dementias; and

(2) annually publish a summary of the information compiled under paragraph (1) during the preceding 12-month period, and make such information available upon request to appropriate individuals and entities, including educational institutions, research entities, and Federal and public agencies.

(b) The Clearinghouse may charge an appropriate fee for information provided through the toll-free telephone line established under subsection (a)(3).<sup>32</sup>

(c) The Director of the Institute, the Director of the National Institute of Mental Health, and the Director of the National Center for Health Services Research and Health Care Technology Assessment shall provide to the Clearinghouse summaries of the findings of research conducted under part D.

## DISSEMINATION PROJECT

SEC. 445F. [285e–8] (a) The Director of the Institute shall make a grant to, or enter into a contract with, a national organization representing individuals with Alzheimer’s disease and related dementias for the conduct of the activities described in subsection (b).

(b) The organization receiving a grant or contract under this section shall—

(1) establish a central computerized information system to—

(A) compile and disseminate information concerning initiatives by State and local governments and private entities to provide programs and services for individuals with Alzheimer’s disease and related dementias; and

(B) translate scientific and technical information concerning such initiatives into information readily understandable by the general public, and make such information available upon request; and

(2) establish a national toll-free telephone line to make available the information described in paragraph (1), and infor-

<sup>32</sup> So in law. Section 445E does not contain a subsection (a)(3). Section 445F(b)(2) provides for a toll-free telephone line.

mation concerning Federal programs, services and benefits for individuals with Alzheimer's disease and related dementias and their families.

(c) The organization receiving a grant or contract under this section may charge appropriate fees for information provided through the toll-free telephone line established under subsection (b)(2), and may make exceptions to such fees for individuals and organizations who are not financially able to pay such fees.

(d) In order to receive a grant or contract under this section, an organization shall submit an application to the Director of the Institute. Such application shall contain—

(1) information demonstrating that such organization has a network of contacts which will enable such organization to receive information necessary to the operation of the central computerized information system described in subsection (b)(1);

(2) information demonstrating that, by the end of fiscal year 1991, such organization will be financially able to, and will, carry out the activities described in subsection (b) without a grant or contract from the Federal Government; and

(3) such other information as the Director may prescribe.

#### ALZHEIMER'S DISEASE REGISTRY

SEC. 445G. [285e-9] (a) IN GENERAL.—The Director of the Institute may make a grant to develop a registry for the collection of epidemiological data about Alzheimer's disease and its incidence in the United States, to train personnel in the collection of such data, and for other matters respecting such disease.

(b) QUALIFICATIONS.—To qualify for a grant under subsection (a) an applicant shall—

(1) be an accredited school of medicine or public health which has expertise in the collection of epidemiological data about individuals with Alzheimer's disease and in the development of disease registries, and

(2) have access to a large patient population, including a patient population representative of diverse ethnic backgrounds.

#### AGING PROCESSES REGARDING WOMEN

SEC. 445H. [285e-10] The Director of the Institute, in addition to other special functions specified in section 444 and in cooperation with the Directors of the other national research institutes and agencies of the National Institutes of Health, shall conduct research into the aging processes of women, with particular emphasis given to the effects of menopause and the physiological and behavioral changes occurring during the transition from pre- to post-menopause, and into the diagnosis, disorders, and complications related to aging and loss of ovarian hormones in women.

#### SEC. 445I. [285e-10a] ALZHEIMER'S CLINICAL RESEARCH AND TRAINING AWARDS.

(a) IN GENERAL.—The Director of the Institute is authorized to establish and maintain a program to enhance and promote the translation of new scientific knowledge into clinical practice related

to the diagnosis, care and treatment of individuals with Alzheimer's disease.

(b) **SUPPORT OF PROMISING CLINICIANS.**—In order to foster the application of the most current developments in the etiology, pathogenesis, diagnosis, prevention and treatment of Alzheimer's disease, amounts made available under this section shall be directed to the support of promising clinicians through awards for research, study, and practice at centers of excellence in Alzheimer's disease research and treatment.

(c) **EXCELLENCE IN CERTAIN FIELDS.**—Research shall be carried out under awards made under subsection (b) in environments of demonstrated excellence in neuroscience, neurobiology, geriatric medicine, and psychiatry and shall foster innovation and integration of such disciplines or other environments determined suitable by the Director of the Institute.

#### Subpart 6—National Institute of Allergy and Infectious Diseases

##### PURPOSE OF THE INSTITUTE

**SEC. 446. [285f]** The general purpose of the National Institute of Allergy and Infectious Diseases is the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases, including tropical diseases.

##### RESEARCH CENTERS REGARDING CHRONIC FATIGUE SYNDROME

**SEC. 447. [285f–1]** (a) The Director of the Institute, after consultation with the advisory council for the Institute, may make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct basic and clinical research on chronic fatigue syndrome.

(b) Each center assisted under this section shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

##### RESEARCH AND RESEARCH TRAINING REGARDING TUBERCULOSIS

**SEC. 447A. [285f–2]** In carrying out section 446, the Director of the Institute shall conduct or support research and research training regarding the cause, diagnosis, early detection, prevention and treatment of tuberculosis.

##### **SEC. 447B. [285f–3] SEXUALLY TRANSMITTED DISEASE CLINICAL RESEARCH AND TRAINING AWARDS.**

(a) **IN GENERAL.**—The Director of the Institute is authorized to establish and maintain a program to enhance and promote the translation of new scientific knowledge into clinical practice related to the diagnosis, care and treatment of individuals with sexually transmitted diseases.

(b) **SUPPORT OF PROMISING CLINICIANS.**—In order to foster the application of the most current developments in the etiology, pathogenesis, diagnosis, prevention and treatment of sexually transmitted diseases, amounts made available under this section shall be directed to the support of promising clinicians through awards

for research, study, and practice at centers of excellence in sexually transmitted disease research and treatment.

(c) **EXCELLENCE IN CERTAIN FIELDS.**—Research shall be carried out under awards made under subsection (b) in environments of demonstrated excellence in the etiology and pathogenesis of sexually transmitted diseases and shall foster innovation and integration of such disciplines or other environments determined suitable by the Director of the Institute.

**SEC. 447C. [285f-4] MICROBICIDE RESEARCH AND DEVELOPMENT.**

The Director of the Institute, acting through the head of the Division of AIDS, shall, consistent with the peer-review process of the National Institutes of Health, carry out research on, and development of, safe and effective methods for use by women to prevent the transmission of the human immunodeficiency virus, which may include microbicides.

**SEC. 447D. [285f-5] RESEARCH CENTERS FOR PATHOGENS OF PANDEMIC CONCERN.**

(a) **IN GENERAL.**—The Director of the Institute, in collaboration, as appropriate, with the directors of applicable institutes, centers, and divisions of the National Institutes of Health, the Assistant Secretary for Preparedness and Response, and the Director of the Biomedical Advanced Research and Development Authority, shall establish or continue a multidisciplinary research program to advance the discovery and preclinical development of medical products for priority virus families and other viral pathogens with a significant potential to cause a pandemic, through support for research centers.

(b) **USES OF FUNDS.**—The Director of the Institute shall award funding through grants, contracts, or cooperative agreements to public or private entities to provide support for research centers described in subsection (a) for the purpose of—

(1) conducting basic research through preclinical development of new medical products or technologies, including platform technologies, to address pathogens of pandemic concern;

(2) identifying potential targets for therapeutic candidates, including antivirals, to treat such pathogens;

(3) identifying existing medical products with the potential to address such pathogens, including candidates that could be used in outpatient settings; and

(4) carrying out or supporting other research related to medical products to address such pathogens, as determined appropriate by the Director.

(c) **COORDINATION.**—The Director of the Institute shall, as appropriate, provide for the coordination of activities among the centers described in subsection (a), including through—

(1) facilitating the exchange of information and regular communication among the centers, as appropriate; and

(2) requiring the periodic preparation and submission to the Director of reports on the activities of each center.

(d) **PRIORITY.**—In awarding funding through grants, contracts, or cooperative agreements under subsection (a), the Director of the Institute shall, as appropriate, give priority to applicants with ex-



isting frameworks and partnerships, as applicable, to support the advancement of such research.

(e) **COLLABORATION.**—The Director of the Institute shall—

(1) collaborate with the heads of other appropriate Federal departments, agencies, and offices with respect to the identification of additional priority virus families and other viral pathogens with a significant potential to cause a pandemic; and

(2) collaborate with the Director of the Biomedical Advanced Research and Development Authority with respect to the research conducted by centers described in subsection (a), including, as appropriate, providing any updates on the research advancements made by such centers, identifying any advanced research and development needs for such countermeasures, consistent with section 319L(a)(6), and taking into consideration existing manufacturing capacity and future capacity needs for such medical products or technologies, including platform technologies, supported by the centers described in subsection (a).

(f) **SUPPLEMENT, NOT SUPPLANT.**—Any support received by a center described in subsection (a) under this section shall be used to supplement, and not supplant, other public or private support for activities authorized to be supported.

#### Subpart 7—Eunice Kennedy Shriver National Institute of Child Health and Human Development<sup>33</sup>

##### PURPOSE OF THE INSTITUTE

**SEC. 448. [285g]** The general purpose of the National Institute of Child Health and Human Development<sup>34</sup> (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to gynecologic health, maternal health, child health, intellectual disabilities, human growth and development, including prenatal development, population research, and special health problems and requirements of mothers and children.

##### SUDDEN INFANT DEATH SYNDROME

**SEC. 449. [285g–1]** The Director of the Institute shall conduct and support research which specifically relates to sudden infant death syndrome.

<sup>33</sup> Section 1004 of Public Law 106–310 (114 Stat. 1130) authorizes the Director of the Institute to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children’s health and development. Subsection (d) of such section requires periodic reports to the Congress regarding the study. The first report is required to be submitted not later than three years after the date of the enactment of the Public Law, which was enacted October 17, 2000.

<sup>34</sup> The probable intent of the Congress is to refer to the “Eunice Kennedy Shriver National Institute of Child Health and Human Development”. Section 1(b)(7) of Public Law 110–154 (121 Stat 1827) struck the term “National Institute of Child Health and Human Development” and inserted “Eunice Kennedy Shriver National Institute of Child Health and Human Development” each place such term appeared in the heading of subpart 7 of part C of title IV, but not in the text of section 448.

**SEC. 450. [285g-2] RESEARCH ON INTELLECTUAL DISABILITIES.**

The Director of the Institute shall conduct and support research and related activities into the causes, prevention, and treatment of intellectual disabilities.

## ASSOCIATE DIRECTOR FOR PREVENTION

**SEC. 451. [285g-3]** There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of health problems of mothers and children. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

## NATIONAL CENTER FOR MEDICAL REHABILITATION RESEARCH

**SEC. 452. [285g-4]** (a) There shall be in the Institute an agency to be known as the National Center for Medical Rehabilitation Research (hereafter in this section referred to as the “Center”). The Director of the Institute shall appoint a qualified individual to serve as Director of the Center. The Director of the Center shall report directly to the Director of the Institute.

(b) The general purpose of the Center is the conduct, support, and coordination of research and research training (including research on the development of orthotic and prosthetic devices), the dissemination of health information, and other programs with respect to the rehabilitation of individuals with physical disabilities resulting from diseases or disorders of the neurological, musculoskeletal, cardiovascular, pulmonary, or any other physiological system (hereafter in this section referred to as “medical rehabilitation”).

(c)(1) In carrying out the purpose described in subsection (b), the Director of the Center may—

(A) provide for clinical trials regarding medical rehabilitation;

(B) provide for research regarding model systems of medical rehabilitation;

(C) coordinate the activities within the Center with similar activities of other agencies of the Federal Government, including the other agencies of the National Institutes of Health, and with similar activities of other public entities and of private entities;

(D) support multidisciplinary medical rehabilitation research conducted or supported by more than one such agency;

(E) in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

(i) establish technical and scientific peer review groups in addition to those appointed under section 402(b)(16); and

(ii) appoint the members of peer review groups established under subparagraph (A); and

(F) support medical rehabilitation research and training centers.

Chapter 10 of title 5, United States Code, shall not apply to the duration of a peer review group appointed under subparagraph (E).

(2) In carrying out this section, the Director of the Center may make grants and enter into cooperative agreements and contracts.

(d)(1) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall develop a comprehensive plan (referred to in this section as the “Research Plan”) for the conduct, support, and coordination of medical rehabilitation research.

(2) The Research Plan shall—

(A) identify current medical rehabilitation research activities conducted or supported by the Federal Government, opportunities and needs for additional research, and priorities for such research;

(B) make recommendations for the coordination of such research conducted or supported by the National Institutes of Health and other agencies of the Federal Government; and

(C) include goals and objectives for conducting, supporting, and coordinating medical rehabilitation research, consistent with the purpose described in subsection (b).

(3)(A) Not later than 18 months after the date of the enactment of the National Institutes of Health Revitalization Amendments of 1990,<sup>35</sup> the Director of the Institute shall transmit the Research Plan to the Director of NIH, who shall submit the Plan to the President and the Congress.

(B) Subparagraph (A) shall be carried out independently of the process of reporting that is required in sections 403 and 407.

(4) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall revise and update the Research Plan periodically, as appropriate, or not less than every 5 years. Not later than 30 days after the Research Plan is so revised and updated, the Director of the Center shall transmit the revised and updated Research Plan to the President, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives.

(5) The Director of the Center, in consultation with the Director of the Institute, shall, prior to revising and updating the Research Plan, prepare a report for the coordinating committee established under subsection (e) and the advisory board established under subsection (f) that describes and analyzes the progress during the preceding fiscal year in achieving the goals and objectives described in paragraph (2)(C) and includes expenditures for rehabilitation research at the National Institutes of Health. The report shall include recommendations for revising and updating the Research Plan, and such initiatives as the Director of the Center and the Director of the Institute determine appropriate. In preparing the report, the Director of the Center and the Director of the Insti-

<sup>35</sup> So in law. No Act with such a short title was enacted during 1990. The probable intent of the Congress was to make a reference to Public Law 101-613, the National Institutes of Health Amendments of 1990, which added section 452 and which was enacted November 16, 1990.

tute shall consult with the Director of the National Institutes of Health.

(e)(1) The Director of NIH shall establish a committee to be known as the Medical Rehabilitation Coordinating Committee (hereafter in this section referred to as the “Coordinating Committee”).

(2) The Coordinating Committee shall periodically host a scientific conference or workshop on medical rehabilitation research and make recommendations to the Director of the Institute and the Director of the Center with respect to the content of the Research Plan and with respect to the activities of the Center that are carried out in conjunction with other agencies of the National Institutes of Health and with other agencies of the Federal Government.

(3) The Coordinating Committee shall be composed of the Director of the Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director of the National Institutes of Health, the Director of the Center, the Director of the Institute, and the Directors of the National Institute on Aging, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Heart, Lung, and Blood Institute, the National Institute of Neurological Disorders and Stroke, and such other national research institutes and such representatives of other agencies of the Federal Government as the Director of NIH determines to be appropriate.

(4) The Coordinating Committee shall be chaired by the Director of the Center.

(f)(1) Not later than 90 days after the date of the enactment of the National Institutes of Health Revitalization Amendments of 1990,<sup>36</sup> the Director of NIH shall establish a National Advisory Board on Medical Rehabilitation Research (hereafter in this section referred to as the “Advisory Board”).

(2) The Advisory Board shall review and assess Federal research priorities, activities, and findings regarding medical rehabilitation research, and shall advise the Director of the Center and the Director of the Institute on the provisions of the Research Plan.

(3)(A) The Director of NIH shall appoint to the Advisory Board 18 qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, 12 shall be representatives of health and scientific disciplines with respect to medical rehabilitation and 6 shall be individuals representing the interests of individuals undergoing, or in need of, medical rehabilitation.

(B) The following officials shall serve as ex officio members of the Advisory Board:

- (i) The Director of the Center.
- (ii) The Director of the Institute.
- (iii) The Director of the National Institute on Aging.
- (iv) The Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.
- (v) The Director of the National Institute on Deafness and Other Communication Disorders.

<sup>36</sup> See footnote for subsection (d)(3)(A).

(vi) The Director of the National Heart, Lung, and Blood Institute.

(vii) The Director of the National Institute of Neurological Disorders and Stroke.

(viii) The Director of the National Institute on Disability and Rehabilitation Research.

(ix) The Director of the Division of Program Coordination, Planning, and Strategic Initiatives.

(x) The Commissioner for Rehabilitation Services Administration.

(xi) The Assistant Secretary of Defense (Health Affairs).

(xii) The Chief Medical Director of the Department of Veterans Affairs.

(4) The members of the Advisory Board shall, from among the members appointed under paragraph (3)(A), designate an individual to serve as the chair of the Advisory Board.

(g)(1) The Secretary and the heads of other Federal agencies shall jointly review the programs carried out (or proposed to be carried out) by each such official with respect to medical rehabilitation research and, as appropriate, enter into agreements preventing duplication among such programs.

(2) The Secretary shall, as appropriate, enter into interagency agreements relating to the coordination of medical rehabilitation research conducted by agencies of the National Institutes of Health and other agencies of the Federal Government.

(h) For purposes of this section, the term “medical rehabilitation research” means the science of mechanisms and interventions that prevent, improve, restore, or replace lost, underdeveloped, or deteriorating function.

#### RESEARCH CENTERS WITH RESPECT TO CONTRACEPTION AND INFERTILITY

SEC. 452A. [285g–5] (a) The Director of the Institute, after consultation with the advisory council for the Institute, shall make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct activities for the purpose of improving methods of contraception and centers to conduct activities for the purpose of improving methods of diagnosis and treatment of infertility.

(b) In carrying out subsection (a), the Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the establishment of three centers with respect to contraception and for two centers with respect to infertility.

(c)(1) Each center assisted under this section shall, in carrying out the purpose of the center involved—

(A) conduct clinical and other applied research, including—

(i) for centers with respect to contraception, clinical trials of new or improved drugs and devices for use by males and females (including barrier methods); and

(ii) for centers with respect to infertility, clinical trials of new or improved drugs and devices for the diagnosis and treatment of infertility in males and females;

(B) develop protocols for training physicians, scientists, nurses, and other health and allied health professionals;

(C) conduct training programs for such individuals;

(D) develop model continuing education programs for such professionals; and

(E) disseminate information to such professionals and the public.

(2) A center may use funds provided under subsection (a) to provide stipends for health and allied health professionals enrolled in programs described in subparagraph (C) of paragraph (1), and to provide fees to individuals serving as subjects in clinical trials conducted under such paragraph.

(d) The Director of the Institute shall, as appropriate, provide for the coordination of information among the centers assisted under this section.

(e) Each center assisted under subsection (a) shall use the facilities of a single institution, or be formed from a consortium of co-operating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

(f) Support of a center under subsection (a) may be for a period not exceeding 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

#### PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

SEC. 452B. [285g-6] The Director of the Institute shall establish and maintain within the Institute an intramural laboratory and clinical research program in obstetrics and gynecology.

#### CHILD HEALTH RESEARCH CENTERS

SEC. 452C. [285g-7] The Director of the Institute shall develop and support centers for conducting research with respect to child health. Such centers shall give priority to the expeditious transfer of advances from basic science to clinical applications and improving the care of infants and children.

#### PROSPECTIVE LONGITUDINAL STUDY ON ADOLESCENT HEALTH

SEC. 452D. [285g-8] (a) IN GENERAL.—Not later than October 1, 1993, the Director of the Institute shall commence a study for the purpose of providing information on the general health and well-being of adolescents in the United States, including, with respect to such adolescents, information on—

(1) the behaviors that promote health and the behaviors that are detrimental to health; and

(2) the influence on health of factors particular to the communities in which the adolescents reside.

(b) DESIGN OF STUDY.—

(1) IN GENERAL.—The study required in subsection (a) shall be a longitudinal study in which a substantial number of adolescents participate as subjects. With respect to the purpose

described in such subsection, the study shall monitor the subjects throughout the period of the study to determine the health status of the subjects and any change in such status over time.

(2) POPULATION-SPECIFIC ANALYSES.—The study required in subsection (a) shall be conducted with respect to the population of adolescents who are female, the population of adolescents who are male, various socioeconomic populations of adolescents, and various racial and ethnic populations of adolescents. The study shall be designed and conducted in a manner sufficient to provide for a valid analysis of whether there are significant differences among such populations in health status and whether and to what extent any such differences are due to factors particular to the populations involved.

(c) COORDINATION WITH WOMEN'S HEALTH INITIATIVE.—With respect to the national study of women being conducted by the Secretary and known as the Women's Health Initiative, the Secretary shall ensure that such study is coordinated with the component of the study required in subsection (a) that concerns adolescent females, including coordination in the design of the 2 studies.

#### FRAGILE X

SEC. 452E. [285g–9] (a) EXPANSION AND COORDINATION OF RESEARCH ACTIVITIES.—The Director of the Institute, after consultation with the advisory council for the Institute, shall expand, intensify, and coordinate the activities of the Institute with respect to research on the disease known as fragile X.

(b) RESEARCH CENTERS.—

(1) IN GENERAL.—The Director of the Institute shall make grants or enter into contracts for the development and operation of centers to conduct research for the purposes of improving the diagnosis and treatment of, and finding the cure for, fragile X.

(2) NUMBER OF CENTERS.—

(A) IN GENERAL.—In carrying out paragraph (1), the Director of the Institute shall, to the extent that amounts are appropriated, and subject to subparagraph (B), provide for the establishment of at least three fragile X research centers.

(B) PEER REVIEW REQUIREMENT.—The Director of the Institute shall make a grant to, or enter into a contract with, an entity for purposes of establishing a center under paragraph (1) only if the grant or contract has been recommended after technical and scientific peer review required by regulations under section 492.

(3) ACTIVITIES.—The Director of the Institute, with the assistance of centers established under paragraph (1), shall conduct and support basic and biomedical research into the detection and treatment of fragile X.

(4) COORDINATION AMONG CENTERS.—The Director of the Institute shall, as appropriate, provide for the coordination of the activities of the centers assisted under this section, includ-

ing providing for the exchange of information among the centers.

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

(6) DURATION OF SUPPORT.—Support may be provided to a center under paragraph (1) for a period not exceeding 5 years. Such period may be extended for one or more additional periods, each of which may not exceed 5 years, if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period be extended.

#### INVESTMENT IN TOMORROW'S PEDIATRIC RESEARCHERS

SEC. 452G.<sup>37</sup> [285g–10] In order to ensure the future supply of researchers dedicated to the care and research needs of children, the Director of the Institute, after consultation with the Administrator of the Health Resources and Services Administration, shall support activities to provide for—

(1) an increase in the number and size of institutional training grants to institutions supporting pediatric training; and

(2) an increase in the number of career development awards for health professionals who intend to build careers in pediatric basic and clinical research, including pediatric pharmacological research.

#### Subpart 8—National Institute of Dental Research<sup>38</sup>

##### PURPOSE OF THE INSTITUTE

SEC. 453. [285h] The general purpose of the National Institute of Dental Research<sup>38</sup> is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, prevention, and methods of diagnosis and treatment of dental and oral diseases and conditions.

#### Subpart 9—National Eye Institute

##### PURPOSE OF THE INSTITUTE

SEC. 455. [285i] The general purpose of the National Eye Institute (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the

<sup>37</sup>So in law. Probably should be “SEC. 452F.”. See amendments made by sections 201 and 1002 of Public Law 106–310 (114 Stat. 1109, 1128). (In amending this subpart to add section 452G above, such section 1002 made a reference to this subpart “as amended by section 921” of Public Law 106–310, but no section 921 appeared in the Public Law.)

<sup>38</sup>See footnote for section 401(b)(1)(H).



blind. Subject to section 456, the Director of the Institute may carry out a program of grants for public and private nonprofit vision research facilities.

#### CLINICAL RESEARCH ON EYE CARE AND DIABETES

SEC. 456. [285i-1] (a) PROGRAM OF GRANTS.—The Director of the Institute, in consultation with the advisory council for the Institute, may award research grants to one or more Diabetes Eye Research Institutions for the support of programs in clinical or health services aimed at—

- (1) providing comprehensive eye care services for people with diabetes, including a full complement of preventive, diagnostic and treatment procedures;
- (2) developing new and improved techniques of patient care through basic and clinical research;
- (3) assisting in translation of the latest research advances into clinical practice; and
- (4) expanding the knowledge of the eye and diabetes through further research.

(b) USE OF FUNDS.—Amounts received under a grant awarded under this section shall be used for the following:

- (1) Establishing the biochemical, cellular, and genetic mechanisms associated with diabetic eye disease and the earlier detection of pending eye abnormalities. The focus of work under this paragraph shall require that ophthalmologists have training in the most up-to-date molecular and cell biological methods.

- (2) Establishing new frontiers in technology, such as video-based diagnostic and research resources, to—

- (A) provide improved patient care;
- (B) provide for the evaluation of retinal physiology and its affect on diabetes; and
- (C) provide for the assessment of risks for the development and progression of diabetic eye disease and a more immediate evaluation of various therapies aimed at preventing diabetic eye disease.

Such technologies shall be designed to permit evaluations to be performed both in humans and in animal models.

- (3) The translation of the results of vision research into the improved care of patients with diabetic eye disease. Such translation shall require the application of institutional resources that encompass patient care, clinical research and basic laboratory research.

- (4) The conduct of research concerning the outcomes of eye care treatments and eye health education programs as they relate to patients with diabetic eye disease, including the evaluation of regional approaches to such research.

(c) AUTHORIZED EXPENDITURES.—The purposes for which a grant under subsection (a) may be expended include equipment for the research described in such subsection.

Subpart 10—National Institute of Neurological Disorders and Stroke

PURPOSE OF THE INSTITUTE

SEC. 457. [285j] The general purpose of the National Institute of Neurological Disorders and Stroke (hereafter in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to neurological disease and disorder and stroke.

SPINAL CORD REGENERATION RESEARCH

SEC. 458. [285j–1] The Director of the Institute shall conduct and support research into spinal cord regeneration.

BIOENGINEERING RESEARCH

SEC. 459. [285j–2] The Director of the Institute shall make grants or enter into contracts for research on the means to overcome paralysis of the extremities through electrical stimulation and the use of computers.

RESEARCH ON MULTIPLE SCLEROSIS

SEC. 460. [285j–3] The Director of the Institute shall conduct and support research on multiple sclerosis, especially research on effects of genetics and hormonal changes on the progress of the disease.

Subpart 11—National Institute of General Medical Sciences

SEC. 461. [285k] NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES.

(a) GENERAL PURPOSE.—The general purpose of the National Institute of General Medical Sciences is the conduct and support of research, training, and, as appropriate, health information dissemination, and other programs with respect to general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other national research institutes or are outside the general area of responsibility of any other national research institute.

(b) INSTITUTIONAL DEVELOPMENT AWARD PROGRAM.—

(1)(A) In the case of entities described in subparagraph (B), the Director of NIH, acting through the Director of the National Institute of General Medical Sciences, shall establish a program to enhance the competitiveness of such entities in obtaining funds from the national research institutes for conducting biomedical and behavioral research.

(B) The entities referred to in subparagraph (A) are entities that conduct biomedical and behavioral research and are located in a State in which the aggregate success rate for applications to the national research institutes for assistance for such research by the entities in the State has historically constituted a low success rate of obtaining such funds, relative to such aggregate rate for such entities in other States.

(C) With respect to enhancing competitiveness for purposes of subparagraph (A), the Director of NIH, in carrying out the program established under such subparagraph, may—

- (i) provide technical assistance to the entities involved, including technical assistance in the preparation of applications for obtaining funds from the national research institutes;
  - (ii) assist the entities in developing a plan for biomedical or behavioral research proposals; and
  - (iii) assist the entities in implementing such plan.
- (2) The Director of NIH shall establish a program of supporting projects of biomedical or behavioral research whose principal researchers are individuals who have not previously served as the principal researchers of such projects supported by the Director.

#### Subpart 12—National Institute of Environmental Health Sciences

##### PURPOSE OF THE INSTITUTE

SEC. 463. [2851] The general purpose of the National Institute of Environmental Health Sciences (in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly.

##### APPLIED TOXICOLOGICAL RESEARCH AND TESTING PROGRAM

SEC. 463A. [2851–1] (a) There is established within the Institute a program for conducting applied research and testing regarding toxicology, which program shall be known as the Applied Toxicological Research and Testing Program.

(b) In carrying out the program established under subsection (a), the Director of the Institute shall, with respect to toxicology, carry out activities—

- (1) to expand knowledge of the health effects of environmental agents;
- (2) to broaden the spectrum of toxicology information that is obtained on selected chemicals;
- (3) to develop and validate assays and protocols, including alternative methods that can reduce or eliminate the use of animals in acute or chronic safety testing;
- (4) to establish criteria for the validation and regulatory acceptance of alternative testing and to recommend a process through which scientifically validated alternative methods can be accepted for regulatory use;
- (5) to communicate the results of research to government agencies, to medical, scientific, and regulatory communities, and to the public; and
- (6) to integrate related activities of the Department of Health and Human Services.

METHODS OF CONTROLLING CERTAIN INSECT AND VERMIN  
POPULATIONS

SEC. 463B. [285l–6] The Director of the Institute shall conduct or support research to identify or develop methods of controlling insect and vermin populations that transmit to humans diseases that have significant adverse health consequences.

Subpart 13—National Institute on Deafness and Other  
Communication Disorders

## PURPOSE OF THE INSTITUTE

SEC. 464. [285m] The general purpose of the National Institute on Deafness and Other Communication Disorders (hereafter referred to in this subpart as the “Institute”) is the conduct and support of research and training, the dissemination of health information, and other programs with respect to disorders of hearing and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell.

NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS  
PROGRAM

SEC. 464A. [285m–1] (a) The Director of the Institute, with the advice of the Institute’s advisory council, shall establish a National Deafness and Other Communication Disorders Program (hereafter in this section referred to as the “Program”). The Director or<sup>39</sup> the Institute shall, with respect to the Program, prepare and transmit to the Director of NIH a plan to initiate, expand, intensify and coordinate activities of the Institute respecting disorders of hearing (including tinnitus) and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Director of NIH.

(b) Activities under the Program shall include—

(1) investigation into the etiology, pathology, detection, treatment, and prevention of all forms of disorders of hearing and other communication processes, primarily through the support of basic research in such areas as anatomy, audiology, biochemistry, bioengineering, epidemiology, genetics, immunology, microbiology, molecular biology, the neurosciences, otolaryngology, psychology, pharmacology, physiology, speech and language pathology, and any other scientific disciplines that can contribute important knowledge to the understanding and elimination of disorders of hearing and other communication processes;

(2) research into the evaluation of techniques (including surgical, medical, and behavioral approaches) and devices (including hearing aids, implanted auditory and nonauditory

<sup>39</sup> So in law. See section 2(4) of Public Law 100–553 (102 Stat. 2769). Probably should be “Director of”.

prosthetic devices and other communication aids) used in diagnosis, treatment, rehabilitation, and prevention of disorders of hearing and other communication processes;

(3) research into prevention, and early detection and diagnosis, of hearing loss and speech and language disturbances (including stuttering) and research into preventing the effects of such disorders on learning and learning disabilities with extension of programs for appropriate referral and rehabilitation;

(4) research into the detection, treatment, and prevention of disorders of hearing and other communication processes in the growing elderly population with extension of rehabilitative programs to ensure continued effective communication skills in such population;

(5) research to expand knowledge of the effects of environmental agents that influence hearing or other communication processes; and

(6) developing and facilitating intramural programs on clinical and fundamental aspects of disorders of hearing and all other communication processes.

#### DATA SYSTEM AND INFORMATION CLEARINGHOUSE

SEC. 464B. [285m-2] (a) The Director of the Institute shall establish a National Deafness and Other Communication Disorders Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with disorders of hearing or other communication processes, including where possible, data involving general populations for the purpose of identifying individuals at risk of developing such disorders.

(b) The Director of the Institute shall establish a National Deafness and Other Communication Disorders Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of disorders of hearing and other communication processes by health professionals, patients, industry, and the public.

#### MULTIPURPOSE DEAFNESS AND OTHER COMMUNICATION DISORDERS CENTER

SEC. 464C. [285m-3] (a) The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including care required for research) of new and existing centers for studies of disorders of hearing and other communication processes. For purposes of this section, the term “modernization” means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

(b) Each center assisted under this section shall—

(1) use the facilities of a single institution or a consortium of cooperating institutions; and

(2) meet such qualifications as may be prescribed by the Secretary.

(c) Each center assisted under this section shall, at least, conduct—

(1) basic and clinical research into the cause diagnosis, early detection, prevention, control and treatment of disorders of hearing and other communication processes and complications resulting from such disorders, including research into rehabilitative aids, implantable biomaterials, auditory speech processors, speech production devices, and other otolaryngologic procedures;

(2) training programs for physicians, scientists, and other health and allied health professionals;

(3) information and continuing education programs for physicians and other health and allied health professionals who will provide care for patients with disorders of hearing or other communication processes; and

(4) programs for the dissemination to the general public of information—

(A) on the importance of early detection of disorders of hearing and other communication processes, of seeking prompt treatment, rehabilitation, and of following an appropriate regimen; and

(B) on the importance of avoiding exposure to noise and other environmental toxic agents that may affect disorders of hearing or other communication processes.

(d) A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in subsection (c)(2).

(e) Each center assisted under this section may conduct programs—

(1) to establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals at risk of developing disorders of hearing or other communication processes; and

(2) to disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping.

(f) The Director of the Institute shall, to the extent practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of the elderly, and of children (particularly with respect to their education and training), affected by disorders of hearing or other communication processes.

(g) Support of a center under this section may be for a period not to exceed seven years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director, with the advice of the Institute's advisory council, if such group has recommended to the Director that such period should be extended.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION  
DISORDERS ADVISORY BOARD

SEC. 464D. [285m–4] (a) The Secretary shall establish in the Institute the National Deafness and Other Communications Disorders Advisory Board (hereafter in this section referred to as the “Advisory Board”).

(b) The Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health and rehabilitation professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to deafness and other communication disorders, including not less than two persons with a communication disorder; and

(B) six members from the general public who are knowledgeable with respect to such disorders, including not less than one person with a communication disorder and not less than one person who is a parent of an individual with such a disorder.

Of the appointed members, not less than five shall by virtue of training or experience be knowledgeable in diagnoses and rehabilitation of communication disorders, education of the hearing, speech, or language impaired, public health, public information, community program development, occupational hazards to communications senses, or the aging process.

(2) The following shall be ex officio members of each Advisory Board:

(A) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute on Deafness and Other Communication Disorders, the Director of the Centers for Disease Control and Prevention, the Chief Medical Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers).

(B) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(c) Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

(d) The term of office of an appointed member of the Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member’s term until a successor has taken office. If a va-

cancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

(e) The members of the Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) The Advisory Board shall—

(1) review and evaluate the implementation of the plan prepared under section 464A(a) and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting deafness and other communication disorders, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan and with key non-Federal entities involved in activities affecting the control of such disorders.

(i) In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(k)<sup>40</sup> The National Deafness and Other Communication Disorders Advisory Board shall be established not later than April 1, 1989.

#### INTERAGENCY COORDINATING COMMITTEE

SEC. 464E. [285m–5] (a) The Secretary may establish a committee to be known as the Deafness and Other Communication Disorders Interagency Coordinating Committee (hereafter in this section referred to as the “Coordinating Committee”).

(b) The Coordinating Committee shall, with respect to deafness and other communication disorders—

<sup>40</sup> So in law. There is no subsection (j) in section 464D.



(1) provide for the coordination of the activities of the national research institutes; and

(2) coordinate the aspects of all Federal health programs and activities relating to deafness and other communication disorders in order to assure the adequacy and technical soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities.

(c) The Coordinating Committee shall be composed of the directors of each of the national research institutes and divisions involved in research with respect to deafness and other communication disorders and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to deafness and other communication disorders.

(d) The Coordinating Committee shall be chaired by the Director of NIH (or the designee of the Director). The Committee shall meet at the call of the chair, but not less often than four times a year.

#### LIMITATION ON ADMINISTRATIVE EXPENSES

SEC. 464F. [285m–6] With respect to amounts appropriated for a fiscal year for the National Institutes of Health, the limitation established in section 408(a)(1) on the expenditure of such amounts for administrative expenses shall apply to administrative expenses of the National Institute on Deafness and Other Communication Disorders.

#### Subpart 14—National Institute on Alcohol Abuse and Alcoholism

##### PURPOSE OF INSTITUTE

SEC. 464H. [285n] (a) IN GENERAL.—The general purpose of the National Institute on Alcohol Abuse and Alcoholism (hereafter in this subpart referred to as the “Institute”) is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of alcohol abuse and the treatment of alcoholism.

(b) RESEARCH PROGRAM.—The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of alcohol abuse and alcoholism. In carrying out the program, the Director of the Institute is authorized to—

(1) collect and disseminate through publications and other appropriate means (including the development of curriculum materials), information as to, and the practical application of, the research and other activities under the program;

(2) make available research facilities of the Public Health Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants to universities, hospitals, laboratories, and other public or nonprofit institutions, and to individuals for

such research projects as are recommended by the National Advisory Council on Alcohol Abuse and Alcoholism, giving special consideration to projects relating to—

- (A) the relationship between alcohol abuse and domestic violence,
  - (B) the effects of alcohol use during pregnancy,
  - (C) the impact of alcoholism and alcohol abuse on the family, the workplace, and systems for the delivery of health services,
  - (D) the relationship between the abuse of alcohol and other drugs,
  - (E) the effect on the incidence of alcohol abuse and alcoholism of social pressures, legal requirements respecting the use of alcoholic beverages, the cost of such beverages, and the economic status and education of users of such beverages,
  - (F) the interrelationship between alcohol use and other health problems,
  - (G) the comparison of the cost and effectiveness of various treatment methods for alcoholism and alcohol abuse and the effectiveness of prevention and intervention programs for alcoholism and alcohol abuse, and
  - (H) alcoholism and alcohol abuse among women;
- (4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;
- (5) promote the coordination of research programs conducted by the Institute, and similar programs conducted by the National Institute of Drug Abuse and by other departments, agencies, organizations, and individuals, including all National Institutes of Health research activities which are or may be related to the problems of individuals suffering from alcoholism or alcohol abuse or those of their families or the impact of alcohol abuse on other health problems;
- (6) conduct an intramural program of biomedical, behavioral, epidemiological, and social research, including research into the most effective means of treatment and service delivery, and including research involving human subjects, which is—
- (A) located in an institution capable of providing all necessary medical care for such human subjects, including complete 24-hour medical diagnostic services by or under the supervision of physicians, acute and intensive medical care, including 24-hour emergency care, psychiatric care, and such other care as is determined to be necessary for individuals suffering from alcoholism and alcohol abuse; and
  - (B) associated with an accredited medical or research training institution;
- (7) for purposes of study, admit and treat at institutions, hospitals, and stations of the Public Health Service, persons not otherwise eligible for such treatment;
- (8) provide to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, tech-

nical advice and assistance on the application of statistical and other scientific research methods to experiments, studies, and surveys in health and medical fields;

(9) enter into contracts under this title without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529;<sup>41</sup> 41 U.S.C. 5); and

(10) adopt, upon recommendation of the National Advisory Council on Alcohol Abuse and Alcoholism, such additional means as he deems necessary or appropriate to carry out the purposes of this section.

(c) COLLABORATION.—The Director of the Institute shall collaborate with the Administrator of the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

#### ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 464I. [285n–1] (a) IN GENERAL.—There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of alcohol abuse and alcoholism. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in alcohol abuse and alcoholism or the prevention of such.

(b) BIENNIAL REPORT.—The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

#### NATIONAL ALCOHOL RESEARCH CENTER

SEC. 464J. [285n–2] (a) The Secretary acting through the Institute may designate National Alcohol Research Centers for the purpose of interdisciplinary research relating to alcoholism and other biomedical, behavioral, and social issues related to alcoholism and alcohol abuse. No entity may be designated as a Center unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reasonably require. The Secretary may not approve such an application unless—

(1) the application contains or is supported by reasonable assurances that—

(A) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on alcoholism and other alcohol problems and to provide coordination of such research among such disciplines;

(B) the applicant has available to it sufficient facilities (including laboratory, reference, and data analysis facili-

<sup>41</sup>Now codified to section 3324 of title 31, United States Code.

ties) to carry out the research plan contained in the application,

(C) the applicant has facilities and personnel to provide training in the prevention and treatment of alcoholism and other alcohol problems;

(D) the applicant has the capacity to train predoctoral and postdoctoral students for careers in research on alcoholism and other alcohol problems;

(E) the applicant has the capacity to conduct courses on alcohol problems and research on alcohol problems for undergraduate and graduate students, and medical and osteopathic, nursing, social work, and other specialized graduate students; and

(F) the applicant has the capacity to conduct programs of continuing education in such medical, legal, and social service fields as the Secretary may require.<sup>42</sup>

(2) the application contains a detailed five-year plan for research relating to alcoholism and other alcohol problems.

(b) The Secretary shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term “construction” has the meaning given that term by section 701(1).<sup>43</sup> The Secretary shall include in the grants made under this section for fiscal year beginning after September 30, 1981, a grant to a designated Center for research on the effects of alcohol on the elderly.

#### Subpart 15—National Institute on Drug Abuse

##### PURPOSE OF INSTITUTE

SEC. 464L. [285o] (a) IN GENERAL.—The general purpose of the National Institute on Drug Abuse (hereafter in this subpart referred to as the “Institute”) is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers.

(b) RESEARCH PROGRAM.—The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of drug abuse. In carrying out the program, the Director of the Institute shall give special consideration to projects relating to drug abuse among women (particularly with respect to pregnant women).

(c) COLLABORATION.—The Director of the Institute shall collaborate with the Substance Abuse and Mental Health Services Ad-

<sup>42</sup> So in law. See section 16(a)(5) of Public Law 96–180 (93 Stat. 1305). The period probably should be “; and”. (Section 464J formerly was section 504 of another law. The amendment made by Public Law 96–180 was directed to section 504 of that other law, which was Public Law 91–616.)

<sup>43</sup> So in law. See section 2(a) of Public Law 102–352 (106 Stat. 938). Section 701(1) does not provide a definition for the term “construction”, but former section 701(1) did provide such a definition. Public Law 102–408 amended title VII generally; definitions for the title are now provided in section 799, and that section does not define the term “construction”.

ministration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

#### ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 464M. [285o-1] (a) IN GENERAL.—There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of drug abuse. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in drug abuse and the prevention of such abuse.

(b) REPORT.—The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

#### DRUG ABUSE RESEARCH CENTERS

SEC. 464N. [285o-2] (a) AUTHORITY.—The Director of the Institute may designate National Drug Abuse Research Centers for the purpose of interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse. No entity may be designated as a Center unless an application therefore has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reasonably require. The Secretary may not approve such an application unless—

(1) the application contains or is supported by reasonable assurances that—

(A) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on drug abuse and to provide coordination of such research among such disciplines;

(B) the applicant has available to it sufficient facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application;

(C) the applicant has facilities and personnel to provide training in the prevention and treatment of drug abuse;

(D) the applicant has the capacity to train predoctoral and postdoctoral students for careers in research on drug abuse;

(E) the applicant has the capacity to conduct courses on drug abuse problems and research on drug abuse for undergraduate and graduate students, and medical and osteopathic, nursing, social work, and other specialized graduate students; and

(F) the applicant has the capacity to conduct programs of continuing education in such medical, legal, and social service fields as the Secretary may require.<sup>44</sup>

(2) the application contains a detailed five-year plan for research relating to drug abuse.

(b) GRANTS.—The Director of the Institute shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term “construction” has the meaning given that term by section 701(1).<sup>45</sup>

(c) DRUG ABUSE AND ADDICTION<sup>46</sup> RESEARCH.—

(1) GRANTS OR COOPERATIVE AGREEMENTS.—The Director of the Institute may make grants or enter into cooperative agreements to expand the current and ongoing interdisciplinary research and clinical trials with treatment centers of the National Drug Abuse Treatment Clinical Trials Network relating to drug abuse and addiction, including related biomedical, behavioral, and social issues.

(2) USE OF FUNDS.—Amounts made available under a grant or cooperative agreement under paragraph (1) for drug abuse and addiction may be used for research and clinical trials relating to—

(A) the effects of drug abuse on the human body, including the brain;

(B) the addictive nature of drugs and how such effects differ with respect to different individuals;

(C) the connection between drug abuse and mental health;

(D) the identification and evaluation of the most effective methods of prevention of drug abuse and addiction;

(E) the identification and development of the most effective methods of treatment of drug addiction, including pharmacological treatments;

(F) risk factors for drug abuse;

(G) effects of drug abuse and addiction on pregnant women and their fetuses; and

(H) cultural, social, behavioral, neurological, and psychological reasons that individuals abuse drugs, or refrain from abusing drugs.

(3) RESEARCH RESULTS.—The Director shall promptly disseminate research results under this subsection to Federal, State, and local entities involved in combating drug abuse and addiction.

<sup>44</sup> So in law. See section 123(b) of Public Law 102-321 (106 Stat. 361). The period probably should be “; and”.

<sup>45</sup> See footnote for section 464J(b).

<sup>46</sup> Probably should be “ADDICTION”. See section 2203 of Public Law 107-273 (116 Stat. 1794).

## OFFICE ON AIDS

SEC. 464O. [285o–3] The Director of the Institute shall establish within the Institute an Office on AIDS. The Office shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

- (1) primary prevention of the spread of HIV, including transmission via drug abuse;
- (2) drug abuse services research; and
- (3) other matters determined appropriate by the Director.

## MEDICATION DEVELOPMENT PROGRAM

SEC. 464P. [285o–4] (a) ESTABLISHMENT.—There is established in the Institute a Medication Development Program through which the Director of such Institute shall—

- (1) conduct periodic meetings with the Commissioner of Food and Drugs to discuss measures that may facilitate the approval process of drug abuse treatments;
- (2) encourage and promote (through grants, contracts, international collaboration, or otherwise) expanded research programs, investigations, experiments, community trials, and studies, into the development and use of medications to treat drug addiction;
- (3) establish or provide for the establishment of research facilities;
- (4) report on the activities of other relevant agencies relating to the development and use of pharmacotherapeutic treatments for drug addiction;
- (5) collect, analyze, and disseminate data useful in the development and use of pharmacotherapeutic treatments for drug addiction and collect, catalog, analyze, and disseminate through international channels, the results of such research;
- (6) directly or through grants, contracts, or cooperative agreements, support training in the fundamental sciences and clinical disciplines related to the pharmacotherapeutic treatment of drug abuse, including the use of training stipends, fellowships, and awards where appropriate; and
- (7) coordinate the activities conducted under this section with related activities conducted within the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Mental Health, and other appropriate institutes and shall consult with the Directors of such Institutes.

(b) DUTIES.—In carrying out the activities described in subsection (a), the Director of the Institute—

- (1) shall collect and disseminate through publications and other appropriate means, information pertaining to the research and other activities under this section;
- (2) shall make grants to or enter into contracts and cooperative agreements with individuals and public and private entities to further the goals of the program;
- (3) may, in accordance with section 496, and in consultation with the National Advisory Council on Drug Abuse, acquire, construct, improve, repair, operate, and maintain pharmacotherapeutic research centers, laboratories, and other

necessary facilities and equipment, and such other real or personal property as the Director determines necessary, and may, in consultation with such Advisory Council, make grants for the construction or renovation of facilities to carry out the purposes of this section;

(4) may accept voluntary and uncompensated services;

(5) may accept gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible; and

(6) shall take necessary action to ensure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

(c) REPORT.—

(1) IN GENERAL.—Not later than December 31, 1992, and each December 31 thereafter, the Director of the Institute shall submit to the Office of National Drug Control Policy established under section 1002 of the Anti-Drug Abuse Act of 1988 (21 U.S.C. 1501) a report, in accordance with paragraph (3), that describes the objectives and activities of the program assisted under this section.

(2) NATIONAL DRUG CONTROL STRATEGY.—The Director of National Drug Control Policy shall incorporate, by reference or otherwise, each report submitted under this subsection in the National Drug Control Strategy submitted the following February 1 under section 1005 of the Anti-Drug Abuse Act of 1988 (21 U.S.C. 1504).

(d) DEFINITION.—For purposes of this section, the term “pharmacotherapeutics” means medications used to treat the symptoms and disease of drug abuse, including medications to—

(1) block the effects of abused drugs;

(2) reduce the craving for abused drugs;

(3) moderate or eliminate withdrawal symptoms;

(4) block or reverse the toxic effect of abused drugs; or

(5) prevent relapse in persons who have been detoxified from drugs of abuse.

#### Subpart 16—National Institute of Mental Health

##### PURPOSE OF INSTITUTE

SEC. 464R. [285p] (a) IN GENERAL.—The general purpose of the National Institute of Mental Health (hereafter in this subpart referred to as the “Institute”) is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the cause, diagnosis, treatment, control and prevention of mental illness.

(b) RESEARCH PROGRAM.—The research program established under this subpart shall include support for biomedical and behavioral neuroscience and shall be designed to further the treatment and prevention of mental illness, the promotion of mental health, and the study of the psychological, social and legal factors that influence behavior.



(c) **COLLABORATION.**—The Director of the Institute shall collaborate with the Administrator of the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

(d) **INFORMATION WITH RESPECT TO SUICIDE.**—

(1) **IN GENERAL.**—The Director of the Institute shall—

(A) develop and publish information with respect to the causes of suicide and the means of preventing suicide; and

(B) make such information generally available to the public and to health professionals.

(2) **YOUTH SUICIDE.**—Information described in paragraph

(1) shall especially relate to suicide among individuals under 24 years of age.

(e) **ASSOCIATE DIRECTOR FOR SPECIAL POPULATIONS.**—

(1) **IN GENERAL.**—The Director of the Institute shall designate an Associate Director for Special Populations.

(2) **DUTIES.**—The Associate Director for Special Populations shall—

(A) develop and coordinate research policies and programs to assure increased emphasis on the mental health needs of women and minority populations;

(B) support programs of basic and applied social and behavioral research on the mental health problems of women and minority populations;

(C) study the effects of discrimination on institutions and individuals, including majority institutions and individuals;

(D) support and develop research designed to eliminate institutional discrimination; and

(E) provide increased emphasis on the concerns of women and minority populations in training programs, service delivery programs, and research endeavors of the Institute.

#### ASSOCIATE DIRECTOR FOR PREVENTION

**SEC. 464S. [285p–1]** (a) **IN GENERAL.**—There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of mental disorder. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in mental disorder and the prevention of such.

(b) **REPORT.**—The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

#### OFFICE OF RURAL MENTAL HEALTH RESEARCH

**SEC. 464T. [285p–2]** (a) **IN GENERAL.**—There is established within the Institute an office to be known as the Office of Rural

Mental Health Research (hereafter in this section referred to as the “Office”). The Office shall be headed by a director, who shall be appointed by the Director of such Institute from among individuals experienced or knowledgeable in the provision of mental health services in rural areas. The Secretary shall carry out the authorities established in this section acting through the Director of the Office.

(b) **COORDINATION OF ACTIVITIES.**—The Director of the Office, in consultation with the Director of the Institute and with the Director of the Office of Rural Health Policy, shall—

(1) coordinate the research activities of the Department of Health and Human Services as such activities relate to the mental health of residents of rural areas; and

(2) coordinate the activities of the Office with similar activities of public and nonprofit private entities.

(c) **RESEARCH, DEMONSTRATIONS, EVALUATIONS, AND DISSEMINATION.**—The Director of the Office may, with respect to the mental health of adults and children residing in rural areas—

(1) conduct research on conditions that are unique to the residents of rural areas, or more serious or prevalent in such residents;

(2) conduct research on improving the delivery of services in such areas; and

(3) disseminate information to appropriate public and nonprofit private entities.

(d) **AUTHORITY REGARDING GRANTS AND CONTRACTS.**—The Director of the Office may carry out the authorities established in subsection (c) directly and through grants, cooperative agreements, or contracts with public or nonprofit private entities.

#### OFFICE ON AIDS

SEC. 464U. [285p–3] The Director of the Institute shall establish within the Institute an Office on AIDS. The Office shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

(1) primary prevention of the spread of HIV, including transmission via sexual behavior;

(2) mental health services research; and

(3) other matters determined appropriate by the Director.

#### Subpart 17—National Institute of Nursing Research

##### PURPOSE OF THE INSTITUTE

SEC. 464V. [285q] The general purpose of the National Institute of Nursing Research (in this subpart referred to as the “Institute”) is the conduct and support of, and dissemination of information respecting, basic and clinical nursing research, training, and other programs in patient care research.

##### SPECIFIC AUTHORITIES

SEC. 464W. [285q–1] To carry out section 464V, the Director of the Institute may provide research training and instruction and establish, in the Institute and other nonprofit institutions, research

traineeships and fellowships in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with and the families of individuals with acute and chronic illnesses. The Director of the Institute may provide individuals receiving such training and instruction or such traineeships or fellowships with such stipends and allowances (including amounts for travel and subsistence and dependency allowances) as the Director determines necessary. The Director may make grants to non-profit institutions to provide such training and instruction and traineeships and fellowships.

#### ADVISORY COUNCIL

SEC. 464X. [285q-2] (a)(1) The Secretary shall appoint an advisory council for the Institute which shall advise, assist, consult with, and make recommendations to the Secretary and the Director of the Institute on matters related to the activities carried out by and through the Institute and the policies respecting such activities.

(2) The advisory council for the Institute may recommend to the Secretary acceptance, in accordance with section 2701,<sup>47</sup> of conditional gifts for study, investigations, and research and for the acquisition of grounds or construction, equipping, or maintenance of facilities for the Institute.

(3) The advisory council for the Institute—

(A)(i) may make recommendations to the Director of the Institute respecting research conducted at the Institute,

(ii) may review applications for grants and cooperative agreements for research or training and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the Institute is concerned and with the approval of the Director of the Institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b)(1) The advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary.

(2) The ex officio members of the advisory council shall consist of—

<sup>47</sup>Probably should be section 231. That section formerly was section 2701, and was redesignated by subsection (a)(2) of section 2010 of Public Law 103-43 (107 Stat. 213). Subsection (b)(5) of such section purported to conform the above reference, but the amendment cannot be executed because the amendment applied to the incorrect section. (The conforming amendment applied to section 485. Section 464X formerly was section 485, and was redesignated by section 1511(b)(2)(B) of Public Law 103-43 (107 Stat. 179).)

(A) the Secretary, the Director of NIH, the Director of the Institute, the chief nursing officer of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs, the Director of the Division of Nursing of the Health Resources and Services Administration (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of the advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including public health and the behavioral or social sciences) relevant to the activities of the Institute. Of the members appointed pursuant to this subparagraph, at least seven shall be professional nurses who are recognized experts in the area of clinical practice, education, or research.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of the advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of the advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule.

(c) The term of office of an appointed member of the advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) The chairman of the advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the Institute to be the chairman of the advisory council. The term of office of the chairman shall be two years.

(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the Institute, but at least three times each fiscal year. The location of the meetings of the advisory council is subject to the approval of the Director of the Institute.

(f) The Director of the Institute shall designate a member of the staff of the Institute to serve as the executive secretary of the advisory council. The Director of the Institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of the Institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

(g) The advisory council may prepare, for inclusion in the triennial report made under section 403 (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the Institute in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Institute. The advisory council may prepare such additional reports as it may determine appropriate.

【Section 464Y was repealed by section 2042(h)(1) of Public Law 114–255.】

#### Subpart 18—National Institute of Biomedical Imaging and Bioengineering

##### PURPOSE OF THE INSTITUTE

SEC. 464z. 【285r】 (a) The general purpose of the National Institute of Biomedical Imaging and Bioengineering (in this section referred to as the “Institute”) is the conduct and support of research, training, the dissemination of health information, and other programs with respect to biomedical imaging, biomedical engineering, and associated technologies and modalities with biomedical applications (in this section referred to as “biomedical imaging and bioengineering”).

(b)(1) The Director of the Institute, with the advice of the Institute’s advisory council, shall establish a National Biomedical Imaging and Bioengineering Program (in this section referred to as the “Program”).

(2) Activities under the Program shall include the following with respect to biomedical imaging and bioengineering:

(A) Research into the development of new techniques and devices.

(B) Related research in physics, engineering, mathematics, computer science, and other disciplines.

(C) Technology assessments and outcomes studies to evaluate the effectiveness of biologics, materials, processes, devices, procedures, and informatics.

(D) Research in screening for diseases and disorders.

(E) The advancement of existing imaging and bioengineering modalities, including imaging, biomaterials, and informatics.

(F) The development of target-specific agents to enhance images and to identify and delineate disease.

(G) The development of advanced engineering and imaging technologies and techniques for research from the molecular and genetic to the whole organ and body levels.

(H) The development of new techniques and devices for more effective interventional procedures (such as image-guided interventions).

(3)(A) With respect to the Program, the Director of the Institute shall prepare and transmit to the Secretary and the Director of NIH a plan to initiate, expand, intensify, and coordinate activities of the Institute with respect to biomedical imaging and bioengineering. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Secretary and the Director of NIH.

(B) The plan under subparagraph (A) shall include the recommendations of the Director of the Institute with respect to the following:

(i) Where appropriate, the consolidation of programs of the National Institutes of Health for the express purpose of enhancing support of activities regarding basic biomedical imaging and bioengineering research.

(ii) The coordination of the activities of the Institute with related activities of the other agencies of the National Institutes of Health and with related activities of other Federal agencies.

(c) The establishment under section 406 of an advisory council for the Institute is subject to the following:

(1) The number of members appointed by the Secretary shall be 12.

(2) Of such members—

(A) six members shall be scientists, engineers, physicians, and other health professionals who represent disciplines in biomedical imaging and bioengineering and who are not officers or employees of the United States; and

(B) six members shall be scientists, engineers, physicians, and other health professionals who represent other disciplines and are knowledgeable about the applications of biomedical imaging and bioengineering in medicine, and who are not officers or employees of the United States.

(3) In addition to the ex officio members specified in section 406(b)(2), the ex officio members of the advisory council shall include the Director of the Centers for Disease Control and Prevention, the Director of the National Science Foundation, and the Director of the National Institute of Standards and Technology (or the designees of such officers).

## Subpart 19—National Human Genome Research Institute

PURPOSE OF THE CENTER<sup>48</sup>

SEC. 464z-1. [285s] (a) The general purpose of the National Human Genome Research Institute (in this subpart referred to as the “Institute”) is to characterize the structure and function of the human genome, including the mapping and sequencing of individual genes. Such purpose includes—

- (1) planning and coordinating the research goal of the genome project;
- (2) reviewing and funding research proposals;
- (3) developing training programs;
- (4) coordinating international genome research;
- (5) communicating advances in genome science to the public; and
- (6) reviewing and funding proposals to address the ethical and legal issues associated with the genome project (including legal issues regarding patents).

(b) The Director of the Institute may conduct and support research training—

- (1) for which fellowship support is not provided under section 487; and
- (2) that is not residency training of physicians or other health professionals.

(c)(1) Except as provided in paragraph (2), of the amounts appropriated to carry out subsection (a) for a fiscal year, the Director of the Institute shall make available not less than 5 percent for carrying out paragraph (6) of such subsection.

(2) With respect to providing funds under subsection (a)(6) for proposals to address the ethical issues associated with the genome project, paragraph (1) shall not apply for a fiscal year if the Director of the Institute certifies to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, that the Director has determined that an insufficient number of such proposals meet the applicable requirements of sections 491 and 492.

## Subpart 20—National Institute on Minority Health and Health Disparities

SEC. 464z-3. [285t] PURPOSE OF CENTER<sup>49</sup>.

(a) IN GENERAL.—The general purpose of the National Institute on Minority Health and Health Disparities (in this subpart referred to as the “Institute”) is the conduct and support of research, training, dissemination of information, and other programs with respect to minority health conditions and other populations with health disparities.

<sup>48</sup>The word “CENTER” in the section heading probably should read “INSTITUTE”. Section 101(c)(4)(C) of Public Law 109–482 (120 Stat. 3675) struck “center” each place such term appeared in this subpart and inserted “institute”. However, this amendment was not effective with respect to the section heading because the word “CENTER” appears in small caps.

<sup>49</sup>The word “CENTER” in the section heading for section 464z-3 probably should read “INSTITUTE”. See amendment made by section 10334(c)(1)(D)(iii) of Public Law 111–148.

(b) **PRIORITIES.**—The Director of the Institute shall in expending amounts appropriated under this subpart give priority to conducting and supporting minority health disparities research.

(c) **MINORITY HEALTH DISPARITIES RESEARCH.**—For purposes of this subpart:

(1) The term “minority health disparities research” means basic, clinical, and behavioral research on minority health conditions (as defined in paragraph (2)), including research to prevent, diagnose, and treat such conditions.

(2) The term “minority health conditions”, with respect to individuals who are members of minority groups, means all diseases, disorders, and conditions (including with respect to mental health and substance abuse)—

(A) unique to, more serious, or more prevalent in such individuals;

(B) for which the factors of medical risk or types of medical intervention may be different for such individuals, or for which it is unknown whether such factors or types are different for such individuals; or

(C) with respect to which there has been insufficient research involving such individuals as subjects or insufficient data on such individuals.

(3) The term “minority group” has the meaning given the term “racial and ethnic minority group” in section 1707.

(4) The terms “minority” and “minorities” refer to individuals from a minority group.

(d) **HEALTH DISPARITY POPULATIONS.**—For purposes of this subpart:

(1) A population is a health disparity population if, as determined by the Director of the Institute after consultation with the Director of the Agency for Healthcare Research and Quality, there is a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population.

(2) The Director shall give priority consideration to determining whether minority groups qualify as health disparity populations under paragraph (1).

(3) The term “health disparities research” means basic, clinical, and behavioral research on health disparity populations (including individual members and communities of such populations) that relates to health disparities as defined under paragraph (1), including the causes of such disparities and methods to prevent, diagnose, and treat such disparities.

(e) **COORDINATION OF ACTIVITIES.**—The Director of the Institute shall act as the primary Federal official with responsibility for coordinating all minority health disparities research and other health disparities research conducted or supported by the National Institutes of Health, and—

(1) shall represent the health disparities research program of the National Institutes of Health, including the minority health disparities research program, at all relevant Executive branch task forces, committees and planning activities; and



(2) shall maintain communications with all relevant Public Health Service agencies, including the Indian Health Service, and various other departments of the Federal Government to ensure the timely transmission of information concerning advances in minority health disparities research and other health disparities research between these various agencies for dissemination to affected communities and health care providers.

(f) COLLABORATIVE COMPREHENSIVE PLAN AND BUDGET.—

(1) IN GENERAL.—Subject to the provisions of this section and other applicable law, the Director of NIH, the Director of the Institute, and the directors of the other agencies of the National Institutes of Health in collaboration (and in consultation with the advisory council for the Institute) shall—

(A) establish a comprehensive plan and budget for the conduct and support of all minority health disparities research and other health disparities research activities of the agencies of the National Institutes of Health (which plan and budget shall be first established under this subsection not later than 12 months after the date of the enactment of this subpart);

(B) ensure that the plan and budget establish priorities among the health disparities research activities that such agencies are authorized to carry out;

(C) ensure that the plan and budget establish objectives regarding such activities, describes the means for achieving the objectives, and designates the date by which the objectives are expected to be achieved;

(D) ensure that, with respect to amounts appropriated for activities of the Institute, the plan and budget give priority in the expenditure of funds to conducting and supporting minority health disparities research;

(E) ensure that all amounts appropriated for such activities are expended in accordance with the plan and budget;

(F) review the plan and budget not less than annually, and revise the plan and budget as appropriate;

(G) ensure that the plan and budget serve as a broad, binding statement of policies regarding minority health disparities research and other health disparities research activities of the agencies, but do not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other details of the daily administration of such activities, in accordance with the plan and budget; and

(H) promote coordination and collaboration among the agencies conducting or supporting minority health or other health disparities research.

(2) CERTAIN COMPONENTS OF PLAN AND BUDGET.—With respect to health disparities research activities of the agencies of the National Institutes of Health, the Director of the Institute shall ensure that the plan and budget under paragraph (1) provide for—

(A) basic research and applied research, including research and development with respect to products;

- (B) research that is conducted by the agencies;
  - (C) research that is supported by the agencies;
  - (D) proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and
  - (E) behavioral research and social sciences research, which may include cultural and linguistic research in each of the agencies.
- (3) MINORITY HEALTH DISPARITIES RESEARCH.—The plan and budget under paragraph (1) shall include a separate statement of the plan and budget for minority health disparities research.
- (g) PARTICIPATION IN CLINICAL RESEARCH.—The Director of the Institute shall work with the Director of NIH and the directors of the agencies of the National Institutes of Health to carry out the provisions of section 492B that relate to minority groups.
- (h) RESEARCH ENDOWMENTS.—
- (1) IN GENERAL.—The Director of the Institute may carry out a program to facilitate minority health disparities research and other health disparities research by providing for research endowments—
    - (A) at current or former centers of excellence under section 736; and
    - (B) at current or former centers of excellence under section 464z-4.
  - (2) ELIGIBILITY.—The Director of the Institute may provide for a research endowment under paragraph (1) only if the institution involved meets the following conditions:
    - (A) The institution does not have an endowment that is worth in excess of an amount equal to 50 percent of the national median of endowment funds at institutions that conduct similar biomedical research or training of health professionals.
    - (B) The application of the institution under paragraph (1) regarding a research endowment has been recommended pursuant to technical and scientific peer review and has been approved by the advisory council under subsection (j).
  - (i) CERTAIN ACTIVITIES.—In carrying out subsection (a), the Director of the Institute—
    - (1) shall assist the Director of NIH<sup>50</sup> in carrying out section 404I(c)(2) and in committing resources for construction at Institutions of Emerging Excellence under such section;
    - (2) shall establish projects to promote cooperation among Federal agencies, State, local, tribal, and regional public health agencies, and private entities in health disparities research; and
    - (3) may utilize information from previous health initiatives concerning minorities and other health disparity populations.
  - (j) ADVISORY COUNCIL.—

<sup>50</sup> Section 221(d)(3)(A) of division F of Public Law 112-74 provided for an amendment to strike “Director of National Institute for Research Resources” and inserting “Director of NIH”. The amendment probably should have been to strike “Director of National Institute for Research Resources”, but was carried out to reflect the probable intent of Congress.

(1) IN GENERAL.—The Secretary shall, in accordance with section 406, establish an advisory council to advise, assist, consult with, and make recommendations to the Director of the Institute on matters relating to the activities described in subsection (a), and with respect to such activities to carry out any other functions described in section 406 for advisory councils under such section. Functions under the preceding sentence shall include making recommendations on budgetary allocations made in the plan under subsection (f), and shall include reviewing reports under subsection (k) before the reports are submitted under such subsection.

(2) MEMBERSHIP.—With respect to the membership of the advisory council under paragraph (1), a majority of the members shall be individuals with demonstrated expertise regarding minority health disparity and other health disparity issues; representatives of communities impacted by minority and other health disparities shall be included; and a diversity of health professionals shall be represented. The membership shall in addition include a representative of the Office of Behavioral and Social Sciences Research under section 404A.

(k) INTRA-NATIONAL INSTITUTES OF HEALTH COORDINATION.—The Director of the Institute, as the primary Federal official with responsibility for coordinating all research and activities conducted or supported by the National Institutes of Health on minority health and health disparities, shall plan, coordinate, review, and evaluate research and other activities conducted or supported by the national research institutes and national centers. The Director of the Institute may foster partnerships between the national research institutes and national centers and may encourage the funding of collaborative research projects to achieve the goals of the National Institutes of Health that are related to minority health and health disparities.

**SEC. 464z-4. [285t-1] CENTERS OF EXCELLENCE FOR RESEARCH EDUCATION AND TRAINING.**

(a) IN GENERAL.—The Director of the Institute shall make awards of grants or contracts to designated biomedical and behavioral research institutions under paragraph (1) of subsection (c), or to consortia under paragraph (2) of such subsection, for the purpose of assisting the institutions in supporting programs of excellence in biomedical and behavioral research training for individuals who are members of minority health disparity populations or other health disparity populations.

(b) REQUIRED USE OF FUNDS.—An award may be made under subsection (a) only if the applicant involved agrees that the grant will be expended—

(1) to train members of minority health disparity populations or other health disparity populations as professionals in the area of biomedical or behavioral research or both; or

(2) to expand, remodel, renovate, or alter existing research facilities or construct new research facilities for the purpose of conducting minority health disparities research and other health disparities research.

(c) CENTERS OF EXCELLENCE.—

(1) IN GENERAL.—For purposes of this section, a designated biomedical and behavioral research institution is a biomedical and behavioral research institution that—

(A) has a significant number of members of minority health disparity populations or other health disparity populations enrolled as students in the institution (including individuals accepted for enrollment in the institution);

(B) has been effective in assisting such students of the institution to complete the program of education or training and receive the degree involved;

(C) has made significant efforts to recruit minority students to enroll in and graduate from the institution, which may include providing means-tested scholarships and other financial assistance as appropriate; and

(D) has made significant recruitment efforts to increase the number of minority or other members of health disparity populations serving in faculty or administrative positions at the institution.

(2) CONSORTIUM.—Any designated biomedical and behavioral research institution involved may, with other biomedical and behavioral institutions (designated or otherwise), including tribal health programs, form a consortium to receive an award under subsection (a).

(3) APPLICATION OF CRITERIA TO OTHER PROGRAMS.—In the case of any criteria established by the Director of the Institute for purposes of determining whether institutions meet the conditions described in paragraph (1), this section may not, with respect to minority health disparity populations or other health disparity populations, be construed to authorize, require, or prohibit the use of such criteria in any program other than the program established in this section.

(d) DURATION OF GRANT.—The period during which payments are made under a grant under subsection (a) may not exceed 5 years. Such payments shall be subject to annual approval by the Director of the Institute and to the availability of appropriations for the fiscal year involved to make the payments.

(e) MAINTENANCE OF EFFORT.—

(1) IN GENERAL.—With respect to activities for which an award under subsection (a) is authorized to be expended, the Director of the Institute may not make such an award to a designated research institution or consortium for any fiscal year unless the institution, or institutions in the consortium, as the case may be, agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the institutions involved for the fiscal year preceding the fiscal year for which such institutions receive such an award.

(2) USE OF FEDERAL FUNDS.—With respect to any Federal amounts received by a designated research institution or consortium and available for carrying out activities for which an award under subsection (a) is authorized to be expended, the Director of the Institute may make such an award only if the institutions involved agree that the institutions will, before ex-

pending the award, expend the Federal amounts obtained from sources other than the award.

(f) **CERTAIN EXPENDITURES.**—The Director of the Institute may authorize a designated biomedical and behavioral research institution to expend a portion of an award under subsection (a) for research endowments.

(g) **DEFINITIONS.**—For purposes of this section:

(1) The term “designated biomedical and behavioral research institution” has the meaning indicated for such term in subsection (c)(1). Such term includes any health professions school receiving an award of a grant or contract under section 736.

(2) The term “program of excellence” means any program carried out by a designated biomedical and behavioral research institution with an award under subsection (a), if the program is for purposes for which the institution involved is authorized in subsection (b) to expend the grant.

【Section 464z–5 was repealed by section 2022(c)(1) of Public Law 114–255.】

**SEC. 464z–6. [285t–3] GENERAL PROVISIONS REGARDING THE CENTER.**

The Secretary, acting through the Director of the National Institutes of Health, shall provide administrative support and support services to the Director of the Institute and shall ensure that such support takes maximum advantage of existing administrative structures at the agencies of the National Institutes of Health.

**PART D—NATIONAL LIBRARY OF MEDICINE**

**Subpart 1—General Provisions**

**PURPOSE, ESTABLISHMENT, AND FUNCTIONS OF THE NATIONAL LIBRARY OF MEDICINE**

**SEC. 465. [286]** (a) In order to assist the advancement of medical and related sciences and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health, there is established the National Library of Medicine (hereafter in this part referred to as the “Library”).

(b) The Secretary, through the Library and subject to subsection (d), shall—

(1) acquire and preserve books, periodicals, prints, films, recordings, and other library materials pertinent to medicine;

(2) organize the materials specified in paragraph (1) by appropriate cataloging, indexing, and bibliographical listings;

(3) publish and disseminate the catalogs, indexes, and bibliographies referred to in paragraph (2);

(4) make available, through loans, photographic or other copying procedures, or otherwise, such materials in the Library as the Secretary determines appropriate;

(5) provide reference and research assistance;

(6) publicize the availability from the Library of the products and services described in any of paragraphs (1) through (5);

(7) promote the use of computers and telecommunications by health professionals (including health professionals in rural areas) for the purpose of improving access to biomedical information for health care delivery and medical research; and

(8) engage in such other activities as the Secretary determines appropriate and as the Library's resources permit.

(c) The Secretary may exchange, destroy, or otherwise dispose of any books, periodicals, films, and other library materials not needed for the permanent use of the Library.

(d)(1) The Secretary may, after obtaining the advice and recommendations of the Board of Regents, prescribe rules under which the Library will—

(A) provide copies of its publications or materials,

(B) will make available its facilities for research, or

(C) will make available its bibliographic, reference, or other services, to public and private entities and individuals.

(2) Rules prescribed under paragraph (1) may provide for making available such publications, materials, facilities, or services—

(A) without charge as a public service,

(B) upon a loan, exchange, or charge basis, or

(C) in appropriate circumstances, under contract arrangements made with a public or other nonprofit entity.

(e) Whenever the Secretary, with the advice of the Board of Regents, determines that—

(1) in any geographic area of the United States there is no regional medical library adequate to serve such area;

(2) under criteria prescribed for the administration of section 475, there is a need for a regional medical library to serve such area; and

(3) because there is no medical library located in such area which, with financial assistance under section 475, can feasibly be developed into a regional medical library adequate to serve such area,

the Secretary may establish, as a branch of the Library, a regional medical library to serve the needs of such area.

(f) Section 231 shall be applicable to the acceptance and administration of gifts made for the benefit of the Library or for carrying out any of its functions, and the Board of Regents shall make recommendations to the Secretary relating to establishment within the Library of suitable memorials to the donors.

(g) For purposes of this part, the terms "medicine" and "medical", except when used in section 466, include preventive and therapeutic medicine, dentistry, pharmacy, hospitalization, nursing, public health, and the fundamental sciences related thereto, and other related fields of study, research, or activity.

#### BOARD OF REGENTS

SEC. 466. [286a] (a)(1)(A) The Board of Regents of the National Library of Medicine consists of ex officio members and ten members appointed by the Secretary.

(B) The ex officio members are the Surgeons General of the Public Health Service, the Army, the Navy, and the Air Force, the

Chief Medical Director of the Department of Veterans Affairs, the Dean of the Uniformed Services University of the Health Sciences, the Assistant Director for Biological, Behavioral, and Social Sciences of the National Science Foundation, the Director of the National Agricultural Library, and the Librarian of Congress (or their designees).

(C) The appointed members shall be selected from among leaders in the various fields of the fundamental sciences, medicine, dentistry, public health, hospital administration, pharmacology, health communications technology, or scientific or medical library work, or in public affairs. At least six of the appointed members shall be selected from among leaders in the fields of medical, dental, or public health research or education.

(2) The Board shall annually elect one of the appointed members to serve as chairman until the next election. The Secretary shall designate a member of the Library staff to act as executive secretary of the Board.

(b) The Board shall advise, consult with, and make recommendations to the Secretary on matters of policy in regard to the Library, including such matters as the acquisition of materials for the Library, the scope, content, and organization of the Library's services, and the rules under which its materials, publications, facilities, and services shall be made available to various kinds of users. The Secretary shall include in the annual report of the Secretary to the Congress a statement covering the recommendations made by the Board and the disposition thereof. The Secretary may use the services of any member of the Board in connection with matters related to the work of the Library, for such periods, in addition to conference periods, as the Secretary may determine.

(c) Each appointed member of the Board shall hold office for a term of four years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the predecessor of such member was appointed shall be appointed for the remainder of such term. None of the appointed members shall be eligible for reappointment within one year after the end of the preceding term of such member.

#### LIBRARY FACILITIES

SEC. 467. [286a-1] The Administrator of General Services may acquire, by purchase, condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for suitable and adequate buildings and facilities for use of the Library and to erect thereon, furnish, and equip such buildings and facilities. Amounts appropriated to carry out this section may be used for the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.

## Subpart 2—Financial Assistance

## DEFINITIONS

SEC. 470. [286b–1] As used in this subpart—

(1) the term “medical library” means a library related to the sciences related to health; and

(2) the term “sciences related to health” includes medicine, osteopathy, dentistry, and public health, and fundamental and applied sciences when related thereto.

## NATIONAL MEDICAL LIBRARIES ASSISTANCE ADVISORY BOARD

SEC. 471. [286b–2] (a) The Board of Regents of the National Library of Medicine shall also serve as the National Medical Libraries Assistance Advisory Board (hereafter in this subpart referred to as the “Board”).

(b) The Board shall advise and assist the Secretary in the preparation of general regulations and with respect to policy matters arising in the administration of this subpart.

(c) The Secretary may use the services of any member of the Board, in connection with matters related to the administration of this part for such periods, in addition to conference periods, as the Secretary may determine.

(d) Appointed members of the Board who are not otherwise in the employ of the United States, while attending conferences of the Board or otherwise serving at the request of the Secretary in connection with the administration of this subpart, shall be entitled to receive compensation, per diem in lieu of subsistence, and travel expenses in the same manner and under the same conditions as that prescribed under section 208(c) when attending conferences, traveling, or serving at the request of the Secretary in connection with the Board’s function under this section.

## GRANTS FOR TRAINING IN MEDICAL LIBRARY SCIENCES

SEC. 472. [286b–3] The Secretary shall make grants—

(1) to individuals to enable them to accept traineeships and fellowships leading to postbaccalaureate academic degrees in the field of medical library science, in related fields pertaining to sciences related to health, or in the field of the communication of information;

(2) to individuals who are librarians or specialists in information on sciences relating to health, to enable them to undergo intensive training or retraining so as to attain greater competence in their occupations (including competence in the fields of automatic data processing and retrieval);

(3) to assist appropriate public and private nonprofit institutions in developing, expanding, and improving training programs in library science and the field of communications of information pertaining to sciences relating to health; and

(4) to assist in the establishment of internship programs in established medical libraries meeting standards which the Secretary shall prescribe.



ASSISTANCE FOR SPECIAL SCIENTIFIC PROJECTS, AND FOR RESEARCH  
AND DEVELOPMENT IN MEDICAL LIBRARY SCIENCE AND RELATED  
FIELDS

SEC. 473. [286b–4] (a) The Secretary shall make grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists for the compilation of existing, or the writing of original, contributions relating to scientific, social, or cultural advancements in sciences related to health. In making such grants, the Secretary shall make appropriate arrangements under which the facilities of the Library and the facilities of libraries of public and private nonprofit institutions of higher learning may be made available in connection with the projects for which such grants are made.

(b) The Secretary shall make grants to appropriate public or private nonprofit institutions and enter into contracts with appropriate persons, for purposes of carrying out projects of research, investigations, and demonstrations in the field of medical library science and related activities and for the development of new techniques, systems, and equipment, for processing, storing, retrieving, and distributing information pertaining to sciences related to health.

(c)(1) The Secretary shall make grants to public or nonprofit private institutions for the purpose of carrying out projects of research on, and development and demonstration of, new education technologies.

(2) The purposes for which a grant under paragraph (1) may be made include projects concerning—

(A) computer-assisted teaching and testing of clinical competence at health professions and research institutions;

(B) the effective transfer of new information from research laboratories to appropriate clinical applications;

(C) the expansion of the laboratory and clinical uses of computer-stored research databases; and

(D) the testing of new technologies for training health care professionals.

(3) The Secretary may not make a grant under paragraph (1) unless the applicant for the grant agrees to make the projects available with respect to—

(A) assisting in the training of health professions students; and

(B) enhancing and improving the capabilities of health professionals regarding research and teaching.

GRANTS FOR ESTABLISHING, EXPANDING, AND IMPROVING THE BASIC  
RESOURCES OF MEDICAL LIBRARIES AND RELATED INSTRUMENTAL-  
ITIES

SEC. 474. [286b–5] (a) The Secretary shall make grants of money, materials, or both, to public or private nonprofit medical libraries and related scientific communication instrumentalities for the purpose of establishing, expanding, and improving their basic medical library or related resources. A grant under this subsection may be used for—

(1) the acquisition of books, journals, photographs, motion picture and other films, and other similar materials;

(2) cataloging, binding, and other services and procedures for processing library resource materials for use by those who are served by the library or related instrumentality;

(3) the acquisition of duplication devices, facsimile equipment, film projectors, recording equipment, and other equipment to facilitate the use of the resources of the library or related instrumentality by those who are served by it; and

(4) the introduction of new technologies in medical librarianship.

(b)(1) The amount of any grant under this section to any medical library or related instrumentality shall be determined by the Secretary on the basis of the scope of library or related services provided by such library or instrumentality in relation to the population and purposes served by it. In making a determination of the scope of services served by any medical library or related instrumentality, the Secretary shall take into account—

(A) the number of graduate and undergraduate students making use of the resources of such library or instrumentality;

(B) the number of physicians and other practitioners in the sciences related to health utilizing the resources of such library or instrumentality;

(C) the type of supportive staffs, if any, available to such library or instrumentality;

(D) the type, size, and qualifications of the faculty of any school with which such library or instrumentality is affiliated;

(E) the staff of any hospital or hospitals or of any clinic or clinics with which such library or instrumentality is affiliated; and

(F) the geographic area served by such library or instrumentality and the availability within such area of medical library or related services provided by other libraries or related instrumentalities.

(2) Grants to such medical libraries or related instrumentalities under this section shall be in such amounts as the Secretary may by regulation prescribe with a view to assuring adequate continuing financial support for such libraries or instrumentalities from other sources during and after the period for which grants are provided, except that in no case shall any grant under this section to a medical library or related instrumentality for any fiscal year exceed \$1,000,000.

#### GRANTS AND CONTRACTS FOR ESTABLISHMENT OF REGIONAL MEDICAL LIBRARIES

SEC. 475. [286b–6] (a) The Secretary, with the advice of the Board, shall make grants to and enter into contracts with existing public or private nonprofit medical libraries so as to enable each of them to serve as the regional medical library for the geographical area in which it is located.

(b) The uses for which grants and contracts under this section may be employed include the—

- (1) acquisition of books, journals, and other similar materials;
  - (2) cataloging, binding, and other procedures for processing library resource materials for use by those who are served by the library;
  - (3) acquisition of duplicating devices and other equipment to facilitate the use of the resources of the library by those who are served by it;
  - (4) acquisition of mechanisms and employment of personnel for the speedy transmission of materials from the regional library to local libraries in the geographic area served by the regional library; and
  - (5) planning for services and activities under this section.
- (c)(1) Grants and contracts under this section shall only be made to or entered into with medical libraries which agree—
- (A) to modify and increase their library resources, and to supplement the resources of cooperating libraries in the region, so as to be able to provide adequate supportive services to all libraries in the region as well as to individual users of library services; and
  - (B) to provide free loan services to qualified users and make available photoduplicated or facsimile copies of biomedical materials which qualified requesters may retain.
- (2) The Secretary, in awarding grants and contracts under this section, shall give priority to medical libraries having the greatest potential of fulfilling the needs for regional medical libraries. In determining the priority to be assigned to any medical library, the Secretary shall consider—
- (A) the adequacy of the library (in terms of collections, personnel, equipment, and other facilities) as a basis for a regional medical library; and
  - (B) the size and nature of the population to be served in the region in which the library is located.
- (d) Grants and contracts under this section for basic resource materials to a library may not exceed—
- (1) 50 percent of the library's annual operating expense (exclusive of Federal financial assistance under this part) for the preceding year; or
  - (2) in case of the first year in which the library receives a grant under this section for basic resource materials, 50 percent of its average annual operating expenses over the past three years (or if it had been in operation for less than three years, its annual operating expenses determined by the Secretary in accordance with regulations).

#### FINANCIAL SUPPORT OF BIOMEDICAL SCIENTIFIC PUBLICATIONS

SEC. 476. [286b–7] (a) The Secretary, with the advice of the Board, shall make grants to, and enter into appropriate contracts with, public or private nonprofit institutions of higher education and individual scientists for the purpose of supporting biomedical scientific publications of a nonprofit nature and to procure the compilation, writing, editing, and publication of reviews, abstracts, in-

dices, handbooks, bibliographies, and related matter pertaining to scientific works and scientific developments.

(b) Grants under subsection (a) in support of any single periodical publication may not be made for more than three years, except in those cases in which the Secretary determines that further support is necessary to carry out the purposes of subsection (a).

#### GRANT PAYMENTS, RECORDS, AND AUDIT

SEC. 477. [286b–8] (a) Payments under grants made under sections 472, 473, 474, 475, and 476 may be made in advance or by way of reimbursement and in such installments as the Secretary shall prescribe by regulation after consultation with the Board.

(b)(1) Each recipient of a grant under this subpart shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to any grant received under this subpart.

#### Subpart 3—National Center for Biotechnology Information

##### PURPOSE, ESTABLISHMENT, FUNCTIONS, AND FUNDING OF THE NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

SEC. 478. [286c] (a) In order to focus and expand the collection, storage, retrieval, and dissemination of the results of biotechnology research by information systems, and to support and enhance the development of new information technologies to aid in the understanding of the molecular processes that control health and disease, there is established the National Center for Biotechnology Information (hereinafter in this section referred to as the “Center”) in the National Library of Medicine.

(b) The Secretary, through the Center and subject to section 465(d), shall—

(1) design, develop, implement, and manage automated systems for the collection, storage, retrieval, analysis, and dissemination of knowledge concerning human molecular biology, biochemistry, and genetics;

(2) perform research into advanced methods of computer-based information processing capable of representing and analyzing the vast number of biologically important molecules and compounds;

(3) enable persons engaged in biotechnology research and medical care to use systems developed under paragraph (1) and methods described in paragraph (2); and

(4) coordinate, as much as is practicable, efforts to gather biotechnology information on an international basis.

Subpart 4—National Information Center on Health Services  
Research and Health Care Technology

NATIONAL INFORMATION CENTER

SEC. 478A. [286d] (a) There is established within the Library an entity to be known as the National Information Center on Health Services Research and Health Care Technology (in this section referred to as the “Center”).

(b) The purpose of the Center is the collection, storage, analysis, retrieval, and dissemination of information on health services research, clinical practice guidelines, and on health care technology, including the assessment of such technology. Such purpose includes developing and maintaining data bases and developing and implementing methods of carrying out such purpose.

(c) The Director of the Center shall ensure that information under subsection (b) concerning clinical practice guidelines is collected and maintained electronically and in a convenient format. Such Director shall develop and publish criteria for the inclusion of practice guidelines and technology assessments in the information center database.

(d) The Secretary, acting through the Center, shall coordinate the activities carried out under this section through the Center with related activities of the Administrator for Health Care Policy and Research.

PART E—OTHER AGENCIES OF NIH

Subpart 1—National Center for Advancing Translational Sciences

SEC. 479. [287] NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES.

(a) PURPOSE.—The purpose of the National Center for Advancing Translational Sciences (in this subpart referred to as the “Center”) is to advance translational sciences, including by—

(1) coordinating and developing resources that leverage basic research in support of translational science; and

(2) developing partnerships and working cooperatively to foster synergy in ways that do not create duplication, redundancy, and competition with industry activities.

(b) CLINICAL TRIAL ACTIVITIES.—

(1) IN GENERAL.—The Center may develop and provide infrastructure and resources for all phases of clinical trials research. Except as provided in paragraph (2), the Center may support clinical trials only through the end of phase IIB.

(2) EXCEPTION.—The Center may support clinical trial activities through the end of phase III for a treatment for a rare disease or condition (as defined in section 526 of the Federal Food, Drug, and Cosmetic Act) so long as—

(A) the Center gives public notice for a period of at least 120 days of the Center’s intention to support the clinical trial activities in phase III;

(B) no public or private organization provides credible written intent to the Center that the organization has timely plans to further the clinical trial activities or con-

duct clinical trials of a similar nature beyond phase IIB; and

(C) the Center ensures that support of the clinical trial activities in phase III will not increase the Federal Government's liability beyond the award value of the Center's support.

(c) BIENNIAL REPORT.—The Center shall publish a report on a biennial basis that, with respect to all research supported by the Center, includes a complete list of—

- (1) the molecules being studied;
- (2) clinical trial activities being conducted;
- (3) the methods and tools in development;
- (4) ongoing partnerships, including—
  - (A) the rationale for each partnership;
  - (B) the status of each partnership;
  - (C) the funding provided by the Center to other entities pursuant to each partnership, and
  - (D) the activities which have been transferred to industry pursuant to each partnership;
- (5) known research activity of other entities that is or will expand upon research activity of the Center;
- (6) the methods and tools, if any, that have been developed since the last biennial report was prepared; and
- (7) the methods and tools, if any, that have been developed and are being utilized by the Food and Drug Administration to support medical product reviews.

(d) INCLUSION OF LIST.—The first biennial report submitted under this section after the date of enactment of the 21st Century Cures Act shall include a complete list of all of the methods and tools, if any, which have been developed by research supported by the Center.

(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

**SEC. 480. [287a] CURES ACCELERATION NETWORK.**

(a) DEFINITIONS.—In this section:

(1) BIOLOGICAL PRODUCT.—The term “biological product” has the meaning given such term in section 351 of the Public Health Service Act.

(2) DRUG; DEVICE.—The terms “drug” and “device” have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act.

(3) HIGH NEED CURE.—The term “high need cure” means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, biological product (as that term is defined by section 262(i)), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act) that, in the determination of the Director of the Center—

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

(B) for which the incentives of the commercial market are unlikely to result in its adequate or timely development.

(4) MEDICAL PRODUCT.—The term “medical product” means a drug, device, biological product, or product that is a combination of drugs, devices, and biological products.

(b) ESTABLISHMENT OF THE CURES ACCELERATION NETWORK.—Subject to the appropriation of funds as described in subsection (g), there is established within the Center a program to be known as the Cures Acceleration Network (referred to in this section as “CAN”), which shall—

(1) be under the direction of the Director of the Center, taking into account the recommendations of a CAN Review Board (referred to in this section as the “Board”), described in subsection (d); and

(2) award grants and contracts to eligible entities, as described in subsection (e), to accelerate the development of high need cures, including through the development of medical products and behavioral therapies.

(c) FUNCTIONS.—The functions of the CAN are to—

(1) conduct and support revolutionary advances in basic research, translating scientific discoveries from bench to bedside;

(2) award grants and contracts to eligible entities to accelerate the development of high need cures;

(3) provide the resources necessary for government agencies, independent investigators, research organizations, biotechnology companies, academic research institutions, and other entities to develop high need cures;

(4) reduce the barriers between laboratory discoveries and clinical trials for new therapies; and

(5) facilitate review in the Food and Drug Administration for the high need cures funded by the CAN, through activities that may include—

(A) the facilitation of regular and ongoing communication with the Food and Drug Administration regarding the status of activities conducted under this section;

(B) ensuring that such activities are coordinated with the approval requirements of the Food and Drug Administration, with the goal of expediting the development and approval of countermeasures and products; and

(C) connecting interested persons with additional technical assistance made available under section 565 of the Federal Food, Drug, and Cosmetic Act.

(d) CAN BOARD.—

(1) ESTABLISHMENT.—There is established a Cures Acceleration Network Review Board (referred to in this section as the “Board”), which shall advise the Director of the Center on the conduct of the activities of the Cures Acceleration Network.

(2) MEMBERSHIP.—

(A) IN GENERAL.—

(i) APPOINTMENT.—The Board shall be comprised of 24 members who are appointed by the Secretary and who serve at the pleasure of the Secretary.

(ii) CHAIRPERSON AND VICE CHAIRPERSON.—The Secretary shall designate, from among the 24 members appointed under clause (i), one Chairperson of the Board (referred to in this section as the “Chairperson”) and one Vice Chairperson.

(B) TERMS.—

(i) IN GENERAL.—Each member shall be appointed to serve a 4-year term, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member’s predecessor was appointed shall be appointed for the remainder of such term.

(ii) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member may be appointed to serve not more than 3 terms on the Board, and may not serve more than 2 such terms consecutively.

(C) QUALIFICATIONS.—

(i) IN GENERAL.—The Secretary shall appoint individuals to the Board based solely upon the individual’s established record of distinguished service in one of the areas of expertise described in clause (ii). Each individual appointed to the Board shall be of distinguished achievement and have a broad range of disciplinary interests.

(ii) EXPERTISE.—The Secretary shall select individuals based upon the following requirements:

(I) For each of the fields of—

(aa) basic research;

(bb) medicine;

(cc) biopharmaceuticals;

(dd) discovery and delivery of medical products;

(ee) bioinformatics and gene therapy;

(ff) medical instrumentation; and

(gg) regulatory review and approval of medical products,

the Secretary shall select at least 1 individual who is eminent in such fields.

(II) At least 4 individuals shall be recognized leaders in professional venture capital or private equity organizations and have demonstrated experience in private equity investing.

(III) At least 8 individuals shall represent disease advocacy organizations.

(3) EX-OFFICIO MEMBERS.—

(A) APPOINTMENT.—In addition to the 24 Board members described in paragraph (2), the Secretary shall appoint as ex-officio members of the Board—

(i) a representative of the National Institutes of Health, recommended by the Secretary of the Department of Health and Human Services;

(ii) a representative of the Office of the Assistant Secretary of Defense for Health Affairs, recommended by the Secretary of Defense;



(iii) a representative of the Office of the Under Secretary for Health for the Veterans Health Administration, recommended by the Secretary of Veterans Affairs;

(iv) a representative of the National Science Foundation, recommended by the Chair of the National Science Board; and

(v) a representative of the Food and Drug Administration, recommended by the Commissioner of Food and Drugs.

(B) TERMS.—Each ex-officio member shall serve a 3-year term on the Board, except that the Chairperson may adjust the terms of the initial ex-officio members in order to provide for a staggered term of appointment for all such members.

(4) RESPONSIBILITIES OF THE BOARD AND THE DIRECTOR OF THE CENTER.—

(A) RESPONSIBILITIES OF THE BOARD.—

(i) IN GENERAL.—The Board shall advise, and provide recommendations to, the Director of the Center with respect to—

(I) policies, programs, and procedures for carrying out the duties of the Director of the Center under this section; and

(II) significant barriers to successful translation of basic science into clinical application (including issues under the purview of other agencies and departments).

(ii) REPORT.—In the case that the Board identifies a significant barrier, as described in clause (i)(II), the Board shall submit to the Secretary a report regarding such barrier.

(B) RESPONSIBILITIES OF THE DIRECTOR OF THE CENTER.—With respect to each recommendation provided by the Board under subparagraph (A)(i), the Director of the Center shall respond in writing to the Board, indicating whether such Director will implement such recommendation. In the case that the Director of the Center indicates a recommendation of the Board will not be implemented, such Director shall provide an explanation of the reasons for not implementing such recommendation.

(5) MEETINGS.—

(A) IN GENERAL.—The Board shall meet 4 times per calendar year, at the call of the Chairperson.

(B) QUORUM; REQUIREMENTS; LIMITATIONS.—

(i) QUORUM.—A quorum shall consist of a total of 13 members of the Board, excluding ex-officio members, with diverse representation as described in clause (iii).

(ii) CHAIRPERSON OR VICE CHAIRPERSON.—Each meeting of the Board shall be attended by either the Chairperson or the Vice Chairperson.

(iii) DIVERSE REPRESENTATION.—At each meeting of the Board, there shall be not less than one scientist,

one representative of a disease advocacy organization, and one representative of a professional venture capital or private equity organization.

(6) COMPENSATION AND TRAVEL EXPENSES.—

(A) COMPENSATION.—Members shall receive compensation at a rate to be fixed by the Chairperson but not to exceed a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, 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) of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Board.

(e) GRANT PROGRAM.—

(1) SUPPORTING INNOVATION.—To carry out the purposes described in this section, the Director of the Center shall award contracts, grants, or cooperative agreements to the entities described in paragraph (2), to—

(A) promote innovation in technologies supporting the advanced research and development and production of high need cures, including through the development of medical products and behavioral therapies.

(B) accelerate the development of high need cures, including through the development of medical products, behavioral therapies, and biomarkers that demonstrate the safety or effectiveness of medical products; or

(C) help the award recipient establish protocols that comply with Food and Drug Administration standards and otherwise permit the recipient to meet regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product.

(2) ELIGIBLE ENTITIES.—To receive assistance under paragraph (1), an entity shall—

(A) be a public or private entity, which may include a private or public research institution, an institution of higher education, a medical center, a biotechnology company, a pharmaceutical company, a disease 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 the Center may require.

(3) AWARDS.—

(A) THE CURES ACCELERATION PARTNERSHIP AWARDS.—

(i) INITIAL AWARD AMOUNT.—Each award under this subparagraph shall be not more than \$15,000,000 per project for the first fiscal year for which the project is funded, which shall be payable in one payment.

(ii) FUNDING IN SUBSEQUENT FISCAL YEARS.—An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Director of the Center the information required under subparagraphs (B) and (C) of paragraph (2). The Director may fund a project of such eligible entity in an amount not to exceed \$15,000,000 for a fiscal year subsequent to the initial award under clause (i).

(iii) MATCHING FUNDS.—As a condition for receiving an award under this subsection, an eligible entity shall contribute to the project non-Federal funds in the amount of \$1 for every \$3 awarded under clauses (i) and (ii), except that the Director of the Center may waive or modify such matching requirement in any case where the Director determines that the goals and objectives of this section cannot adequately be carried out unless such requirement is waived.

(B) THE CURES ACCELERATION GRANT AWARDS.—

(i) INITIAL AWARD AMOUNT.—Each award under this subparagraph shall be not more than \$15,000,000 per project for the first fiscal year for which the project is funded, which shall be payable in one payment.

(ii) FUNDING IN SUBSEQUENT FISCAL YEARS.—An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Board the information required under subparagraphs (B) and (C) of paragraph (2). The Director of the Center may fund a project of such eligible entity in an amount not to exceed \$15,000,000 for a

fiscal year subsequent to the initial award under clause (i).

(C) THE CURES ACCELERATION FLEXIBLE RESEARCH AWARDS.—If the Director of the Center determines that the goals and objectives of this section cannot adequately be carried out through a contract, grant, or cooperative agreement, the Director of the Center shall have flexible research authority to use other transactions to fund projects in accordance with the terms and conditions of this section. Awards made under such flexible research authority for a fiscal year shall not exceed 20 percent of the total funds appropriated under subsection (g)(1) for such fiscal year.

(4) SUSPENSION OF AWARDS FOR DEFAULTS, NONCOMPLIANCE WITH PROVISIONS AND PLANS, AND DIVERSION OF FUNDS; REPAYMENT OF FUNDS.—The Director of the Center may suspend the award to any entity upon noncompliance by such entity with provisions and plans under this section or diversion of funds.

(5) AUDITS.—The Director of the Center may enter into agreements with other entities to conduct periodic audits of the projects funded by grants or contracts awarded under this subsection.

(6) CLOSEOUT PROCEDURES.—At the end of a grant or contract period, a recipient shall follow the closeout procedures under section 74.71 of title 45, Code of Federal Regulations (or any successor regulation).

(7) REVIEW.—A determination by the Director of the Center as to whether a drug, device, or biological product is a high need cure (for purposes of subsection (a)(3)) shall not be subject to judicial review.

(f) COMPETITIVE BASIS OF AWARDS.—Any grant, cooperative agreement, or contract awarded under this section shall be awarded on a competitive basis.

(g) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For purposes of carrying out this section, there are authorized to be appropriated \$500,000,000 for fiscal year 2010, and such sums as may be necessary for subsequent fiscal years. Funds appropriated under this section shall be available until expended.

(2) LIMITATION ON USE OF FUNDS OTHERWISE APPROPRIATED.—No funds appropriated under this Act, other than funds appropriated under paragraph (1), may be allocated to the Cures Acceleration Network.

#### OFFICE OF RARE DISEASES

SEC. 481. [287a-1] (a) ESTABLISHMENT.—There is established within the Center an office to be known as the Office of Rare Diseases (in this section referred to as the “Office”), which shall be headed by a Director (in this section referred to as the “Director”), appointed by the Director of the Center.

(b) DUTIES.—

(1) IN GENERAL.—The Director of the Office shall carry out the following:

(A) The Director shall recommend an agenda for conducting and supporting research on rare diseases through the national research institutes and centers. The agenda shall provide for a broad range of research and education activities, including scientific workshops and symposia to identify research opportunities for rare diseases.

(B) The Director shall, with respect to rare diseases, promote coordination and cooperation among the national research institutes and centers and entities whose research is supported by such institutes.

(C) The Director, in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants for regional centers of excellence on rare diseases in accordance with section 481A.

(D) The Director shall promote the sufficient allocation of the resources of the National Institutes of Health for conducting and supporting research on rare diseases.

(E) The Director shall promote and encourage the establishment of a centralized clearinghouse for rare and genetic disease information that will provide understandable information about these diseases to the public, medical professionals, patients and families.

(2) PRINCIPAL ADVISOR REGARDING ORPHAN DISEASES.—With respect to rare diseases, the Director shall serve as the principal advisor to the Director of NIH and shall provide advice to other relevant agencies. The Director shall provide liaison with national and international patient, health and scientific organizations concerned with rare diseases.

(c) DEFINITION.—For purposes of this section, the term “rare disease” means any disease or condition that affects less than 200,000 persons in the United States.

#### RARE DISEASE REGIONAL CENTERS OF EXCELLENCE

SEC. 481A. [287a–2] (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 activi-

ties conducted by other national research institutes, centers and agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

(c) **USES FOR FEDERAL PAYMENTS UNDER COOPERATIVE AGREEMENTS OR GRANTS.**—Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

(3) clinical research and demonstration programs.

(d) **PERIOD OF SUPPORT; ADDITIONAL PERIODS.**—Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

**SEC. 481B. [287a–3] GENERAL CLINICAL RESEARCH CENTERS.**

(a) **GRANTS.**—The Director of the Center shall award grants for the establishment of general clinical research centers to provide the infrastructure for clinical research including clinical research training and career enhancement. Such centers shall support clinical studies and career development in all settings of the hospital or academic medical center involved.

(b) **ACTIVITIES.**—In carrying out subsection (a), the Director of National Institutes of Health shall expand the activities of the general clinical research centers through the increased use of telecommunications and telemedicine initiatives.

**Subpart 2—John E. Fogarty International Center for Advanced Study in the Health Sciences**

**GENERAL PURPOSE**

**SEC. 482. [287b]** The general purpose of the John E. Fogarty International Center for Advanced Study in the Health Sciences is to—

(1) facilitate the assembly of scientists and others in the biomedical, behavioral, and related fields for discussion, study, and research relating to the development of health science internationally;

(2) provide research programs, conferences, and seminars to further international cooperation and collaboration in the life sciences;

(3) provide postdoctorate fellowships for research training in the United States and abroad and promote exchanges of senior scientists between the United States and other countries;

(4) coordinate the activities of the National Institutes of Health concerned with the health sciences internationally; and

(5) receive foreign visitors to the National Institutes of Health.

#### Subpart 4—Office of Dietary Supplements<sup>51</sup>

##### **SEC. 485C. [287c-11] DIETARY SUPPLEMENTS.**

(a) **ESTABLISHMENT.**—The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.

(b) **PURPOSE.**—The purposes of the Office are—

(1) to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and

(2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

(c) **DUTIES.**—The Director of the Office of Dietary Supplements shall—

(1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;

(2) collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine;

(3) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including—

(A) dietary intake regulations;

(B) the safety of dietary supplements;

(C) claims characterizing the relationship between—

(i) dietary supplements; and

(ii)(I) prevention of disease or other health-related conditions; and

(II) maintenance of health; and

(D) scientific issues arising in connection with the labeling and composition of dietary supplements;

(4) compile a database of scientific research on dietary supplements and individual nutrients; and

(5) coordinate funding relating to dietary supplements for the National Institutes of Health.

(d) **DEFINITION.**—As used in this section, the term “dietary supplement” has the meaning given the term in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

<sup>51</sup>Subpart 3 of this part was transferred and redesignated as subpart 19 of part C by section 101(c) of Public Law 109-482.

Subpart 5—National Center for Complementary and Integrative Health

**SEC. 485D. [287c-21] PURPOSE OF CENTER.**

(a) **IN GENERAL.**—The general purposes of the National Center for Complementary and Integrative Health (in this subpart referred to as the “Center”) are the conduct and support of basic and applied research (including both intramural and extramural research), research training, the dissemination of health information, and other programs with respect to identifying, investigating, and validating complementary and integrative health, diagnostic and prevention modalities, disciplines and systems. The Center shall be headed by a director, who shall be appointed by the Secretary. The Director of the Center shall report directly to the Director of NIH.

(b) **ADVISORY COUNCIL.**—The Secretary shall establish an advisory council for the Center in accordance with section 406, except that at least half of the members of the advisory council who are not ex officio members shall include practitioners licensed in one or more of the major systems with which the Center is concerned, and at least 3 individuals representing the interests of individual consumers of complementary and integrative health.

(c) In carrying out subsection (a), the Director of the Center shall, as appropriate, study the integration of new and non-traditional approaches to health care treatment and consumption, including but not limited to non-traditional treatment, diagnostic and prevention systems, modalities, and disciplines.

(d) **APPROPRIATE SCIENTIFIC EXPERTISE AND COORDINATION WITH INSTITUTES AND FEDERAL AGENCIES.**—The Director of the Center, after consultation with the advisory council for the Center and the division of research grants, shall ensure that scientists with appropriate expertise in research on complementary and integrative health are incorporated into the review, oversight, and management processes of all research projects and other activities funded by the Center. In carrying out this subsection, the Director of the Center, as necessary, may establish review groups with appropriate scientific expertise. The Director of the Center shall coordinate efforts with other Institutes and Federal agencies to ensure appropriate scientific input and management.

(e) **EVALUATION OF VARIOUS DISCIPLINES AND SYSTEMS.**—In carrying out subsection (a), the Director of the Center shall identify and evaluate complementary and integrative health, diagnostic and prevention modalities in each of the disciplines and systems with which the Center is concerned, including each discipline and system in which accreditation, national certification, or a State license is available.

(f) **ENSURING HIGH QUALITY, RIGOROUS SCIENTIFIC REVIEW.**—In order to ensure high quality, rigorous scientific review of complementary and alternative, diagnostic and prevention modalities, disciplines and systems, the Director of the Center shall conduct or support the following activities:

- (1) Outcomes research and investigations.
- (2) Epidemiological studies.
- (3) Health services research.
- (4) Basic science research.



(5) Clinical trials.

(6) Other appropriate research and investigational activities.

The Director of NIH, in coordination with the Director of the Center, shall designate specific personnel in each Institute to serve as full-time liaisons with the Center in facilitating appropriate coordination and scientific input.

(g) DATA SYSTEM; INFORMATION CLEARINGHOUSE.—

(1) DATA SYSTEM.—The Director of the Center shall establish a bibliographic system for the collection, storage, and retrieval of worldwide research relating to complementary and integrative health, diagnostic and prevention modalities, disciplines and systems. Such a system shall be regularly updated and publicly accessible.

(2) CLEARINGHOUSE.—The Director of the Center shall establish an information clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of integrative health treatment, diagnostic and prevention practices by health professionals, patients, industry, and the public.

(h) RESEARCH CENTERS.—The Director of the Center, after consultation with the advisory council for the Center, shall provide support for the development and operation of multipurpose centers to conduct research and other activities described in subsection (a) with respect to complementary and integrative health, diagnostic and prevention modalities, disciplines and systems. The provision of support for the development and operation of such centers shall include accredited complementary and integrative health research and education facilities.

(i) AVAILABILITY OF RESOURCES.—After consultation with the Director of the Center, the Director of NIH shall ensure that resources of the National Institutes of Health, including laboratory and clinical facilities, fellowships (including research training fellowship and junior and senior clinical fellowships), and other resources are sufficiently available to enable the Center to appropriately and effectively carry out its duties as described in subsection (a). The Director of NIH, in coordination with the Director of the Center, shall designate specific personnel in each Institute to serve as full-time liaisons with the Center in facilitating appropriate coordination and scientific input.

(j) AVAILABILITY OF APPROPRIATIONS.—Amounts appropriated to carry out this section for fiscal year 1999 are available for obligation through September 30, 2001. Amounts appropriated to carry out this section for fiscal year 2000 are available for obligation through September 30, 2001.

#### PART F—RESEARCH ON WOMEN'S HEALTH

##### SEC. 486. [287d] OFFICE OF RESEARCH ON WOMEN'S HEALTH.

(a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Research on Women's Health (in this part referred to as the "Office"). The Office shall be headed by a director, who shall be appointed by the Director of NIH and who shall report directly to the Director.

(b) PURPOSE.—The Director of the Office shall—

(1) identify projects of research on women's health that should be conducted or supported by the national research institutes;

(2) identify multidisciplinary research relating to research on women's health that should be so conducted or supported;

(3) carry out paragraphs (1) and (2) with respect to the aging process in women, with priority given to menopause;

(4) promote coordination and collaboration among entities conducting research identified under any of paragraphs (1) through (3);

(5) encourage the conduct of such research by entities receiving funds from the national research institutes;

(6) recommend an agenda for conducting and supporting such research;

(7) promote the sufficient allocation of the resources of the national research institutes for conducting and supporting such research;

(8) assist in the administration of section 492B with respect to the inclusion of women as subjects in clinical research; and

(9) prepare the report required in section 486B.

(c) COORDINATING COMMITTEE.—

(1) In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (in this subsection referred to as the "Coordinating Committee").

(2) The Coordinating Committee shall be composed of the Directors of the national research institutes (or the senior-level staff designees of the Directors).

(3) The Director of the Office shall serve as the chair of the Coordinating Committee.

(4) With respect to research on women's health, the Coordinating Committee shall assist the Director of the Office in—

(A) identifying the need for such research, and making an estimate each fiscal year of the funds needed to adequately support the research;

(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities;

(C) supporting the development of methodologies to determine the circumstances in which obtaining data specific to women (including data relating to the age of women and the membership of women in ethnic or racial groups) is an appropriate function of clinical trials of treatments and therapies;

(D) supporting the development and expansion of clinical trials of treatments and therapies for which obtaining such data has been determined to be an appropriate function; and

(E) encouraging the national research institutes to conduct and support such research, including such clinical trials.

## (d) ADVISORY COMMITTEE.—

(1) In carrying out subsection (b), the Director of the Office shall establish an advisory committee to be known as the Advisory Committee on Research on Women's Health (in this subsection referred to as the "Advisory Committee").

(2) The Advisory Committee shall be composed of no fewer than 12, and not more than 18 individuals, who are not officers or employees of the Federal Government. The Director of NIH shall make appointments to the Advisory Committee from among physicians, practitioners, scientists, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on research on women's health. A majority of the members of the Advisory Committee shall be women.

(3) The Director of the Office shall serve as the chair of the Advisory Committee.

## (4) The Advisory Committee shall—

(A) advise the Director of the Office on appropriate research activities to be undertaken by the national research institutes with respect to—

- (i) research on women's health;
- (ii) research on gender differences in clinical drug trials, including responses to pharmacological drugs;
- (iii) research on gender differences in disease etiology, course, and treatment;
- (iv) research on obstetrical and gynecological health conditions, diseases, and treatments, including preventable maternal mortality and severe maternal morbidity; and

(v) research on women's health conditions which require a multidisciplinary approach;

(B) report to the Director of the Office on such research;

(C) provide recommendations to such Director regarding activities of the Office (including recommendations on the development of the methodologies described in subsection (c)(4)(C) and recommendations on priorities in carrying out research described in subparagraph (A)); and

(D) assist in monitoring compliance with section 492B regarding the inclusion of women in clinical research.

(5)(A) The Advisory Committee shall prepare a biennial report describing the activities of the Committee, including findings made by the Committee regarding—

- (i) compliance with section 492B;
- (ii) the extent of expenditures made for research on women's health by the agencies of the National Institutes of Health; and
- (iii) the level of funding needed for such research.

(B) The report required in subparagraph (A) shall be submitted to the Director of NIH for inclusion in the report required in section 403.

(e) REPRESENTATION OF WOMEN AMONG RESEARCHERS.—The Secretary, acting through the Assistant Secretary for Personnel and in collaboration with the Director of the Office, shall determine

the extent to which women are represented among senior physicians and scientists of the national research institutes and among physicians and scientists conducting research with funds provided by such institutes, and as appropriate, carry out activities to increase the extent of such representation.

(f) DEFINITIONS.—For purposes of this part:

(1) The term “women’s health conditions”, with respect to women of all age, ethnic, and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)—

(A) unique to, more serious, or more prevalent in women;

(B) for which the factors of medical risk or types of medical intervention are different for women, or for which it is unknown whether such factors or types are different for women; or

(C) with respect to which there has been insufficient clinical research involving women as subjects or insufficient clinical data on women.

(2) The term “research on women’s health” means research on women’s health conditions, including research on preventing such conditions.

**SEC. 486A. [287d-1] NATIONAL DATA SYSTEM AND CLEARINGHOUSE ON RESEARCH ON WOMEN’S HEALTH.**

(a) DATA SYSTEM.—

(1) The Director of NIH, in consultation with the Director of the Office and the Director of the National Library of Medicine, shall establish a data system for the collection, storage, analysis, retrieval, and dissemination of information regarding research on women’s health that is conducted or supported by the national research institutes. Information from the data system shall be available through information systems available to health care professionals and providers, researchers, and members of the public.

(2) The data system established under paragraph (1) shall include a registry of clinical trials of experimental treatments that have been developed for research on women’s health. Such registry shall include information on subject eligibility criteria, sex, age, ethnicity or race, and the location of the trial site or sites. Principal investigators of such clinical trials shall provide this information to the registry within 30 days after it is available. Once a trial has been completed, the principal investigator shall provide the registry with information pertaining to the results, including potential toxicities or adverse effects associated with the experimental treatment or treatments evaluated.

(b) CLEARINGHOUSE.—The Director of NIH, in consultation with the Director of the Office and with the National Library of Medicine, shall establish, maintain, and operate a program to provide information on research and prevention activities of the national research institutes that relate to research on women’s health.

**SEC. 486B. [287d-2] BIENNIAL REPORT.**

(a) **IN GENERAL.**—With respect to research on women’s health, the Director of the Office shall, not later than February 1, 1994, and biennially thereafter, prepare a report—

(1) describing and evaluating the progress made during the preceding 2 fiscal years in research and treatment conducted or supported by the National Institutes of Health;

(2) describing and analyzing the professional status of women physicians and scientists of such Institutes, including the identification of problems and barriers regarding advancements;

(3) summarizing and analyzing expenditures made by the agencies of such Institutes (and by such Office) during the preceding 2 fiscal years; and

(4) making such recommendations for legislative and administrative initiatives as the Director of the Office determines to be appropriate.

(b) **INCLUSION IN BIENNIAL REPORT OF DIRECTOR OF NIH.**—The Director of the Office shall submit each report prepared under subsection (a) to the Director of NIH for inclusion in the report submitted to the President and the Congress under section 403.

**PART G—AWARDS AND TRAINING****RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARDS**<sup>52</sup>

**SEC. 487. [288]** (a)(1) The Secretary shall—

(A) provide Ruth L. Kirschstein National Research Service Awards<sup>53</sup> for—

(i) biomedical and behavioral research at the National Institutes of Health in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the National Institutes of Health and Administration<sup>54</sup> are directed;

(ii) training at the National Institutes of Health and at the Administration<sup>54</sup> of individuals to undertake such research;

(iii) biomedical and behavioral research and health services research (including research in primary medical care) at public and nonprofit private entities; and

(iv) pre-doctoral and post-doctoral training at public and private institutions of individuals to undertake biomedical and behavioral research;

(B) make grants to public and nonprofit private institutions to enable such institutions to make Ruth L. Kirschstein National Research Service Awards for research (and training to undertake biomedical and behavioral research) in the mat-

<sup>52</sup>The typeface is so in law. See section 804(b) of Public Law 107–206 (116 Stat. 874).

<sup>53</sup>Section 804(c) of Public Law 107–206 (116 Stat. 874) provides as follows:

“(c) Any reference in any law (other than this Act), regulation, document, record, map, or other paper of the United States to ‘National Research Service Awards’ shall be considered to be a reference to ‘Ruth L. Kirschstein National Research Service Awards’.”

<sup>54</sup>So in law. Section 163(b)(4)(B) of Public Law 102–321 (106 Stat. 376) struck a reference in paragraph (1) to the former Alcohol, Drug Abuse, and Mental Health Administration, but failed to conform related references.

ters described in subparagraph (A)(i) to individuals selected by such institutions; and

(C) provide contracts for scholarships and loan repayments in accordance with sections 487D and 487E, subject to providing not more than an aggregate 50 such contracts during the fiscal years 1994 through 1996.

A reference in this subsection to the National Institutes of Health shall be considered to include the institutes, agencies, divisions, and bureaus included in the National Institutes of Health or under the Administration,<sup>54</sup> as the case may be.

(2) Ruth L. Kirschstein National Research Service Awards may not be used to support residency training of physicians and other health professionals.

(3) In awarding Ruth L. Kirschstein National Research Service Awards under this section, the Secretary shall take account of the Nation's overall need for biomedical research personnel by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

(4) The Secretary shall carry out paragraph (1) in a manner that will result in the recruitment of women, and individuals from disadvantaged backgrounds (including racial and ethnic minorities), into fields of biomedical or behavioral research and in the provision of research training to women and such individuals.

(b)(1) No Ruth L. Kirschstein National Research Service Award may be made by the Secretary to any individual unless—

(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c); and

(C) in the case of a Ruth L. Kirschstein National Research Service Award for a purpose described in subsection (a)(1)(A)(iii), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institution at which the research or training under the award will be conducted.

An application for an award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

(2) The making of grants under subsection (a)(1)(B) for Ruth L. Kirschstein National Research Service Awards shall be subject to review and approval by the appropriate advisory councils within the Department of Health and Human Services (A) whose activities relate to the research or training under the awards, or (B) for the entity at which such research or training will be conducted.

(3) No grant may be made under subsection (a)(1)(B) unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section (other than paragraph (1)), Ruth L. Kirschstein National Research Service Awards made under a grant under subsection (a)(1)(B)

shall be made in accordance with such regulations as the Secretary shall prescribe.

(4) The period of any Ruth L. Kirschstein National Research Service Award made to any individual under subsection (a) may not exceed—

(A) five years in the aggregate for pre-doctoral training; and

(B) three years in the aggregate for post-doctoral training; unless the Secretary for good cause shown waives the application of such limit to such individual.

(5) Ruth L. Kirschstein National Research Service Awards shall provide for such stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), adjusted periodically to reflect increases in the cost of living, for the recipients of the awards as the Secretary may deem necessary. A Ruth L. Kirschstein National Research Service Award made to an individual for research or research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

(c)(1) Each individual who is awarded a Ruth L. Kirschstein National Research Service Award for postdoctoral research training shall, in accordance with paragraph (3), engage in research training, research, or teaching that is health-related (or any combination thereof) for the period specified in paragraph (2). Such period shall be served in accordance with the usual patterns of scientific employment.

(2)(A) The period referred to in paragraph (1) is 12 months, or one month for each month for which the individual involved receives a Ruth L. Kirschstein National Research Service Award for postdoctoral research training, whichever is less.

(B) With respect to postdoctoral research training, in any case in which an individual receives a Ruth L. Kirschstein National Research Service Award for more than 12 months, the 13th month and each subsequent month of performing activities under the Award shall be considered to be activities engaged in toward satisfaction of the requirement established in paragraph (1) regarding a period of service.

(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's award, as the Secretary shall by regulation prescribe. The Secretary shall by regulation prescribe the type of research and teaching in which an individual may engage to comply with such requirement and such other requirements respecting research and teaching as the Secretary considers appropriate.

(4)(A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph

(3), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A = \Phi \left( \frac{t-s}{t} \right)$$

in which “A” is the amount the United States is entitled to recover; “Φ” is the sum of the total amount paid under one or more Ruth L. Kirschstein National Research Service Awards to such individual; “t” is the total number of months in such individual’s service obligation; and “s” is the number of months of such obligation served by such individual in accordance with paragraphs (1) and (2) of this subsection.

(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any Ruth L. Kirschstein National Research Service Award is paid, there shall accrue to the United States interest on such amount at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount.

(5)(A) Any obligation of an individual under paragraph (1) shall be canceled upon the death of such individual.

(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve substantial hardship to such individual or would be against equity and good conscience.

#### INTRAMURAL LOAN REPAYMENT PROGRAM<sup>55</sup>

SEC. 487A. [288–1] (a) IN GENERAL.—The Director of the National Institutes of Health shall, as appropriate and based on work-force and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2)) of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the National Institutes of Health, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than \$50,000 of the principal and interest of the educational loans of such health professionals.

(b) SUBCATEGORIES OF RESEARCH.—

(1) IN GENERAL.—In carrying out the program under subsection (a), the Director of the National Institutes of Health—

(A) shall continue to focus on—

(i) general research;

<sup>55</sup>The font/style of the section heading shown above conforms with the style of the original section heading for section 487A in all small caps centered heading. See typeface for the amendment made by section 2022(a)(1) of Public Law 114–255.



(ii) research on acquired immune deficiency syndrome; and

(iii) clinical research conducted by appropriately qualified health professional who are from disadvantaged backgrounds; and

(B) may focus on an area of emerging scientific or workforce need.

(2) ELIMINATION OR ESTABLISHMENT OF SUBCATEGORIES.—

The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

(c) LIMITATION.—The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director).

(d) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

(e) AVAILABILITY OF APPROPRIATIONS.—Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which such amounts are made available.

#### EXTRAMURAL LOAN REPAYMENT PROGRAM<sup>56</sup>

SEC. 487B. [288–2] (a) IN GENERAL.—The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2)), of entering into contracts with qualified health professionals under which such health professionals agree to conduct research in consideration of the Federal Government agreeing to repay, for each year of such research, not more than \$50,000 of the principal and interest of the educational loans of such health professionals.

(b) SUBCATEGORIES OF RESEARCH.—

(1) IN GENERAL.—In carrying out the program under subsection (a), the Director of the National Institutes of Health—

(A) shall continue to focus on—

(i) contraception or infertility research;

<sup>56</sup>The font/style of the section heading shown above conforms with the style of the original section heading for section 487B in all small caps centered heading. See typeface for the amendment made by section 2022(b)(1) of Public Law 114–255.

- (ii) pediatric research, including pediatric pharmacological research;
- (iii) minority health disparities research;
- (iv) clinical research; and
- (v) clinical research conducted by appropriately qualified health professional who are from disadvantaged backgrounds; and

(B) may focus on an area of emerging scientific or workforce need.

(2) ELIMINATION OR ESTABLISHMENT OF SUBCATEGORIES.—

The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

(c) LIMITATION.—The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director).

(d) APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with subsection (a) of this section, apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

(e) AVAILABILITY OF APPROPRIATIONS.—Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were made available.

【Section 487C was repealed by section 2022(c)(2) of Public Law 114–255.】

UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS  
NEEDED BY NATIONAL RESEARCH INSTITUTES

SEC. 487D. 【288–4】 (a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH, may carry out a program of entering into contracts with individuals described in paragraph (2) under which—

(A) the Director of NIH agrees to provide to the individuals scholarships for pursuing, as undergraduates at accredited institutions of higher education, academic programs appropriate for careers in professions needed by the National Institutes of Health; and

(B) the individuals agree to serve as employees of the National Institutes of Health, for the period described in subsection (c), in positions that are needed by the National Institutes of Health and for which the individuals are qualified.

(2) INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS.—The individuals referred to in paragraph (1) are individuals who—

(A) are enrolled or accepted for enrollment as full-time undergraduates at accredited institutions of higher education; and

(B) are from disadvantaged backgrounds.

(b) FACILITATION OF INTEREST OF STUDENTS IN CAREERS AT NATIONAL INSTITUTES OF HEALTH.—In providing employment to individuals pursuant to contracts under subsection (a)(1), the Director of NIH shall carry out activities to facilitate the interest of the individuals in pursuing careers as employees of the National Institutes of Health.

(c) PERIOD OF OBLIGATED SERVICE.—

(1) DURATION OF SERVICE.—For purposes of subparagraph (B) of subsection (a)(1), the period of service for which an individual is obligated to serve as an employee of the National Institutes of Health is, subject to paragraph (2)(A), 12 months for each academic year for which the scholarship under such subsection is provided.

(2) SCHEDULE FOR SERVICE.—

(A) Subject to subparagraph (B), the Director of NIH may not provide a scholarship under subsection (a) unless the individual applying for the scholarship agrees that—

(i) the individual will serve as an employee of the National Institutes of Health full-time for not less than 10 consecutive weeks of each year during which the individual is attending the educational institution involved and receiving such a scholarship;

(ii) the period of service as such an employee that the individual is obligated to provide under clause (i) is in addition to the period of service as such an employee that the individual is obligated to provide under subsection (a)(1)(B); and

(iii) not later than 60 days after obtaining the educational degree involved, the individual will begin serving full-time as such an employee in satisfaction of the period of service that the individual is obligated to provide under subsection (a)(1)(B).

(B) The Director of NIH may defer the obligation of an individual to provide a period of service under subsection (a)(1)(B), if the Director determines that such a deferral is appropriate.

(3) APPLICABILITY OF CERTAIN PROVISIONS RELATING TO APPOINTMENT AND COMPENSATION.—For any period in which an individual provides service as an employee of the National Institutes of Health in satisfaction of the obligation of the individual under subsection (a)(1)(B) or paragraph (2)(A)(i), the individual may be appointed as such an employee without regard to the provisions of title 5, United States Code, relating to appointment and compensation.

(d) PROVISIONS REGARDING SCHOLARSHIP.—

(1) APPROVAL OF ACADEMIC PROGRAM.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless—

(A) the individual applying for the scholarship has submitted to the Director a proposed academic program for the year and the Director has approved the program; and

(B) the individual agrees that the program will not be altered without the approval of the Director.

(2) ACADEMIC STANDING.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless the individual applying for the scholarship agrees to maintain an acceptable level of academic standing, as determined by the educational institution involved in accordance with regulations issued by the Secretary.

(3) LIMITATION ON AMOUNT.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year in an amount exceeding \$20,000.

(4) AUTHORIZED USES.—A scholarship provided under subsection (a) may be expended only for tuition expenses, other reasonable educational expenses, and reasonable living expenses incurred in attending the school involved.

(5) CONTRACT REGARDING DIRECT PAYMENTS TO INSTITUTION.—In the case of an institution of higher education with respect to which a scholarship under subsection (a) is provided, the Director of NIH may enter into a contract with the institution under which the amounts provided in the scholarship for tuition and other educational expenses are paid directly to the institution.

(e) PENALTIES FOR BREACH OF SCHOLARSHIP CONTRACT.—The provisions of section 338E shall apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

(f) REQUIREMENT OF APPLICATION.—The Director of NIH may not provide a scholarship under subsection (a) unless an application for the scholarship is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

(g) AVAILABILITY OF AUTHORIZATION OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for scholarships under this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

#### VISITING SCIENTIST AWARDS

SEC. 488. [288a] (a) The Secretary may make awards (hereafter in this section referred to as “Visiting Scientist Awards”) to outstanding scientists who agree to serve as visiting scientists at institutions of postsecondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists

from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe.

STUDIES RESPECTING BIOMEDICAL AND BEHAVIORAL RESEARCH  
PERSONNEL

SEC. 489. [288b] (a) The Secretary shall, in accordance with subsection (b), arrange for the conduct of a continuing study to—

(1) establish (A) the Nation's overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel;

(2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this Act, at or through national research institutes under the National Institutes of Health, and (B) other current training programs available for the training of such personnel;

(3) identify the kinds of research positions available to and held by individuals completing such programs;

(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

(b)(1) The Secretary shall request the National Academy of Sciences to conduct the study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of such study.

(2) If the National Academy of Sciences is unwilling to conduct such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in subsection (c).

(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of NIH.

(c) A report on the results of the study required under subsection (a) shall be submitted by the Secretary to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least once every four years.

## PART H—GENERAL PROVISIONS

### INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

SEC. 491. [289] (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an “Institutional Review Board”) to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such violations.

### PEER REVIEW REQUIREMENTS

SEC. 492. [289a] (a)(1) The Secretary, acting through the Director of NIH, shall by regulation require appropriate technical and scientific peer review of—

(A) applications made for grants and cooperative agreements under this Act for biomedical and behavioral research; and

(B) applications made for biomedical and behavioral research and development contracts to be administered through the National Institutes of Health.

(2) Regulations promulgated under paragraph (1) shall require that the review of applications made for grants, contracts, and cooperative agreements required by the regulations be conducted—

(A) to the extent practical, in a manner consistent with the system for technical and scientific peer review applicable on the date of the date of enactment of the Health Research Ex-

tension Act of 1985 to grants under this Act for biomedical and behavioral research, and

(B) to the extent practical, by technical and scientific peer review groups performing such review on or before such date, and shall authorize such review to be conducted by groups appointed under sections 402(b)(16) and 405(c)(3).

(b) The Director of NIH shall establish procedures for periodic technical and scientific peer review of research at the National Institutes of Health. Such procedures shall require that—

(1) the reviewing entity be provided a written description of the research to be reviewed, and

(2) the reviewing entity provide the advisory council of the national research institute involved with such description and the results of the review by the entity, and shall authorize such review to be conducted by groups appointed under sections 402(b)(6) and 405(c)(3).

(c)(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding compliance with section 492B.

(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 492B, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.

#### CERTAIN PROVISIONS REGARDING REVIEW AND APPROVAL OF PROPOSALS FOR RESEARCH

SEC. 492A. [289a-1] (a) REVIEW AS PRECONDITION TO RESEARCH.—

(1) PROTECTION OF HUMAN RESEARCH SUBJECTS.—

(A) In the case of any application submitted to the Secretary for financial assistance to conduct research, the Secretary may not approve or fund any application that is subject to review under section 491(a) by an Institutional Review Board unless the application has undergone review in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting such review.

(B) In the case of research that is subject to review under procedures established by the Secretary for the protection of human subjects in clinical research conducted by the National Institutes of Health, the Secretary may not authorize the conduct of the research unless the research has, pursuant to such procedures, been recommended for approval.

(2) PEER REVIEW.—In the case of any proposal for the National Institutes of Health to conduct or support research, the Secretary may not approve or fund any proposal that is subject to technical and scientific peer review under section 492 unless the proposal has undergone such review in accordance with

such section and has been recommended for approval by a majority of the members of the entity conducting such review, and unless a majority of the voting members of the appropriate advisory council under section 406, or as applicable, of the advisory council under section 402(k), has recommended the proposal for approval.

(b) ETHICAL REVIEW OF RESEARCH.—

(1) PROCEDURES REGARDING WITHHOLDING OF FUNDS.—If research has been recommended for approval for purposes of subsection (a), the Secretary may not withhold funds for the research because of ethical considerations unless—

(A) the Secretary convenes an advisory board in accordance with paragraph (5) to study such considerations; and

(B)(i) the majority of the advisory board recommends that, because of such considerations, the Secretary withhold funds for the research; or

(ii) the majority of such board recommends that the Secretary not withhold funds for the research because of such considerations, but the Secretary finds, on the basis of the report submitted under paragraph (5)(B)(ii), that the recommendation is arbitrary and capricious.

(2) RULES OF CONSTRUCTION.—Paragraph (1) may not be construed as prohibiting the Secretary from withholding funds for research on the basis of—

(A) the inadequacy of the qualifications of the entities that would be involved with the conduct of the research (including the entity that would directly receive the funds from the Secretary), subject to the condition that, with respect to the process of review through which the research was recommended for approval for purposes of subsection (a), all findings regarding such qualifications made in such process are conclusive; or

(B) the priorities established by the Secretary for the allocation of funds among projects of research that have been so recommended.

(3) APPLICABILITY.—The limitation established in paragraph (1) regarding the authority to withhold funds because of ethical considerations shall apply without regard to whether the withholding of funds on such basis is characterized as a disapproval, a moratorium, a prohibition, or other characterization.

(4) PRELIMINARY MATTERS REGARDING USE OF PROCEDURES.—

(A) If the Secretary makes a determination that an advisory board should be convened for purposes of paragraph (1), the Secretary shall, through a statement published in the Federal Register, announce the intention of the Secretary to convene such a board.

(B) A statement issued under subparagraph (A) shall include a request that interested individuals submit to the Secretary recommendations specifying the particular individuals who should be appointed to the advisory board in-



volved. The Secretary shall consider such recommendations in making appointments to the board.

(C) The Secretary may not make appointments to an advisory board under paragraph (1) until the expiration of the 30-day period beginning on the date on which the statement required in subparagraph (A) is made with respect to the board.

(5) ETHICS ADVISORY BOARDS.—

(A) Any advisory board convened for purposes of paragraph (1) shall be known as an ethics advisory board (in this paragraph referred to as an “ethics board”).

(B)(i) An ethics board shall advise, consult with, and make recommendations to the Secretary regarding the ethics of the project of biomedical or behavioral research with respect to which the board has been convened.

(ii) Not later than 180 days after the date on which the statement required in paragraph (4)(A) is made with respect to an ethics board, the board shall submit to the Secretary, and to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report describing the findings of the board regarding the project of research involved and making a recommendation under clause (i) of whether the Secretary should or should not withhold funds for the project. The report shall include the information considered in making the findings.

(C) An ethics board shall be composed of no fewer than 14, and no more than 20, individuals who are not officers or employees of the United States. The Secretary shall make appointments to the board from among individuals with special qualifications and competence to provide advice and recommendations regarding ethical matters in biomedical and behavioral research. Of the members of the board—

- (i) no fewer than 1 shall be an attorney;
- (ii) no fewer than 1 shall be an ethicist;
- (iii) no fewer than 1 shall be a practicing physician;
- (iv) no fewer than 1 shall be a theologian; and
- (v) no fewer than one-third, and no more than one-half, shall be scientists with substantial accomplishments in biomedical or behavioral research.

(D) The term of service as a member of an ethics board shall be for the life of the board. If such a member does not serve the full term of such service, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(E) A member of an ethics board shall be subject to removal from the board by the Secretary for neglect of duty or malfeasance or for other good cause shown.

(F) The Secretary shall designate an individual from among the members of an ethics board to serve as the chair of the board.

(G) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall conduct inquiries and hold public hearings.

(H) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall have access to all relevant information possessed by the Department of Health and Human Services, or available to the Secretary from other agencies.

(I) Members of an ethics board shall receive compensation for each day engaged in carrying out the duties of the board, including time engaged in traveling for purposes of such duties. Such compensation may not be provided in an amount in excess of the maximum rate of basic pay payable for GS-18 of the General Schedule.

(J) The Secretary, acting through the Director of the National Institutes of Health, shall provide to each ethics board reasonable staff and assistance to carry out the duties of the board.

(K) An ethics board shall terminate 30 days after the date on which the report required in subparagraph (B)(ii) is submitted to the Secretary and the congressional committees specified in such subparagraph.

(6) DEFINITION.—For purposes of this subsection, the term “ethical considerations” means considerations as to whether the nature of the research involved is such that it is unethical to conduct or support the research.

#### INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

##### SEC. 492B. [289a-2] (a) REQUIREMENT OF INCLUSION.—

(1) IN GENERAL.—In conducting or supporting clinical research for purposes of this title, the Director of NIH shall, subject to subsection (b), ensure that—

(A) women are included as subjects in each project of such research; and

(B) members of minority groups are included as subjects in such research.

(2) OUTREACH REGARDING PARTICIPATION AS SUBJECTS.—The Director of NIH, in consultation with the Director of the Office of Research on Women’s Health and the Director of the Office of Research on Minority Health, shall conduct or support outreach programs for the recruitment of women and members of minority groups as subjects in projects of clinical research.

##### (3) STRATEGIC PLANNING.—

(A) IN GENERAL.—The directors of the national institutes and national centers shall consult at least once annually with the Director of the National Institute on Minority Health and Health Disparities and the Director of the Office of Research on Women’s Health regarding objectives of the national institutes and national centers to ensure that future activities by such institutes and centers take into account women and minorities and are focused on reducing health disparities.

(B) STRATEGIC PLANS.—Any strategic plan issued by a national institute or national center shall include details on the objectives described in subparagraph (A).

(b) INAPPLICABILITY OF REQUIREMENT.—The requirement established in subsection (a) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

(1) is inappropriate with respect to the health of the subjects;

(2) is inappropriate with respect to the purpose of the research; or

(3) is inappropriate under such other circumstances as the Director of NIH may designate.

(c) DESIGN OF CLINICAL TRIALS.—

(1) IN GENERAL.—In the case of any clinical trial in which women or members of minority groups will under subsection (a) be included as subjects, the Director of NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

(2) REPORTING REQUIREMENTS.—For any new and competing project of clinical research subject to the requirements under this section that receives a grant award 1 year after the date of enactment of the 21st Century Cures Act, or any date thereafter, for which a valid analysis is provided under paragraph (1)—

(A) and which is an applicable clinical trial as defined in section 402(j), the entity conducting such clinical research shall submit the results of such valid analysis to the clinical trial registry data bank expanded under section 402(j)(3), and the Director of the National Institutes of Health shall, as appropriate, consider whether such entity has complied with the reporting requirement described in this subparagraph in awarding any future grant to such entity, including pursuant to section 402(j)(5)(A)(ii) when applicable; and

(B) the Director of the National Institutes of Health shall encourage the reporting of the results of such valid analysis described in paragraph (1) through any additional means determined appropriate by the Director.

(d) GUIDELINES.—

(1) IN GENERAL.—Subject to paragraph (2), the Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall establish guidelines regarding the requirements of this section. The guidelines shall include guidelines regarding—

(A) the circumstances under which the inclusion of women and minorities as subjects in projects of clinical research is inappropriate for purposes of subsection (b);

(B) the manner in which clinical trials are required to be designed and carried out for purposes of subsection (c); and

(C) the operation of outreach programs under subsection (a).

(2) CERTAIN PROVISIONS.—With respect to the circumstances under which the inclusion of women or members of minority groups (as the case may be) as subjects in a project of clinical research is inappropriate for purposes of subsection (b), the following applies to guidelines under paragraph (1):

(A)(i) In the case of a clinical trial, the guidelines shall provide that the costs of such inclusion in the trial is not a permissible consideration in determining whether such inclusion is inappropriate.

(ii) In the case of other projects of clinical research, the guidelines shall provide that the costs of such inclusion in the project is not a permissible consideration in determining whether such inclusion is inappropriate unless the data regarding women or members of minority groups, respectively, that would be obtained in such project (in the event that such inclusion were required) have been or are being obtained through other means that provide data of comparable quality.

(B) In the case of a clinical trial, the guidelines may provide that such inclusion in the trial is not required if there is substantial scientific data demonstrating that there is no significant difference between—

(i) the effects that the variables to be studied in the trial have on women or members of minority groups, respectively; and

(ii) the effects that the variables have on the individuals who would serve as subjects in the trial in the event that such inclusion were not required.

(e) DATE CERTAIN FOR GUIDELINES; APPLICABILITY.—

(1) DATE CERTAIN.—The guidelines required in subsection (d) shall be established and published in the Federal Register not later than 180 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993.

(2) APPLICABILITY.—For fiscal year 1995 and subsequent fiscal years, the Director of NIH may not approve any proposal of clinical research to be conducted or supported by any agency of the National Institutes of Health unless the proposal specifies the manner in which the research will comply with this section.

(f) REPORTS BY ADVISORY COUNCILS.—

(1) IN GENERAL.—The advisory council of each national research institute shall prepare triennial reports describing the manner in which the institute has complied with this section. Each such report shall be submitted to the Director of the institute involved for inclusion in the triennial report under section 403.

(2) CONTENTS.—Each triennial report prepared by an advisory council of each national research institute as described in paragraph (1) shall include each of the following:

(A) The number of women included as subjects, and the proportion of subjects that are women, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease, and accounting for single-sex studies.

(B) The number of members of minority groups included as subjects, and the proportion of subjects that are members of minority groups, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease and accounting for single-race and single-ethnicity studies.

(C) For the applicable reporting period, the number of projects of clinical research that include women and members of minority groups and that—

(i) have been completed during such reporting period; and

(ii) are being carried out during such reporting period and have not been completed.

(D) The number of studies completed during the applicable reporting period for which reporting has been submitted in accordance with subsection (c)(2)(A).

(g) DEFINITIONS.—For purposes of this section:

(1) The term “project of clinical research” includes a clinical trial.

(2) The term “minority group” includes subpopulations of minority groups. The Director of NIH shall, through the guidelines established under subsection (d), define the terms “minority group” and “subpopulation” for purposes of the preceding sentence.

#### OFFICE OF RESEARCH INTEGRITY

SEC. 493. [289b] (a) IN GENERAL.—

(1) ESTABLISHMENT OF OFFICE.—Not later than 90 days after the date of enactment of this section, the Secretary shall establish an office to be known as the Office of Research Integrity (referred to in this section as the “Office”), which shall be established as an independent entity in the Department of Health and Human Services.

(2) APPOINTMENT OF DIRECTOR.—The Office shall be headed by a Director, who shall be appointed by the Secretary, be experienced and specially trained in the conduct of research, and have experience in the conduct of investigations of research misconduct. The Secretary shall carry out this section acting through the Director of the Office. The Director shall report to the Secretary.

(3) DEFINITIONS.—

(A) The Secretary shall by regulation establish a definition for the term “research misconduct” for purposes of this section.

(B) For purposes of this section, the term “financial assistance” means a grant, contract, or cooperative agreement.

(b) EXISTENCE OF ADMINISTRATIVE PROCESSES AS CONDITION OF FUNDING FOR RESEARCH.—The Secretary shall by regulation require that each entity that applies for financial assistance under this Act for any project or program that involves the conduct of biomedical or behavioral research submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity;

(2) an agreement that the entity will report to the Director any investigation of alleged research misconduct in connection with projects for which funds have been made available under this Act that appears substantial; and

(3) an agreement that the entity will comply with regulations issued under this section.

(c) PROCESS FOR RESPONSE OF DIRECTOR.—The Secretary shall by regulation establish a process to be followed by the Director for the prompt and appropriate—

(1) response to information provided to the Director respecting research misconduct in connection with projects for which funds have been made available under this Act;

(2) receipt of reports by the Director of such information from recipients of funds under this Act;

(3) conduct of investigations, when appropriate; and

(4) taking of other actions, including appropriate remedies, with respect to such misconduct.

(d) MONITORING BY DIRECTOR.—The Secretary shall by regulation establish procedures for the Director to monitor administrative processes and investigations that have been established or carried out under this section.

(e) PROTECTION OF WHISTLEBLOWERS.—

(1) IN GENERAL.—In the case of any entity required to establish administrative processes under subsection (b), the Secretary shall by regulation establish standards for preventing, and for responding to the occurrence of retaliation by such entity, its officials or agents, against an employee in the terms and conditions of employment in response to the employee having in good faith—

(A) made an allegation that the entity, its officials or agents, has engaged in or failed to adequately respond to an allegation of research misconduct; or

(B) cooperated with an investigation of such an allegation.

(2) MONITORING BY SECRETARY.—The Secretary shall by regulation establish procedures for the Director to monitor the implementation of the standards established by an entity under paragraph (1) for the purpose of determining whether the procedures have been established, and are being utilized, in accordance with the standards established under such paragraph.

(3) NONCOMPLIANCE.—The Secretary shall by regulation establish remedies for noncompliance by an entity, its officials or agents, which has engaged in retaliation in violation of the standards established under paragraph (1). Such remedies may include termination of funding provided by the Secretary for such project or recovery of funding being provided by the Secretary for such project, or other actions as appropriate.

PROTECTION AGAINST FINANCIAL CONFLICTS OF INTEREST IN CERTAIN PROJECTS OF RESEARCH

SEC. 493A. [289b–1] (a) ISSUANCE OF REGULATIONS.—The Secretary shall by regulation define the specific circumstances that constitute the existence of a financial interest in a project on the part of an entity or individual that will, or may be reasonably expected to, create a bias in favor of obtaining results in such project that are consistent with such financial interest. Such definition shall apply uniformly to each entity or individual conducting a research project under this Act. In the case of any entity or individual receiving assistance from the Secretary for a project of research described in subsection (b), the Secretary shall by regulation establish standards for responding to, including managing, reducing, or eliminating, the existence of such a financial interest. The entity may adopt individualized procedures for implementing the standards.

(b) RELEVANT PROJECTS.—A project of research referred to in subsection (a) is a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment and for which such entity is receiving assistance from the Secretary.

(c) IDENTIFYING AND REPORTING TO SECRETARY.—The Secretary shall by regulation require that each entity described in subsection (a) that applies for assistance under this Act for any project described in subsection (b) submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect an administrative process under subsection (a) to identify financial interests (as defined under subsection (a)) that exist regarding the project; and

(2) an agreement that the entity will report to the Secretary such interests identified by the entity and how any such interests identified by the entity will be managed or eliminated in order that the project in question will be protected from bias that may stem from such interests; and

(3) an agreement that the entity will comply with regulations issued under this section.

(d) MONITORING OF PROCESS.—The Secretary shall monitor the establishment and conduct of the administrative process established by an entity pursuant to subsection (a).

(e) RESPONSE.—In any case in which the Secretary determines that an entity has failed to comply with subsection (c) regarding a project of research described in subsection (b), the Secretary—

(1) shall require that, as a condition of receiving assistance, the entity disclose the existence of a financial interest (as

defined under subsection (a)) in each public presentation of the results of such project; and

(2) may take such other actions as the Secretary determines to be appropriate.

(f) DEFINITIONS.—For purposes of this section:

(1) The term “financial interest” includes the receipt of consulting fees or honoraria and the ownership of stock or equity.

(2) The term “assistance”, with respect to conducting a project of research, means a grant, contract, or cooperative agreement.

#### RESEARCH ON PUBLIC HEALTH EMERGENCIES

SEC. 494. [289c] If the Secretary determines, after consultation with the Director of NIH, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control and Prevention, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of NIH—

(1) shall expedite the review by advisory councils under section 406 and by peer review groups under section 492 of applications for grants for research on such disease or disorder or proposals for contracts for such research;

(2) shall exercise the authority in section 3709 of the Revised Statutes (41 U.S.C. 5) respecting public exigencies to waive the advertising requirements of such section in the case of proposals for contracts for such research;

(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; and

(4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatment of such disease or disorder that has been developed in research assisted under this section.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.

#### COLLABORATIVE USE OF CERTAIN HEALTH SERVICES RESEARCH FUNDS

SEC. 494A. [289c–1] The Secretary shall ensure that amounts made available under subparts 14, 15 and 16 of part C for health services research relating to alcohol abuse and alcoholism, drug abuse and mental health be used collaboratively, as appropriate, and in consultation with the Agency for Health Care Policy Research.

#### ANIMALS IN RESEARCH

SEC. 495. [289d] (a) The Secretary, acting through the Director of NIH, shall establish guidelines for the following:

(1) The proper care of animals to be used in biomedical and behavioral research.

(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall require—



(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

(3) The organization and operation of animal care committees in accordance with subsection (b).

(b)(1) Guidelines of the Secretary under subsection (a)(3) shall require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act (including the National Institutes of Health and the national research institutes) to assure compliance with the guidelines established under subsection (a).

(2) Each animal care committee shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than three members, and shall include at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

(3) Each animal care committee of a research entity shall—

(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semi-annually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment;

(B) keep appropriate records of reviews conducted under subparagraph (A); and

(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

Reports filed under subparagraph (C) shall include any minority views filed by members of the committee.

(c) The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in its application or contract proposal, submitted after the expiration of the twelve-month period beginning on the date of enactment of this section—

(1) assurances satisfactory to the Director of NIH that—

(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of re-

search or testing methods that limit the use of animals or limit animal distress; and  
 (2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract.

Notwithstanding subsection (a)(2) of section 553 of title 5, United States Code, regulations under this subsection shall be promulgated in accordance with the notice and comment requirements of such section.

(d) If the Director of NIH determines that—

(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this title do not meet applicable guidelines established under subsection (a);

(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

(3) no action has been taken by the entity to correct such conditions;

the Director of NIH shall suspend or revoke such grant or contract under such conditions as the Director determines appropriate.

(e) No guideline or regulation promulgated under subsection (a) or (c) may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential.

#### USE OF APPROPRIATIONS UNDER THIS TITLE

SEC. 496. [289e] (a) Appropriations to carry out the purposes of this title, unless otherwise expressly provided, may be expended in the District of Columbia for—

- (1) personal services;
- (2) stenographic recording and translating services;
- (3) travel expenses (including the expenses of attendance at meetings when specifically authorized by the Secretary);
- (4) rental;
- (5) supplies and equipment;
- (6) purchase and exchange of medical books, books of reference, directories, periodicals, newspapers, and press clippings;
- (7) purchase, operation, and maintenance of passenger motor vehicles;
- (8) printing and binding (in addition to that otherwise provided by law); and
- (9) all other necessary expenses in carrying out this title.

Such appropriations may be expended by contract if deemed necessary, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

(b)(1) None of the amounts appropriated under this Act for the purposes of this title may be obligated for the construction of facilities (including the acquisition of land) unless a provision of this title establishes express authority for such purpose and unless the

Act making appropriations under such provision specifies that the amounts appropriated are available for such purpose.

(2) Any grants, cooperative agreements, or contracts authorized in this title for the construction of facilities may be awarded only on a competitive basis.

#### GIFTS

SEC. 497. [289f] The Secretary may, in accordance with section 231, accept conditional gifts for the National Institutes of Health or a national research institute or for the acquisition of grounds or for the erection, equipment, or maintenance of facilities for the National Institutes of Health or a national research institute. Donations of \$50,000 or over for the National Institutes of Health or a national research institute for carrying out the purposes of this title may be acknowledged by the establishment within the National Institutes of Health or a national research institute of suitable memorials to the donors.

#### FETAL RESEARCH

SEC. 498. [289g] (a) The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—

(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

(b) In administering the regulations for the protection of human research subjects which—

(1) apply to research conducted or supported by the Secretary;

(2) involve living human fetuses in utero; and

(3) are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations;

or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

#### RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

SEC. 498A. [289g-1] (a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—The Secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes.

(2) SOURCE OF TISSUE.—Human fetal tissue may be used in research carried out under paragraph (1) regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.

## (b) INFORMED CONSENT OF DONOR.—

(1) IN GENERAL.—In research carried out under subsection (a), human fetal tissue may be used only if the woman providing the tissue makes a statement, made in writing and signed by the woman, declaring that—

(A) the woman donates the fetal tissue for use in research described in subsection (a);

(B) the donation is made without any restriction regarding the identity of individuals who may be the recipients of transplantations of the tissue; and

(C) the woman has not been informed of the identity of any such individuals.

(2) ADDITIONAL STATEMENT.—In research carried out under subsection (a), human fetal tissue may be used only if the attending physician with respect to obtaining the tissue from the woman involved makes a statement, made in writing and signed by the physician, declaring that—

(A) in the case of tissue obtained pursuant to an induced abortion—

(i) the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for a donation of the tissue for use in such research;

(ii) no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; and

(iii) the abortion was performed in accordance with applicable State law;

(B) the tissue has been donated by the woman in accordance with paragraph (1); and

(C) full disclosure has been provided to the woman with regard to—

(i) such physician's interest, if any, in the research to be conducted with the tissue; and

(ii) any known medical risks to the woman or risks to her privacy that might be associated with the donation of the tissue and that are in addition to risks of such type that are associated with the woman's medical care.

(c) INFORMED CONSENT OF RESEARCHER AND DONEE.—In research carried out under subsection (a), human fetal tissue may be used only if the individual with the principal responsibility for conducting the research involved makes a statement, made in writing and signed by the individual, declaring that the individual—

(1) is aware that—

(A) the tissue is human fetal tissue;

(B) the tissue may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and

(C) the tissue was donated for research purposes;

(2) has provided such information to other individuals with responsibilities regarding the research;

(3) will require, prior to obtaining the consent of an individual to be a recipient of a transplantation of the tissue, writ-

ten acknowledgment of receipt of such information by such recipient; and

(4) has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy made solely for the purposes of the research.

(d) AVAILABILITY OF STATEMENTS FOR AUDIT.—

(1) IN GENERAL.—In research carried out under subsection (a), human fetal tissue may be used only if the head of the agency or other entity conducting the research involved certifies to the Secretary that the statements required under subsections (b)(2) and (c) will be available for audit by the Secretary.

(2) CONFIDENTIALITY OF AUDIT.—Any audit conducted by the Secretary pursuant to paragraph (1) shall be conducted in a confidential manner to protect the privacy rights of the individuals and entities involved in such research, including such individuals and entities involved in the donation, transfer, receipt, or transplantation of human fetal tissue. With respect to any material or information obtained pursuant to such audit, the Secretary shall—

(A) use such material or information only for the purposes of verifying compliance with the requirements of this section;

(B) not disclose or publish such material or information, except where required by Federal law, in which case such material or information shall be coded in a manner such that the identities of such individuals and entities are protected; and

(C) not maintain such material or information after completion of such audit, except where necessary for the purposes of such audit.

(e) APPLICABILITY OF STATE AND LOCAL LAW.—

(1) RESEARCH CONDUCTED BY RECIPIENTS OF ASSISTANCE.—The Secretary may not provide support for research under subsection (a) unless the applicant for the financial assistance involved agrees to conduct the research in accordance with applicable State law.

(2) RESEARCH CONDUCTED BY SECRETARY.—The Secretary may conduct research under subsection (a) only in accordance with applicable State and local law.

(f) REPORT.—The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this section during the preceding fiscal year, including a description of whether and to what extent research under subsection (a) has been conducted in accordance with this section.

(g) DEFINITION.—For purposes of this section, the term “human fetal tissue” means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.

## PROHIBITIONS REGARDING HUMAN FETAL TISSUE

**SEC. 498B. [289g-2] (a) PURCHASE OF TISSUE.**—It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.

**(b) SOLICITATION OR ACCEPTANCE OF TISSUE AS DIRECTED DONATION FOR USE IN TRANSPLANTATION.**—It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, the tissue will be or is obtained pursuant to an induced abortion, and—

(1) the donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual;

(2) the donated tissue will be transplanted into a relative of the donating individual; or

(3) the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.

**(c) SOLICITATION OR ACCEPTANCE OF TISSUE FROM FETUSES GESTATED FOR RESEARCH PURPOSES.**—It shall be unlawful for any person or entity involved or engaged in interstate commerce to—

(1) solicit or knowingly acquire, receive, or accept a donation of human fetal tissue knowing that a human pregnancy was deliberately initiated to provide such tissue; or

(2) knowingly acquire, receive, or accept tissue or cells obtained from a human embryo or fetus that was gestated in the uterus of a nonhuman animal.

**(d) CRIMINAL PENALTIES FOR VIOLATIONS.**—

(1) **IN GENERAL.**—Any person who violates subsection (a), (b), or (c) shall be fined in accordance with title 18, United States Code, subject to paragraph (2), or imprisoned for not more than 10 years, or both.

(2) **PENALTIES APPLICABLE TO PERSONS RECEIVING CONSIDERATION.**—With respect to the imposition of a fine under paragraph (1), if the person involved violates subsection (a) or (b)(3), a fine shall be imposed in an amount not less than twice the amount of the valuable consideration received.

**(e) DEFINITIONS.**—For purposes of this section:

(1) The term “human fetal tissue” has the meaning given such term in section 498A(g).

(2) The term “interstate commerce” has the meaning given such term in section 201(b) of the Federal Food, Drug, and Cosmetic Act.

(3) The term “valuable consideration” does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

**SEC. 498C. [289g-3] BREAST IMPLANT RESEARCH.**

**(a) IN GENERAL.**—The Director of NIH may conduct or support research to examine the long-term health implications of silicone

breast implants, both gel and saline filled. Such research studies may include the following:

(1) Developing and examining techniques to measure concentrations of silicone in body fluids and tissues.

(2) Surveillance of recipients of silicone breast implants, including long-term outcomes and local complications.

(b) DEFINITION.—For purposes of this section, the term “breast implant” means a breast prosthesis that is implanted to augment or reconstruct the female breast.

**SEC. 498D. [289g-4] SUPPORT FOR EMERGENCY MEDICINE RESEARCH.**

(a) EMERGENCY MEDICAL RESEARCH.—The Secretary shall support Federal programs administered by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and other agencies involved in improving the emergency care system to expand and accelerate research in emergency medical care systems and emergency medicine, including—

(1) the basic science of emergency medicine;

(2) the model of service delivery and the components of such models that contribute to enhanced patient health outcomes;

(3) the translation of basic scientific research into improved practice; and

(4) the development of timely and efficient delivery of health services.

(b) PEDIATRIC EMERGENCY MEDICAL RESEARCH.—The Secretary shall support Federal programs administered by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and other agencies to coordinate and expand research in pediatric emergency medical care systems and pediatric emergency medicine, including—

(1) an examination of the gaps and opportunities in pediatric emergency care research and a strategy for the optimal organization and funding of such research;

(2) the role of pediatric emergency services as an integrated component of the overall health system;

(3) system-wide pediatric emergency care planning, preparedness, coordination, and funding;

(4) pediatric training in professional education; and

(5) research in pediatric emergency care, specifically on the efficacy, safety, and health outcomes of medications used for infants, children, and adolescents in emergency care settings in order to improve patient safety.

(c) IMPACT RESEARCH.—The Secretary shall support research to determine the estimated economic impact of, and savings that result from, the implementation of coordinated emergency care systems.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014.

**SEC. 498E. [289g-5] PRECISION MEDICINE INITIATIVE.**

(a) **IN GENERAL.**—The Secretary is encouraged to establish and carry out an initiative, to be known as the “Precision Medicine Initiative” (in this section referred to as the “Initiative”), to augment efforts to address disease prevention, diagnosis, and treatment.

(b) **COMPONENTS.**—The Initiative described under subsection (a) may include—

(1) developing a network of scientists to assist in carrying out the purposes of the Initiative;

(2) developing new approaches for addressing scientific, medical, public health, and regulatory science issues;

(3) applying genomic technologies, such as whole genomic sequencing, to provide data on the molecular basis of disease;

(4) collecting information voluntarily provided by a diverse cohort of individuals that can be used to better understand health and disease; and

(5) other activities to advance the goals of the Initiative, as the Secretary determines appropriate.

(c) **AUTHORITY OF THE SECRETARY.**—In carrying out this section, the Secretary may—

(1) coordinate with the Secretary of Energy, private industry, and others, as the Secretary determines appropriate, to identify and address the advanced supercomputing and other advanced technology needs for the Initiative;

(2) develop and utilize public-private partnerships; and

(3) leverage existing data sources.

(d) **REQUIREMENTS.**—In the implementation of the Initiative under subsection (a), the Secretary shall—

(1) ensure the collaboration of the National Institutes of Health, the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology, and the Office for Civil Rights of the Department of Health and Human Services;

(2) comply with existing laws and regulations for the protection of human subjects involved in research, including the protection of participant privacy;

(3) implement policies and mechanisms for appropriate secure data sharing across systems that include protections for privacy and security of data;

(4) consider the diversity of the cohort to ensure inclusion of a broad range of participants, including consideration of biological, social, and other determinants of health that contribute to health disparities;

(5) ensure that only authorized individuals may access controlled or sensitive, identifiable biological material and associated information collected or stored in connection with the Initiative; and

(6) on the appropriate Internet website of the Department of Health and Human Services, identify any entities with access to such information and provide information with respect to the purpose of such access, a summary of the research project for which such access is granted, as applicable, and a description of the biological material and associated information to which the entity has access.



(e) REPORT.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall submit a report on the relevant data access policies and procedures to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Such report shall include steps the Secretary has taken to consult with experts or other heads of departments or agencies of the Federal Government in the development of such policies.

## **PART I—FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH**

### **SEC. 499. [290b] ESTABLISHMENT AND DUTIES OF FOUNDATION.**

(a) IN GENERAL.—The Secretary shall, acting through the Director of NIH, establish a nonprofit corporation to be known as the Foundation for the National Institutes of Health (hereafter in this section referred to as the “Foundation”). The Foundation shall not be an agency or instrumentality of the United States Government.

(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation shall be to support the National Institutes of Health in its mission (including collection of funds for pediatric pharmacologic research), and to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations.

(c) CERTAIN ACTIVITIES OF FOUNDATION.—

(1) IN GENERAL.—In carrying out subsection (b), the Foundation may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of the following activities with respect to the purpose described in such subsection:

(A) A program to provide and administer endowed positions that are associated with the research program of the National Institutes of Health. Such endowments may be expended for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the endowed positions.

(B) A program to provide and administer fellowships and grants to research personnel in order to work and study in association with the National Institutes of Health. Such fellowships and grants may include stipends, travel, health insurance benefits and other appropriate expenses. The recipients of fellowships shall be selected by the donors and the Foundation upon the recommendation of the National Institutes of Health employees in the laboratory where the fellow would serve, and shall be subject to the agreement of the Director of the National Institutes of Health and the Executive Director of the Foundation.

(C) A program to collect funds for pediatric pharmacologic research and studies.

(D) Supplementary programs to provide for—

(i) scientists of other countries to serve in research capacities in the United States in association with the

National Institutes of Health or elsewhere, or opportunities for employees of the National Institutes of Health or other public health officials in the United States to serve in such capacities in other countries, or both;

(ii) the conduct and support of studies, projects, and research, which may include stipends, travel and other support for personnel in collaboration with national and international non-profit and for-profit organizations;

(iii) the conduct and support of forums, meetings, conferences, courses, and training workshops that may include undergraduate, graduate, post-graduate, and post-doctoral accredited courses and the maintenance of accreditation of such courses by the Foundation at the State and national level for college or continuing education credits or for degrees;

(iv) programs to support and encourage teachers and students of science at all levels of education and programs for the general public which promote the understanding of science;

(v) programs for writing, editing, printing, publishing, and vending of books and other materials; and

(vi) the conduct of other activities to carry out and support the purpose described in subsection (b).

(E) The Cures Acceleration Network described in section 480.

(2) FEES.—The Foundation may assess fees for the provision of professional, administrative and management services by the Foundation in amounts determined reasonable and appropriate by the Executive Director.

(3) AUTHORITY OF FOUNDATION.—The Foundation shall be the sole entity responsible for carrying out the activities described in this subsection.

(d) BOARD OF DIRECTORS.—

(1) COMPOSITION.—

(A) The Foundation shall have a Board of Directors (hereafter referred to in this section as the “Board”), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

(B) The ex officio members of the Board shall be—

(i) the Chairman and ranking minority member of the Subcommittee on Health and the Environment (Committee on Energy and Commerce) or their designees, in the case of the House of Representatives;

(ii) the Chairman and ranking minority member of the Committee on Labor and Human Resources or their designees, in the case of the Senate;

(iii) the Director of the National Institutes of Health; and

(iv) the Commissioner of Food and Drugs.

(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board individuals from

among a list of candidates to be provided by the National Academy of Science. Such appointed members shall include—

- (i) representatives of the general biomedical field;
- (ii) representatives of experts in pediatric medicine and research;
- (iii) representatives of the general biobehavioral field, which may include experts in biomedical ethics; and
- (iv) representatives of the general public, which may include representatives of affected industries.

(D)(i) Not later than 30 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993, the Director of the National Institutes of Health shall convene a meeting of the ex officio members of the Board to—

(I) incorporate the Foundation and establish the general policies of the Foundation for carrying out the purposes of subsection (b), including the establishment of the bylaws of the Foundation; and

(II) appoint the members of the Board in accordance with subparagraph (C).

(ii) Upon the appointment of the appointed members of the Board under clause (i)(II), the terms of service as members of the Board of the ex officio members of the Board described in clauses (i) and (ii) of subparagraph (B) shall terminate. The ex officio members of the Board described in clauses (iii) and (iv) of subparagraph (B) shall continue to serve as ex officio members of the Board.

(E) The agreement of not less than three-fifths of the members of the ex officio members of the Board shall be required for the appointment of each member to the initial Board.

(F) No employee of the National Institutes of Health shall be appointed as a member of the Board.

(G) The Board may, through amendments to the bylaws of the Foundation, provide that the number of appointed members of the Board shall be greater than the number specified in subparagraph (C).

(2) CHAIR.—

(A) The ex officio members of the Board under paragraph (1)(B) shall designate an individual to serve as the initial Chair of the Board.

(B) Upon the termination of the term of service of the initial Chair of the Board, the appointed members of the Board shall elect a member of the Board to serve as the Chair of the Board.

(3) TERMS AND VACANCIES.—

(A) The term of office of each member of the Board appointed under paragraph (1)(C) shall be 5 years, except that the terms of offices for the initial appointed members of the Board shall expire as determined by the ex officio members and the Chair.

(B) Any vacancy in the membership of the appointed members of the Board shall be filled in accordance with the bylaws of the Foundation established in accordance with paragraph (6), and shall not affect the power of the remaining appointed members to execute the duties of the Board.

(C) If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(D) A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

(5) MEETINGS AND QUORUM.—A majority of the appointed members of the Board shall constitute a quorum for purposes of conducting the business of the Board.

(6) CERTAIN BYLAWS.—

(A) In establishing bylaws under this subsection, the Board shall ensure that the following are provided for:

(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

(ii) Policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation. Policies with respect to ethical standards shall ensure that officers, employees and agents of the Foundation (including members of the Board) avoid encumbrances that would result in a conflict of interest, including a financial conflict of interest or a divided allegiance. Such policies shall include requirements for the provision of information concerning any ownership or controlling interest in entities related to the activities of the Foundation by such officers, employees and agents and their spouses and relatives.

(iii) Policies for the conduct of the general operations of the Foundation.

(iv) Policies for writing, editing, printing, publishing, and vending of books and other materials.

(B) In establishing bylaws under this subsection, the Board shall ensure that such bylaws (and activities carried out under the bylaws) do not—

(i) reflect unfavorably upon the ability of the Foundation or the National Institutes of Health to carry out its responsibilities or official duties in a fair and objective manner; or

(ii) compromise, or appear to compromise, the integrity of any governmental agency or program, or any officer or employee involved in such program.

(e) INCORPORATION.—The initial members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

(f) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of such section.

(g) EXECUTIVE DIRECTOR.—

(1) IN GENERAL.—The Foundation shall have an Executive Director who shall be appointed by the Board and shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

(2) COMPENSATION.—The rate of compensation of the Executive Director shall be fixed by the Board.

(h) POWERS.—In carrying out subsection (b), the Foundation may—

- (1) operate under the direction of its Board;
- (2) adopt, alter, and use a corporate seal, which shall be judicially noticed;
- (3) provide for 1 or more officers, employees, and agents, as may be necessary, define their duties, and require surety bonds or make other provisions against losses occasioned by acts of such persons;
- (4) hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees;
- (5) with the consent of any executive department or independent agency, use the information, services, staff, and facilities of such in carrying out this section;
- (6) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;
- (7) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this part;
- (8) establish a process for the selection of candidates for positions under subsection (c);
- (9) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;
- (10) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;
- (11) solicit, accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation;
- (12) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation;

(13) appoint other groups of advisors as may be determined necessary from time to time to carry out the functions of the Foundation;

(14) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation; and

(15) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this part.

(i) ADMINISTRATIVE CONTROL.—No participant in the program established under this part shall exercise any administrative control over any Federal employee.

(j) GENERAL PROVISIONS.—

(1) FOUNDATION INTEGRITY.—The members of the Board shall be accountable for the integrity of the operations of the Foundation and shall ensure such integrity through the development and enforcement of criteria and procedures relating to standards of conduct, financial disclosure statements, conflict of interest rules, recusal and waiver rules, audits and other matter determined appropriate by the Board.

(2) FINANCIAL CONFLICTS OF INTEREST.—Any individual who is an officer, employee, or member of the Board of the Foundation may not (in accordance with policies and requirements developed under subsection (d)(6))<sup>57</sup> personally or substantially participate in the consideration or determination by the Foundation of any matter that would directly or predictably affect any financial interest of the individual or a relative (as such term is defined in section 13101(16) of title 5, United States Code) of the individual, of any business organization or other entity, or of which the individual is an officer or employee, or is negotiating for employment, or in which the individual has any other financial interest.

(3) AUDITS; AVAILABILITY OF RECORDS.—The Foundation shall—

(A) provide for annual audits of the financial condition of the Foundation; and

(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

(4) REPORTS.—

(A) Not later than 5 months following the end of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation, including an accounting of the use of amounts transferred under subsection (1).

<sup>57</sup>Section 13(7) of Public Law 107–109 (115 Stat. 1419) provided that paragraphs (1) and (2) of section 499(j) are amended “by striking (including those developed under subsection (d)(2)(B)(i)(II)) each place it appears”. The term to be struck appeared in paragraph (1), but not in paragraph (2).

(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts or grants to the Foundation of real or personal property, and the source and amount of all gifts or grants to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts or grants to the Foundation may be used.

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available—

(i) for public inspection, and shall upon request provide a copy of the report to any individual for a charge that shall not exceed the cost of providing the copy; and

(ii) to the appropriate committees of Congress.

(D) The Board shall annually hold a public meeting to summarize the activities of the Foundation and distribute written reports concerning such activities and the scientific results derived from such activities.

(5) SERVICE OF FEDERAL EMPLOYEES.—Federal employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its function, so long as the employees do not direct or control Foundation activities.

(6) RELATIONSHIP WITH EXISTING ENTITIES.—The Foundation may, pursuant to appropriate agreements, merge with, acquire, or use the resources of existing nonprofit private corporations with missions similar to the purposes of the Foundation, such as the Foundation for Advanced Education in the Sciences.

(7) INTELLECTUAL PROPERTY RIGHTS.—The Board shall adopt written standards with respect to the ownership of any intellectual property rights derived from the collaborative efforts of the Foundation prior to the commencement of such efforts.

(8) NATIONAL INSTITUTES OF HEALTH AMENDMENTS OF 1990.—The activities conducted in support of the National Institutes of Health Amendments of 1990 (Public Law 101–613), and the amendments made by such Act, shall not be nullified by the enactment of this section.

(9) LIMITATION OF ACTIVITIES.—

(A) IN GENERAL.—The Foundation shall exist solely as an entity to work in collaboration with the research programs of the National Institutes of Health. The Foundation may not undertake activities (such as the operation of independent laboratories or competing for Federal research funds) that are independent of those of the National Institutes of Health research programs.

(B) GIFTS, GRANTS, AND OTHER DONATIONS.—

(i) IN GENERAL.—Gifts, grants, and other donations to the Foundation may be designated for pediatric research and studies on drugs, and funds so designated shall be used solely for grants for research and studies under subsection (c)(1)(C).

(ii) OTHER GIFTS.—Other gifts, grants, or donations received by the Foundation and not described in clause (i) may also be used to support such pediatric research and studies.

(iii) REPORT.—The recipient of a grant for research and studies shall agree to provide the Director of the National Institutes of Health and the Commissioner of Food and Drugs, at the conclusion of the research and studies—

(I) a report describing the results of the research and studies; and

(II) all data generated in connection with the research and studies.

(iv) ACTION BY THE COMMISSIONER OF FOOD AND DRUGS.—The Commissioner of Food and Drugs shall take appropriate action in response to a report received under clause (iii) in accordance with paragraphs (7) through (12) of section 409I(c), including negotiating with the holders of approved applications for the drugs studied for any labeling changes that the Commissioner determines to be appropriate and requests the holders to make.

(C) APPLICABILITY.—Subparagraph (A) does not apply to the program described in subsection (c)(1)(C).

(10) TRANSFER OF FUNDS.—The Foundation may transfer funds to the National Institutes of Health and the National Institutes of Health may accept transfers of funds from the Foundation. Any funds transferred under this paragraph shall be subject to all Federal limitations relating to federally-funded research.

(k) DUTIES OF THE DIRECTOR.—

(1) APPLICABILITY OF CERTAIN STANDARDS TO NON-FEDERAL EMPLOYEES.—In the case of any individual who is not an employee of the Federal Government and who serves in association with the National Institutes of Health, with respect to financial assistance received from the Foundation, the Foundation may not provide the assistance of, or otherwise permit the work at the National Institutes of Health to begin until a memorandum of understanding between the individual and the Director of the National Institutes of Health, or the designee of such Director, has been executed specifying that the individual shall be subject to such ethical and procedural standards of conduct relating to duties performed at the National Institutes of Health, as the Director of the National Institutes of Health determines is appropriate.

(2) SUPPORT SERVICES.—The Director of the National Institutes of Health may provide facilities, utilities and support services to the Foundation if it is determined by the Director to be advantageous to the research programs of the National Institutes of Health.

(l) FUNDING.—From amounts appropriated to the National Institutes of Health, for each fiscal year, the Director of NIH shall transfer not less than \$500,000 and not more than \$1,250,000 to the Foundation.



## PART J—ADVANCED RESEARCH PROJECTS AGENCY—HEALTH.

### SEC. 499A. [290c] ADVANCED RESEARCH PROJECTS AGENCY—HEALTH.

#### (a) ESTABLISHMENT.—

(1) IN GENERAL.—There is established within the National Institutes of Health the Advanced Research Projects Agency—Health (referred to in this section as “ARPA–H”). Not later than 180 days after the date of enactment of this section, the Secretary shall transfer all functions, personnel, missions, activities, authorities, and funds of the Advanced Research Projects Agency for Health as in existence on the date of enactment of this section, to ARPA–H established by the preceding sentence.

#### (2) ORGANIZATION.—

(A) IN GENERAL.—There shall be within ARPA–H—

- (i) an Office of the Director;
- (ii) not more than 8 program offices; and
- (iii) such special project offices as the Director may establish.

(B) REQUIREMENT.—Not fewer than two-thirds of the program offices of ARPA–H shall be exclusively dedicated to supporting research and development activities, consistent with the goals and functions described in subsection (b).

(C) NOTIFICATION.—The Director shall submit a notification to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives if the Director determines that additional program offices are required to carry out this section.

#### (3) EXEMPTION FROM CERTAIN POLICIES OF NIH.—

(A) IN GENERAL.—Except as otherwise provided for in this section, and subject to subparagraph (B), in establishing ARPA–H pursuant to paragraph (1), the Secretary may exempt ARPA–H from policies and requirements of the National Institutes of Health that are in effect on the day before the date of enactment of this section as necessary and appropriate to ensure ARPA–H can most effectively achieve the goals described in subsection (b)(1).

(B) NOTICE.—Not later than 90 days after the date of enactment of this section, the Secretary shall publish a notice in the Federal Register describing the specific policies and requirements of the National Institutes of Health from which the Secretary intends to exempt ARPA–H, including a rationale for such exemptions.

#### (b) GOALS AND FUNCTIONS.—

(1) GOALS.—The goals of ARPA–H shall be to—

(A) foster the development of novel, breakthrough, and broadly applicable capabilities and technologies to accelerate transformative innovation in biomedical science and medicine in a manner that cannot be readily accomplished

through traditional Federal biomedical research and development programs or commercial activity;

(B) revolutionize the detection, diagnosis, mitigation, prevention, treatment, and cure of diseases and health conditions by overcoming long-term and significant technological and scientific barriers to developing transformative health technologies;

(C) promote high-risk, high-reward innovation to enable the advancement of transformative health technologies; and

(D) contribute to ensuring the United States—

(i) pursues initiatives that aim to maintain global leadership in science and innovation; and

(ii) improves the health and wellbeing of its citizens by supporting the advancement of biomedical science and innovation.

(2) FUNCTIONS.—ARPA-H shall achieve the goals specified in paragraph (1) by addressing specific scientific or technical questions by involving high-impact transformative, translational, applied, and advanced research in relevant areas of science, by supporting—

(A) discovery, identification, and promotion of revolutionary advancements in science;

(B) translation of scientific discoveries into transformative health technologies with potential application for biomedical science and medicine;

(C) creation of platform capabilities that draw on multiple disciplines;

(D) delivery of proofs of concept that demonstrate meaningful advances with potential clinical application;

(E) development of new capabilities and methods to identify potential targets and technological strategies for early disease detection and intervention, such as advanced computational tools and predictive models; and

(F) acceleration of transformational health technological advances in areas with limited technical certainty.

(c) DIRECTOR.—

(1) IN GENERAL.—The President shall appoint a director of ARPA-H (in this section referred to as the “Director”).

(2) QUALIFICATIONS.—The Director shall be an individual who, by reason of professional background and experience—

(A) is especially qualified to advise the Secretary on, and manage—

(i) research and development programs; and

(ii) large-scale, high-risk initiatives with respect to health research and technology development across multiple sectors, including identifying and supporting potentially transformative health technologies; and

(B) has a demonstrated ability to identify and develop partnerships to address strategic needs in meeting the goals described in subsection (b)(1).

(3) REPORTING.—The Director shall report to the Secretary of Health and Human Services.

(4) DUTIES.—The duties of the Director shall include the following:

(A) Establish strategic goals, objectives, and priorities for ARPA–H to advance the goals described in subsection (b)(1).

(B) Approve the projects and programs of ARPA–H and restructure, expand, or terminate any project or program within ARPA–H that is not achieving its goals.

(C) Develop funding criteria and assess the success of programs through the establishment of technical milestones.

(D) Request that applications for funding disclose current and previous research and development efforts related to such applications, as appropriate, and identify any challenges associated with such efforts, including any scientific or technical barriers encountered in the course of such efforts or challenges in securing sources of funding, as applicable.

(E) Coordinate with the heads of relevant Federal departments and agencies to facilitate sharing of data and information, as applicable and appropriate, and ensure that research supported by ARPA–H is informed by and supplements, not supplants, the activities of such departments and agencies and is free of unnecessary duplication of effort.

(F) Ensure ARPA–H does not provide funding for a project unless the program manager determines that the project aligns with the goals described in subsection (b)(1).

(G) Prioritize investments based on considerations such as—

(i) scientific opportunity and potential impact, especially in areas that fit within the strategies and operating practices of ARPA–H and require public-private partnerships to effectively advance research and development activities; and

(ii) the potential applications that an innovation may have to address areas of currently unmet need in medicine and health, including health disparities and the potential to prevent progression to serious disease.

(H) Encourage strategic collaboration and partnerships with a broad range of entities, which may include institutions of higher education, minority-serving institutions (defined, for the purposes of this section, as institutions and programs described in section 326(e)(1) of the Higher Education Act of 1965 and institutions described in section 371(a) of such Act), industry, nonprofit organizations, Federally funded research and development centers, or consortia of such entities.

(5) TERM.—Notwithstanding section 405(a)(2), the Director—

(A) shall be appointed for a 4-year term; and

(B) may be reappointed for 1 consecutive 4-year term.

(6) AUTONOMY OF AGENCY REGARDING RECOMMENDATIONS AND TESTIMONY.—No office or agency of the United States shall

have authority to require the Director to submit legislative recommendations, or testimony or comments on legislation, to any officer or agency of the United States for approval, comments, or review prior to the submission of such recommendations, testimony or comments to Congress, if such recommendations, testimony, or comments to Congress include a statement indicating that the views expressed therein are those of the Director and do not necessarily reflect the views of the President or another Federal department, agency, or office.

(7) DEPUTY DIRECTOR.—The Director shall appoint a Deputy Director to serve as the principal assistant to the Director.

(8) NONAPPLICATION OF CERTAIN PROVISION.—The restrictions contained in section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note) related to consultants and individual scientists appointed for limited periods of time shall not apply to the Director appointed under this subsection.

(d) APPLICATION OF CERTAIN FLEXIBILITIES.—The flexibilities provided to the National Institutes of Health under section 301(g) shall apply to ARPA–H with respect to the functions described in subsection (b)(2).

(e) PROTECTION OF INFORMATION.—

(1) NO AUTHORIZATION FOR DISCLOSURE.—Nothing in this section shall be construed as authorizing the Director to disclose any information that is a trade secret or other privileged or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(2) REPORTING.—If there have been requests under section 522 of title 5, United States Code, or the Secretary has used such authority to withhold information within the preceding year, not later than 1 year after the date of enactment of this section, and annually thereafter, the Director shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on—

(A) the number of instances in which the Secretary has used the authority under this subsection to withhold information from disclosure; and

(B) the nature of any request under section 552 of title 5, United States Code, or section 1905 of title 18, United States Code, that was denied using such authority.

(3) CLARIFICATION.—The protections for trade secrets or other privileged or confidential information described in paragraph (1) shall not be construed to limit the availability or disclosure of information necessary to inform and facilitate the evaluation required under subsection (k)(2). Any such information made available to members of the National Academies of Sciences, Engineering, and Medicine (referred to in this section as the “National Academies”) for such evaluation shall be kept confidential by such members and shall not be used for any purposes other than informing and facilitating the evaluation required under subsection (k)(2).

(f) COOPERATION WITH THE FOOD AND DRUG ADMINISTRATION.—

(1) IN GENERAL.—In order to facilitate the enhanced collaboration and communication with respect to the most current priorities of ARPA–H, the Food and Drug Administration may meet with ARPA–H and any other Federal partners at appropriate intervals to discuss the development status, and actions that may be taken to facilitate the development, of medical products and projects that are the highest priorities to ARPA–H.

(2) REIMBURSEMENT.—Utilizing interagency agreements or other appropriate resource allocation mechanisms available, the Director shall reimburse, using funds made available to ARPA–H, the Food and Drug Administration, as appropriate, for activities identified by the Commissioner of Food and Drugs and the Director as being conducted by the Food and Drug Administration under the authority of this subsection.

(g) AWARDS.—

(1) IN GENERAL.—In carrying out this section, the Director may—

(A) award grants and cooperative agreements, which shall include requirements to publicly report indirect facilities and administrative costs, broken out by fixed capital costs, administrative overhead, and labor costs;

(B) award contracts, which may include multi-year contracts subject to section 3903 of title 41, United States Code;

(C) award cash prizes, utilizing the authorities and processes established under section 24 of the Stevenson-Wydler Technology Innovation Act of 1980; and

(D) enter into other transactions, as defined by section 319L(a)(3), subject to paragraph (2).

(2) LIMITATIONS ON ENTERING INTO OTHER TRANSACTIONS.—

(A) USE OF COMPETITIVE PROCEDURES.—To the maximum extent practicable, competitive procedures shall be used when entering into other transactions under this section.

(B) WRITTEN DETERMINATION REQUIRED.—The authority of paragraph (1)(D) may be exercised for a project if the program manager—

(i) submits a request to the Director for each individual use of such authority before conducting or supporting a program, including an explanation of why the use of such authority is essential to promoting the success of the project;

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

(iii) for each year in which the program manager has used such authority in accordance with this paragraph, submits a report to the Director on the activities of the program related to such project.

(3) EXEMPTIONS FROM CERTAIN REQUIREMENTS.—Research funded by ARPA-H shall not be subject to the requirements of section 406(a)(3)(A)(ii) or section 492.

(h) FACILITIES AUTHORITY.—

(1) IN GENERAL.—The Director is authorized, for administrative purposes, to—

(A) acquire (by purchase, lease, condemnation or otherwise), construct, improve, repair, operate, and maintain such real and personal property as are necessary to carry out this section; and

(B) lease an interest in property for not more than 20 years, notwithstanding section 1341(a)(1) of title 31, United States Code.

(2) LOCATIONS.—

(A) IN GENERAL.—ARPA-H, including its headquarters, shall not be located on any part of the existing National Institutes of Health campuses.

(B) NUMBER OF LOCATIONS.—ARPA-H shall have offices or facilities in not less than 3 geographic areas.

(C) CONSIDERATIONS.—In determining the location of each office or facility, the Director shall make a fair and open consideration of—

(i) the characteristics of the intended location; and

(ii) the extent to which such location will facilitate advancement of the goals and functions specified in subsection (b).

(i) PERSONNEL.—

(1) IN GENERAL.—The Director may—

(A) appoint and remove scientific, engineering, medical, and professional personnel, which may include temporary or term-limited appointments as determined by the Director to fulfill the mission of ARPA-H, without regard to any provision in title 5, United States Code, governing appointments and removals under the civil service laws;

(B) notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States Code, fix the base pay compensation of such personnel at a rate to be determined by the Director, up to the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code; and

(C) contract with private recruiting firms for assistance in identifying highly qualified candidates for technical positions needed to carry out this section.

(2) SUPPORT STAFF.—The Director may use authorities in existence on the date of enactment of this section that are provided to the Secretary to hire administrative, financial, clerical, and other staff necessary to carry out functions that support the goals and functions described in subsection (b).

(3) NUMBER OF PERSONNEL.—The Director may appoint not more than 210 personnel under this section. The Director shall submit a notification to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and

the Committee on Appropriations of the House of Representatives if the Director determines that additional personnel are required to carry out this section.

(4) CLARIFICATION ON PREVIOUS POSITIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Director shall ensure that the personnel who are appointed to staff or support ARPA–H are individuals who, at the time of appointment and for 3 years prior to such appointment, were not employed by the National Institutes of Health. The Director may grant an exemption only for individuals who are uniquely qualified, by way of professional background and expertise, to advance the goals and functions specified in subsection (b).

(B) NONAPPLICATION OF PROVISION.—The restriction provided under subparagraph (A) shall not apply to any individuals who are employed by ARPA–H on the date of enactment of this section.

(5) ADDITIONAL CONSIDERATIONS.—In appointing personnel under this subsection, the Director—

(A) may contract with private entities for the purposes of recruitment services;

(B) shall make efforts to recruit a diverse workforce, including individuals underrepresented in science, engineering, and medicine, including racial and ethnic minorities, provided such efforts do not conflict with applicable Federal civil rights law, and individuals with a variety of professional experiences or backgrounds; and

(C) shall recruit program managers with demonstrated expertise in a wide range of scientific disciplines and management skills.

(6) USE OF INTERGOVERNMENTAL PERSONNEL ACT.—To the extent needed to carry out the authorities under paragraph (1) and the goals and functions specified in subsection (b), the Director may utilize hiring authorities under sections 3371 through 3376 of title 5, United States Code.

(7) AUTHORITY TO ACCEPT FEDERAL DETAILEES.—The Director may accept officers or employees of the United States or members of the uniformed service on a detail from an element of the Federal Government, on a reimbursable or a nonreimbursable basis, as jointly agreed to by the heads of the receiving and detailing elements, for a period not to exceed 3 years.

(j) PROGRAM MANAGERS.—

(1) IN GENERAL.—The Director shall appoint program managers for 3-year terms (and may reappoint such program managers for 1 additional consecutive 3-year term) for the programs carried out by ARPA–H.

(2) DUTIES.—A program manager shall—

(A) establish, in consultation with the Director, research and development goals for programs, including timelines and milestones, and make such goals available to the public;

(B) manage applications and proposals, through the appropriate officials, for making awards as described in

subsection (g) for activities consistent with the goals and functions described in subsection (b);

(C) issue funding opportunity announcements, using uniform administrative processes, as appropriate;

(D) select, on the basis of merit, each of the projects to be supported under a program carried out by ARPA-H, and taking into consideration—

(i) the scientific, technical merit, and novelty of the proposed project;

(ii) the ability of the applicant to successfully carry out the proposed project;

(iii) the potential future commercial applications of the project proposed by the applicant, including whether such applications may have the potential to address areas of currently unmet need within biomedicine and improve health outcomes;

(iv) the degree to which the proposed project has the potential to transform biomedicine and addresses a scientific or technical question pursuant to subsection (b);

(v) the potential for the project to take an interdisciplinary approach; and

(vi) such other criteria as established by the Director;

(E) provide project oversight and management of strategic initiatives to advance the program, including by conducting project reviews not later than 18 months after the date of funding awards to identify and monitor progress of milestones with respect to each project and prior to disbursement of additional funds;

(F) provide recommendations to the Director with respect to advancing the goals and functions specified in subsection (b);

(G) encourage research collaborations and cultivate opportunities for the application or utilization of successful projects, including through identifying and supporting applicable public-private partnerships or partnerships between or among award recipients;

(H) provide recommendations to the Director to establish, expand, restructure, or terminate partnerships or projects; and

(I) communicate and collaborate with leaders and experts within the health care and biomedical research and development fields, including from both the public and private sectors and, as necessary, through the convening of workshops and meetings, to identify research and development gaps and opportunities and solicit stakeholder input on programs and goals.

(k) REPORTS AND EVALUATION.—

(1) ANNUAL REPORT.—

(A) IN GENERAL.—Beginning not later than 1 year after the date of enactment of this section, as part of the annual budget request submitted for each fiscal year, the



Director shall submit a report on the actions undertaken, and the results generated, by ARPA-H, including—

(i) a description of projects supported by ARPA-H in the previous fiscal year and whether such projects are meeting the goals developed by the Director pursuant to subsection (c)(4)(A);

(ii) a description of projects terminated in the previous fiscal year, and the reason for such termination;

(iii) a description of planned programs starting in the next fiscal year, pending the availability of funding;

(iv) activities conducted in coordination with other Federal departments and agencies;

(v) a description of any successes with, or barriers to, coordinating with other Federal departments and agencies to achieve the goals and functions under subsection (b);

(vi) aggregated demographic information, if available, of direct recipients and performers in funded projects and of the ARPA-H workforce (consistent with the reporting requirements under paragraph (3)); and

(vii) a summary of award recipient compliance with section 2321 of the PREVENT Pandemics Act.

(B) SUBMISSION TO CONGRESS.—The report under subparagraph (A) shall be submitted to—

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

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

(2) EVALUATION.—

(A) IN GENERAL.—Not later than 5 years after the date of the enactment of this section, the Director shall seek to enter into an agreement with the National Academies under which the National Academies conducts an evaluation of whether ARPA-H is meeting the goals and functions specified in subsection (b).

(B) SUBMISSION OF RESULTS.—The agreement entered into under subparagraph (A) shall require the National Academies to submit the evaluation conducted under such agreement to the Director, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, and make the report publicly available.

(3) REPORTING RELATED TO ARPA-H PERSONNEL.—

(A) IN GENERAL.—The Director shall establish and maintain records regarding the use of the authority under subsection (i)(1)(A), including—

(i) the number of positions filled through such authority;

(ii) the types of appointments of such positions;

(iii) the titles, occupational series, and grades of such positions;

(iv) the number of positions publicly noticed to be filled under such authority;

(v) the number of qualified applicants who apply for such positions;

(vi) the qualification criteria for such positions; and

(vii) the demographic information of individuals appointed to such positions.

(B) REPORTS TO CONGRESS.—Not later than 2 years after the date of enactment of this section, and annually thereafter for each fiscal year in which such authority is used, the Director shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing the total number of appointments filled under subsection (i) within the fiscal year and how the positions relate to the goals and functions of ARPA-H.

(C) GAO REPORT.—Not later than 2 years after the date of enactment of this section, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the use of the authority provided under subsection (i)(1)(A). Such report shall, in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum, include information on—

(i) the number of positions publicly noticed and filled under the authority under subsection (i);

(ii) the occupational series, grades, and types of appointments of such positions;

(iii) how such positions related to advancing the goals and functions of ARPA-H;

(iv) how the Director made appointment decisions under subsection (i);

(v) a summary of sources used to identify candidates for filling such positions, as applicable;

(vi) the number of individuals appointed;

(vii) aggregated demographic information related to individuals appointed; and

(viii) any challenges, limitations, or gaps related to the use of the authority under subsection (i) and any related recommendations to address such challenges, limitations, or gaps.

(I) STRATEGIC PLAN.—Not later than 1 year after the date of the enactment of this section, and every 3 years thereafter, the Director shall provide to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a strategic plan describing how ARPA-H will carry out investments each fiscal year

in the following 3-year period. The requirements regarding individual institute and center strategic plans under section 402(m), including paragraph (3) of such subsection, shall not apply to ARPA-H.

(m) INDEPENDENT REVIEW.—Not later than 1 year after the date of the enactment of this section, and every 4 years thereafter, the Comptroller General of the United States shall conduct, and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, an independent review of the biomedical research and development portfolio of the Department of Health and Human Services, including ARPA-H, the National Institutes of Health, the Food and Drug Administration, and the Biomedical Advanced Research and Development Authority—

(1) to assess the degree of any potential duplication of existing Federal programs and projects; and

(2) to make any recommendations regarding any potential reorganization, consolidation, or termination of such programs and projects.

(n) PRIORITIZATION.—

(1) IN GENERAL.—The Director shall—

(A) prioritize awarding grants, cooperative agreements, contracts, prizes, and other transaction awards to entities that will conduct funded work in the United States;

(B) as appropriate and practicable, encourage non-domestic recipients of any grants, cooperative agreements, contracts, prizes, and other transactions under this section to collaborate with a domestic entity;

(C) not make awards under this section to non-domestic entities organized under the laws of a covered foreign country (as defined in section 119C of the National Security Act of 1947 (50 U.S.C. 3059)); and

(D) in accordance with the requirements of chapter 33 of title 41, United States Code, and the Federal Acquisition Regulation, not make awards under this section to entities that have more than 3 ongoing concurrent awards under this section.

(2) CLARIFICATION.—In making an award under this section, the Director may waive the requirements of subparagraphs (A), (B), and (D) of paragraph (1) if such requirements cannot reasonably be met, and the proposed project has the potential to advance the goals described in subsection (b)(1). The Director shall provide notice to Congress not later than 30 days after waiving such requirements.

(o) ADDITIONAL CONSULTATION.—In carrying out this section, the Director may consult with—

(1) the President's Council of Advisors on Science and Technology;

(2) representatives of professional or scientific organizations, including academia and industry, with expertise in specific technologies under consideration or development by ARPA-H;

(3) an existing advisory committee providing advice to the Secretary or the head of any operating or staff division of the Department;

(4) the advisory committee established under subsection (p); and

(5) any other entity the Director may deem appropriate.

(p) ADVISORY COMMITTEE.—

(1) IN GENERAL.—There is established an ARPA–H Inter-agency Advisory Committee (referred to in this subsection as the “Advisory Committee”) to coordinate efforts and provide advice and assistance on specific program or project tasks and the overall direction of ARPA–H.

(2) MEMBERS.—The Advisory Committee established under paragraph (1) shall consist of the heads of the following agencies or their designees:

(A) The National Institutes of Health.

(B) The Centers for Disease Control and Prevention.

(C) The Food and Drug Administration.

(D) The Office of the Assistant Secretary for Preparedness and Response.

(E) The Office of the Assistant Secretary of Health.

(F) The Defense Advanced Research Projects Agency.

(G) The Office of Science of the Department of Energy.

(H) The National Science Foundation.

(I) Any other agency or office with subject matter expertise that the Director of ARPA–H determines appropriate to advance programs or projects under this section.

(3) NONAPPLICABILITY OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Advisory Committee.

(4) ADVISORY NATURE.—The functions of the Advisory Committee shall be advisory in nature, and nothing in this subsection shall be construed as granting such Committee authority over the activities authorized under this section.

(5) PERFORMANCE MEASURES FRAMEWORK.—

(A) IN GENERAL.—The Director, in consultation with the Advisory Committee, shall develop a performance measures framework for programs or projects supported by ARPA–H in order to inform and facilitate the evaluation required under subsection (k)(2), including identification of any data needed to perform such evaluation,

(B) AVAILABILITY OF PERFORMANCE MEASURES.—The Director shall provide to the National Academies such performance measures and data necessary to perform the evaluation required under subsection (k)(2).

(q) RULE OF CONSTRUCTION.—The authorities under this section, with respect to the Director, are additional authorities that do not supersede or modify any existing authorities.

(r) TRANSFORMATIVE HEALTH TECHNOLOGY DEFINED.—In this section, the term “transformative health technology” means a novel, broadly applicable capability or technology—

(1) that has potential to revolutionize the detection, diagnosis, mitigation, prevention, cure, or treatment of a disease or

health condition that can cause severe health outcomes and which is an area of currently unmet need; and

(2) for which—

(A) significant scientific or technical challenges exist;

or

(B) incentives in the commercial market are unlikely to result in the adequate or timely development of such capability or technology.

(s) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated \$500,000,000 for each of the fiscal years 2024 through 2028, to remain available until expended.

(t) ADDITIONAL BUDGET CLARIFICATION.—Any budget request for ARPA–H shall propose a separate appropriation from the other accounts of the National Institutes of Health.