TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A--PUBLIC HEALTH SERVICE

SUBCHAPTER III--NATIONAL RESEARCH INSTITUTES

Part A--National Institutes of Health

Sec. 282. Director of National Institutes of Health

(a) Appointment

The National Institutes of Health shall be headed by the Director of the National Institutes of Health (hereafter in this subchapter referred to as the ``Director of NIH'') who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) of this section and as the Secretary may otherwise prescribe.

(b) Duties and authority

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

(1) shall be responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

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

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

(4) for the national research institutes and administrative entities within the National Institutes of Health--

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

(B) may acquire, without regard to section 34 of title 40, by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

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

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

(7) may secure for the National Institutes of Health

consultation services and advice of persons from the United States or abroad;

(8) 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;

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

(10) may accept voluntary and uncompensated services;

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

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

(13) may conduct and support research training--

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

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

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

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (6). The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

(c) Availability of substances and organisms for research

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

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

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

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

(B) Expenses specified in subparagraph (A) shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(e) Dissemination of research information

The Director of NIH shall--

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

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

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

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

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

(f) Associate Director for Prevention; functions

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

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

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

(g) Enhancing competitiveness of certain entities in obtaining research funds

(1)(A) In the case of entities described in subparagraph (B), the Director of NIH, acting through the Director of the National Center for Research Resources, shall establish a program to enhance the competitiveness of such entities in obtaining funds from the national research institutes for conducting biomedical and behavioral research.

(B) The entities referred to in subparagraph (A) are entities that conduct biomedical and behavioral research and are located in a State in which the aggregate success rate for applications to the national research institutes for assistance for such research by the entities in the State has historically constituted a low success rate of obtaining such funds, relative to such aggregate rate for such entities in other States.

(C) With respect to enhancing competitiveness for purposes of subparagraph (A), the Director of NIH, in carrying out the program established under such subparagraph, may--

(i) provide technical assistance to the entities involved, including technical assistance in the preparation of applications for obtaining funds from the national research institutes;

(ii) assist the entities in developing a plan for biomedical or behavioral research proposals; and

(iii) assist the entities in implementing such plan.

(2) The Director of NIH shall establish a program of supporting projects of biomedical or behavioral research whose principal researchers are individuals who have not previously served as the

principal researchers of such projects supported by the Director.

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

The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research.

(i) Discretionary fund; uses; report to Congressional committees; authorization of appropriations

(1) There is established a fund, consisting of amounts appropriated under paragraph (3) and made available for the fund, for use by the Director of NIH to carry out the activities authorized in this chapter for the National Institutes of Health. The purposes for which such fund may be expended include--

(A) providing for research on matters that have not received significant funding relative to other matters, responding to new issues and scientific emergencies, and acting on research opportunities of high priority;

(B) supporting research that is not exclusively within the authority of any single agency of such Institutes; and

(C) purchasing or renting equipment and quarters for activities of such Institutes.

(2) Not later than February 10 of each fiscal year, the Secretary 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, a report describing the activities undertaken and expenditures made under this section during the preceding fiscal year. The report may contain such comments of the Secretary regarding this section as the Secretary determines to be appropriate.

(3) For the purpose of carrying out this subsection, there are authorized to be appropriated $25,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

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

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

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

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

(3) The data bank shall include the following:

(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated

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

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

(i) under a treatment investigational new drug application that has been submitted to the Secretary under section 360bbb(c) of title 21; or

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

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

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

(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 379h of title 21 shall not be used in carrying out this subsection.

(k) Day care for children of employees

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

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

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

(l) Interagency research on trauma

The Director of NIH shall carry out the program established in part F of subchapter X of this chapter (relating to interagency research on trauma).

(July 1, 1944, ch. 373, title IV, Sec. 402, as added Pub. L. 99-158, Sec. 2, Nov. 20, 1985, 99 Stat. 823; amended Pub. L. 100-607, title I, Sec. 111, Nov. 4, 1988, 102 Stat. 3052; Pub. L. 102-321, title I, Sec. 163(b)(3), July 10, 1992, 106 Stat. 376; Pub. L. 103-43, title I, Sec. 141(b), title II, Secs. 201, 202, 206, 208, 210(b), (c), title III, Sec. 303(b), June 10, 1993, 107 Stat. 139, 144, 148-150, 153; Pub. L. 105-115, title I, Sec. 113(a), Nov. 21, 1997, 111 Stat. 2310; Pub. L. 105-362, title VI, Sec. 601(a)(1)(A), Nov. 10, 1998, 112 Stat. 3285; Pub. L. 105-392, title IV, Sec. 409, Nov. 13, 1998, 112 Stat. 3589; Pub.

L. 107-109, Sec. 15(c)(2), Jan. 4, 2002, 115 Stat. 1420.)

References in Text

The provisions of title 5 governing appointments in the competitive service, referred to in subsec. (b)(6), (14), are classified generally to section 3301 et seq. of Title 5, Government Organization and Employees.

The General Schedule, referred to in subsec. (b)(6), is set out under section 5332 of Title 5, Government Organization and Employees.

The provisions of title 5 relating to classifications, referred to in subsec. (b)(14), are classified generally to chapter 51 (Sec. 5101 et seq.) and to subchapter III (Sec. 5331 et seq.) of chapter 53 of Title 5, Government Organization and Employees.

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

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

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

Amendments

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

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

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

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

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

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

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

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

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

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

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

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

Subsec. (j). Pub. L. 103-43, Sec. 210(c), added subsec. (j).
Subsec. (k). Pub. L. 103-43, Sec. 303(b), added subsec. (k).
1992--Subsec. (d)(1). Pub. L. 102-321 substituted ``220'' for ``two hundred''.
1988--Subsec. (b)(6). Pub. L. 100-607 inserted ``and scientific program advisory committees'' after ``peer review groups''.

Change of Name

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

Effective Date of 1997 Amendment

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

Effective Date of 1992 Amendment

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

Collaboration and Report

Section 113(b) of Pub. L. 105-115 provided that:
``(1) In general.--The Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the data bank under section 402(j) of the Public Health Service Act [subsec. (j) of this section].
``(2) Report.--Not later than two years after the date of enactment of this section [Nov. 21, 1997], the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report--
``(A) of the public health need, if any, for inclusion of device investigations within the scope of the data bank under section 402(j) of the Public Health Service Act;
``(B) on the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigations is required to be publicly disclosed; and
``(C) on such other issues relating to such section 402(j) as the Secretary determines to be appropriate.''

Chronic Fatigue Syndrome; Experts and Research Representatives on Advisory Committees and Boards

Section 902(c) of Pub. L. 103-43 provided that: ``The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall ensure that appropriate individuals with expertise in chronic fatigue syndrome or neuromuscular diseases and representative of a variety of disciplines and fields within the research community are appointed to appropriate National Institutes of Health advisory committees and boards.''

Third-Party Payments Regarding Certain Clinical Trials and Certain Life-Threatening Illnesses

Section 1901(a) of Pub. L. 103-43 provided that: ``The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct a study for the purpose of--

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

``(2) developing recommendations regarding such policies.''

Personnel Study of Recruitment, Retention and Turnover

Section 1905 of Pub. L. 103-43 directed Secretary of Health and Human Services, acting through Director of National Institutes of Health, to conduct a study to review the retention, recruitment, vacancy and turnover rates of support staff, including firefighters, law enforcement, procurement officers, technicians, nurses and clerical employees, to ensure that National Institutes of Health is adequately supporting conduct of efficient, effective and high quality research for the American public, and to submit a report to Congress on results of such study not later than 1 year after June 10, 1993.

Chronic Pain Conditions

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

Support for Bioengineering Research

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

Master Plan for Physical Infrastructure for Research

Section 2002 of Pub. L. 103-43 directed Secretary of Health and Human Services, acting through Director of the National Institutes of Health, not later than June 1, 1994, to present to Congress a master

plan to provide for replacement or refurbishment of less than adequate buildings, utility equipment and distribution systems (including the resources that provide electrical and other utilities, chilled water, air handling, and other services that the Secretary, acting through the Director, deemed necessary), roads, walkways, parking areas, and grounds that underpin the laboratory and clinical facilities of the National Institutes of Health, and provided that the plan could make recommendations for the undertaking of new projects that are consistent with the objectives of this section, such as encircling the National Institutes of Health Federal enclave with an adequate chilled water conduit.

Section Referred to in Other Sections

This section is referred to in sections 283, 284, 285g-4, 289a of this title; title 21 section 360bbb.