

(6) administer and support a systematic program of research concerning smoke inhalation injuries; and

(7) sponsor and support other research and training programs in the treatment and rehabilitation of burn injury victims.

(b) Authorization of appropriations

For purposes of this section, there are authorized to be appropriated not to exceed \$5,000,000 for the fiscal year ending June 30, 1975 and not to exceed \$8,000,000 for the fiscal year ending June 30, 1976.

(Pub. L. 93-498, §19, Oct. 29, 1974, 88 Stat. 1547; Pub. L. 96-88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 106-503, title I, §110(a)(2)(B)(vii), Nov. 13, 2000, 114 Stat. 2302; Pub. L. 112-239, div. A, title XVIII, §1802(b)(1), Jan. 2, 2013, 126 Stat. 2100.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Federal Fire Prevention and Control Act of 1974 (which is classified principally to chapter 49 (§2201 et seq.) of Title 15), and not as a part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2013—Subsec. (a). Pub. L. 112-239 substituted “Administrator of FEMA” for “Director” in introductory provisions.

2000—Subsec. (a). Pub. L. 106-503 substituted “in cooperation with the Director” for “in cooperation with the Secretary”.

Statutory Notes and Related Subsidiaries

CHANGE OF NAME

“Secretary of Health and Human Services” substituted for “Secretary of Health, Education, and Welfare” in subsec. (a) pursuant to section 509(b) of Pub. L. 96-88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of all functions, personnel, assets, components, authorities, grant programs, and liabilities of the Federal Emergency Management Agency, including the functions of the Under Secretary for Federal Emergency Management relating thereto, to the Federal Emergency Management Agency, see section 315(a)(1) of Title 6, Domestic Security.

For transfer of functions, personnel, assets, and liabilities of the Federal Emergency Management Agency, including the functions of the Director of the Federal Emergency Management Agency relating thereto, to the Secretary of Homeland Security, and for treatment of related references, see former section 313(1) and sections 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

DEFINITIONS

For definition of terms used in this section, see section 2203 of Title 15, Commerce and Trade.

PART I—FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

Editorial Notes

CODIFICATION

Pub. L. 105-392, title IV, §418(1), Nov. 13, 1998, 112 Stat. 3591, substituted “Foundation for the National Insti-

tutes of Health” for “National Foundation for Biomedical Research” in part heading.

Pub. L. 103-43, title I, §141(a)(2), June 10, 1993, 107 Stat. 136, redesignated part H “National Foundation for Biomedical Research” as I.

§ 290b. Establishment and duties of Foundation

(a) In general

The Secretary shall, acting through the Director of NIH, establish a nonprofit corporation to be known as the Foundation for the National Institutes of Health (hereafter in this section referred to as the “Foundation”). The Foundation shall not be an agency or instrumentality of the United States Government.

(b) Purpose of Foundation

The purpose of the Foundation shall be to support the National Institutes of Health in its mission (including collection of funds for pediatric pharmacologic research), and to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations.

(c) Certain activities of Foundation

(1) In general

In carrying out subsection (b), the Foundation may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of the following activities with respect to the purpose described in such subsection:

(A) A program to provide and administer endowed positions that are associated with the research program of the National Institutes of Health. Such endowments may be expended for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the endowed positions.

(B) A program to provide and administer fellowships and grants to research personnel in order to work and study in association with the National Institutes of Health. Such fellowships and grants may include stipends, travel, health insurance benefits and other appropriate expenses. The recipients of fellowships shall be selected by the donors and the Foundation upon the recommendation of the National Institutes of Health employees in the laboratory where the fellow would serve, and shall be subject to the agreement of the Director of the National Institutes of Health and the Executive Director of the Foundation.

(C) A program to collect funds for pediatric pharmacologic research and studies.

(D) Supplementary programs to provide for—

(i) scientists of other countries to serve in research capacities in the United States in association with the National Institutes of Health or elsewhere, or opportunities for employees of the National Institutes of Health or other public health officials in the United States to serve in such capacities in other countries, or both;

(ii) the conduct and support of studies, projects, and research, which may include

stipends, travel and other support for personnel in collaboration with national and international non-profit and for-profit organizations;

(iii) the conduct and support of forums, meetings, conferences, courses, and training workshops that may include undergraduate, graduate, post-graduate, and post-doctoral accredited courses and the maintenance of accreditation of such courses by the Foundation at the State and national level for college or continuing education credits or for degrees;

(iv) programs to support and encourage teachers and students of science at all levels of education and programs for the general public which promote the understanding of science;

(v) programs for writing, editing, printing, publishing, and vending of books and other materials; and

(vi) the conduct of other activities to carry out and support the purpose described in subsection (b).

(E) The Cures Acceleration Network described in section 287a of this title.

(2) Fees

The Foundation may assess fees for the provision of professional, administrative and management services by the Foundation in amounts determined reasonable and appropriate by the Executive Director.

(3) Authority of Foundation

The Foundation shall be the sole entity responsible for carrying out the activities described in this subsection.

(d) Board of Directors

(1) Composition

(A) The Foundation shall have a Board of Directors (hereafter referred to in this section as the "Board"), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

(B) The ex officio members of the Board shall be—

(i) the Chairman and ranking minority member of the Subcommittee on Health and the Environment (Committee on Energy and Commerce) or their designees, in the case of the House of Representatives;

(ii) the Chairman and ranking minority member of the Committee on Labor and Human Resources or their designees, in the case of the Senate;

(iii) the Director of the National Institutes of Health; and

(iv) the Commissioner of Food and Drugs.

(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board individuals from among a list of candidates to be provided by the National Academy of Science. Such appointed members shall include—

(i) representatives of the general biomedical field;

(ii) representatives of experts in pediatric medicine and research;

(iii) representatives of the general bio-behavioral field, which may include experts in biomedical ethics; and

(iv) representatives of the general public, which may include representatives of affected industries.

(D)(i) Not later than 30 days after June 10, 1993, the Director of the National Institutes of Health shall convene a meeting of the ex officio members of the Board to—

(I) incorporate the Foundation and establish the general policies of the Foundation for carrying out the purposes of subsection (b), including the establishment of the 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 title 26, and shall be subject to the provisions of such section.

(g) Executive Director

(1) In general

The Foundation shall have an Executive Director who shall be appointed by the Board

and shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

(2) Compensation

The rate of compensation of the Executive Director shall be fixed by the Board.

(h) Powers

In carrying out subsection (b), the Foundation may—

(1) operate under the direction of its Board;

(2) adopt, alter, and use a corporate seal, which shall be judicially noticed;

(3) provide for 1 or more officers, employees, and agents, as may be necessary, define their duties, and require surety bonds or make other provisions against losses occasioned by acts of such persons;

(4) hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees;

(5) with the consent of any executive department or independent agency, use the information, services, staff, and facilities of such in carrying out this section;

(6) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

(7) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this part;

(8) establish a process for the selection of candidates for positions under subsection (c);

(9) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

(10) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

(11) solicit, accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation;

(12) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation;

(13) appoint other groups of advisors as may be determined necessary from time to time to carry out the functions of the Foundation;

(14) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation; and

(15) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this part.

(i) Administrative control

No participant in the program established under this part shall exercise any administrative control over any Federal employee.

(j) General provisions

(1) Foundation integrity

The members of the Board shall be accountable for the integrity of the operations of the

Foundation and shall ensure such integrity through the development and enforcement of criteria and procedures relating to standards of conduct, financial disclosure statements, conflict of interest rules, recusal and waiver rules, audits and other matter determined appropriate by the Board.

(2) Financial conflicts of interest

Any individual who is an officer, employee, or member of the Board of the Foundation may not (in accordance with policies and requirements developed under subsection (d)(6)) personally or substantially participate in the consideration or determination by the Foundation of any matter that would directly or predictably affect any financial interest of the individual or a relative (as such term is defined in section 13101(16) of title 5) of the individual, of any business organization or other entity, or of which the individual is an officer or employee, or is negotiating for employment, or in which the individual has any other financial interest.

(3) Audits; availability of records

The Foundation shall—

(A) provide for annual audits of the financial condition of the Foundation; and

(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

(4) Reports

(A) Not later than 5 months following the end of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation, including an accounting of the use of amounts transferred under subsection (l).

(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts or grants to the Foundation of real or personal property, and the source and amount of all gifts or grants to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts or grants to the Foundation may be used.

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available—

(i) for public inspection, and shall upon request provide a copy of the report to any individual for a charge that shall not exceed the cost of providing the copy; and

(ii) to the appropriate committees of Congress.

(D) The Board shall annually hold a public meeting to summarize the activities of the Foundation and distribute written reports concerning such activities and the scientific results derived from such activities.

(5) Service of Federal employees

Federal employees may serve on committees advisory to the Foundation and otherwise co-

operate 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.¹

(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

¹ So in original. Probably should be "subsection".

to a report received under clause (iii) in accordance with paragraphs (7) through (12)² of section 284m(c) of this title, 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 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 \$1,250,000 and not more than \$5,000,000 to the Foundation.

(July 1, 1944, ch. 373, title IV, §499, formerly §499A, as added Pub. L. 101-613, §2, Nov. 16, 1990, 104 Stat. 3224; amended Pub. L. 102-170, title II, §216, Nov. 26, 1991, 105 Stat. 1128; Pub. L. 102-321, title I, §163(b)(6), July 10, 1992, 106 Stat. 376; renumbered §499 and amended Pub. L. 103-43, title I, §121(b)(3), title XVII, §1701, June 10, 1993, 107 Stat. 133, 186; Pub. L. 104-316, title I, §122(b), Oct. 19, 1996, 110 Stat. 3836; Pub. L. 105-392, title IV, §418(2), Nov. 13, 1998, 112 Stat. 3591; Pub. L. 107-109, §13, Jan. 4, 2002, 115 Stat. 1417; Pub. L. 109-482, title I, §107, Jan. 15, 2007, 120 Stat. 3696; Pub. L. 110-85, title V, §502(c), Sept. 27, 2007, 121

Stat. 889; Pub. L. 111-148, title X, §10409(c), Mar. 23, 2010, 124 Stat. 978; Pub. L. 112-74, div. F, title II, §221(d)(4), Dec. 23, 2011, 125 Stat. 1090; Pub. L. 112-144, title V, §509(f), July 9, 2012, 126 Stat. 1050; Pub. L. 117-101, §2(b), Mar. 15, 2022, 136 Stat. 47; Pub. L. 117-286, §4(c)(39), Dec. 27, 2022, 136 Stat. 4358.)

Editorial Notes

REFERENCES IN TEXT

The National Institutes of Health Amendments of 1990, referred to in subsec. (j)(8), is Pub. L. 101-613, Nov. 16, 1990, 104 Stat. 3224, which enacted this section, section 285g-4 of this title, and provisions set out as notes under section 201 and 285g-4 of this title. For complete classification of this Act to the Code, see Short Title of 1990 Amendments note set out under section 201 of this title and Tables.

Section 284m of this title, referred to in subsec. (j)(9)(B)(iv), was amended generally by Pub. L. 110-85, title V, §502(b), Sept. 27, 2007, 121 Stat. 886, and, as so amended, does not contain a par. (12) in subsec. (c).

PRIOR PROVISIONS

A prior section 499 of act July 1, 1944, was classified to section 289h of this title prior to repeal by Pub. L. 103-43.

AMENDMENTS

2022—Subsec. (j)(2). Pub. L. 117-286 substituted “section 13101(16) of title 5” for “section 109(16) of the Ethics in Government Act of 1978”.

Subsec. (l). Pub. L. 117-101 substituted “\$1,250,000 and not more than \$5,000,000” for “\$500,000 and not more than \$1,250,000”.

2012—Subsec. (c)(1)(C). Pub. L. 112-144 struck out “for which the Secretary issues a certification in the affirmative under section 355a(n)(1)(A) of title 21” before period at end.

2011—Subsec. (c)(1)(E). Pub. L. 112-74 substituted “section 287a” for “section 282d”.

2010—Subsec. (c)(1)(E). Pub. L. 111-148 added subpar. (E).

2007—Subsec. (c)(1)(C). Pub. L. 110-85 substituted “and studies for which the Secretary issues a certification in the affirmative under section 355a(n)(1)(A) of title 21” for “and studies listed by the Secretary pursuant to section 284m(a)(1)(A) of this title and referred under section 355a(d)(4)(C) of title 21”. Amendment, which directed striking out language ending with “section 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(a)(d)(4)(C))” in the original, was executed by striking out language ending with “section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C))” in the original to reflect the probable intent of Congress. That language had been translated as “section 355a(d)(4)(C) of title 21” for purposes of codification.

Subsec. (d)(1)(D)(ii). Pub. L. 109-482, §107(1)(A)(i), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: “Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.”

Subsec. (d)(1)(G). Pub. L. 109-482, §107(1)(A)(ii), inserted “appointed” after “that the number of”.

Subsec. (d)(3)(B). Pub. L. 109-482, §107(1)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: “Any vacancy in the membership of the Board shall be filled in the manner in which the original position was made and shall not affect the power of the remaining members to execute the duties of the Board.”

Subsec. (d)(5). Pub. L. 109-482, §107(1)(C), inserted “appointed” after “majority of the”.

Subsec. (j)(2). Pub. L. 109-482, §107(2)(A), substituted “subsection (d)(6)” for “subsection (d)(2)(B)(i)(II)”.

² See References in Text note below.

Subsec. (j)(4)(A). Pub. L. 109-482, §107(2)(B)(i), inserted “, including an accounting of the use of amounts transferred under subsection (l)” before period at end.

Subsec. (j)(4)(C). Pub. L. 109-482, §107(2)(B)(ii), added subpar. (C) and struck out former subpar. (C) which read as follows: “The Foundation shall make copies of each report submitted under subparagraph (A) available for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.”

Subsec. (j)(10). Pub. L. 109-482, §107(2)(C), substituted “of Health and the National Institutes of Health may accept transfers of funds from the Foundation” for “of Health”.

Subsec. (l). Pub. L. 109-482, §107(3), added subsec. (l) and struck out former subsec. (l) which related to authorization of appropriations and limitation regarding other funds.

2002—Subsec. (b). Pub. L. 107-109, §13(1), inserted “(including collection of funds for pediatric pharmacologic research)” after “mission”.

Subsec. (c)(1)(C), (D). Pub. L. 107-109, §13(2), added subpar. (C) and redesignated former subpar. (C) as (D).

Subsec. (d)(1)(B)(iv). Pub. L. 107-109, §13(3)(A)(i), added cl. (iv).

Subsec. (d)(1)(C). Pub. L. 107-109, §13(3)(A)(ii), added subpar. (C) and struck out former subpar. (C) which read as follows: “The ex officio members of the Board under subparagraph (B) shall appoint to the Board 11 individuals from among a list of candidates to be provided by the National Academy of Science. Of such appointed members—

“(i) 4 shall be representative of the general biomedical field;

“(ii) 2 shall be representatives of the general biobehavioral field; and

“(iii) 5 shall be representatives of the general public.”

Subsec. (d)(2)(B). Pub. L. 107-109, §13(3)(B), realigned margin.

Subsec. (e) to (g). Pub. L. 107-109, §13(5), redesignated subsecs. (f) to (h) as (e) to (g), respectively.

Subsec. (h). Pub. L. 107-109, §13(5), (6), redesignated subsec. (i) as (h) and substituted “solicit,” for “solicit” in par. (11). Former subsec. (h) redesignated (g).

Subsec. (i). Pub. L. 107-109, §13(5), redesignated subsec. (j) as (i). Former subsec. (i) redesignated (h).

Subsec. (j). Pub. L. 107-109, §13(5), redesignated subsec. (k) as (j). Former subsec. (j) redesignated (i).

Subsec. (j)(1). Pub. L. 107-109, §13(7), struck out “(including those developed under subsection (d)(2)(B)(i)(II))” after “procedures relating to standards of conduct”.

Subsec. (j)(2). Pub. L. 107-109, §13(7), which directed striking out “(including those developed under subsection (d)(2)(B)(i)(II))” in par. (2), could not be executed because those words do not appear in par. (2).

Subsec. (k). Pub. L. 107-109, §13(5), redesignated subsec. (l) as (k). Former subsec. (k) redesignated (j).

Subsec. (k)(9). Pub. L. 107-109, §13(4), designated existing provisions as subpar. (A), inserted subpar. heading, and added subpars. (B) and (C).

Subsecs. (l), (m). Pub. L. 107-109, §13(5), redesignated subsec. (m) as (l). Former subsec. (l) redesignated (k).

1998—Subsec. (a). Pub. L. 105-392, §418(2)(A), substituted “Foundation for the National Institutes of Health” for “National Foundation for Biomedical Research”.

Subsec. (k)(10). Pub. L. 105-392, §418(2)(B), struck out “not” after “may” and inserted at end “Any funds transferred under this paragraph shall be subject to all Federal limitations relating to federally-funded research.”

Subsec. (m)(1). Pub. L. 105-392, §418(2)(C), substituted “\$500,000 for each fiscal year” for “\$200,000 for the fiscal years 1994 and 1995”.

1996—Subsec. (n). Pub. L. 104-316 struck out subsec. (n) which required Comptroller General to conduct audit and prepare report to Congress on adequacy of compliance of the Foundation with guidelines established under this section.

1993—Subsec. (a). Pub. L. 103-43, §1701(1), inserted “, acting through the Director of NIH,” after “Secretary shall” and struck out “, except for the purposes of the Ethics in Government Act and the Technology Transfer Act,” after “shall not”.

Subsec. (b). Pub. L. 103-43, §1701(3), added subsec. (b) and struck out heading and text of former subsec. (b). Text related to duties of Foundation.

Subsec. (c). Pub. L. 103-43, §1701(3), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 103-43, §1701(2), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (f).

Subsec. (d)(1). Pub. L. 103-43, §1701(4)(A), substituted “appointed members of the Board” for “members of the Foundation” in subpar. (A), “Board” for “Council” in subpar. (B), and “appoint to the Board” for “appoint to the Council” in subpar. (C), and added subpars. (D) to (G).

Subsec. (d)(2). Pub. L. 103-43, §1701(4)(B), designated existing provisions as subpar. (A), substituted “an individual to serve as the initial Chair” for “an appointed member of the Board to serve as the Chair”, and added subpar. (B).

Subsec. (d)(3)(A). Pub. L. 103-43, §1701(4)(C), substituted “(1)(C)” for “(2)(C)”.

Subsec. (d)(5), (6). Pub. L. 103-43, §1701(4)(D), added pars. (5) and (6).

Subsec. (e). Pub. L. 103-43, §1701(2), redesignated subsec. (e) as (g).

Subsecs. (f) to (h). Pub. L. 103-43, §1701(2), redesignated subsecs. (d) to (f) as (f) to (h), respectively. Former subsecs. (g) and (h) redesignated (i) and (j), respectively.

Subsec. (i). Pub. L. 103-43, §1701(2), redesignated subsec. (g) as (i). Former subsec. (i) redesignated (m).

Subsec. (i)(4). Pub. L. 103-43, §1701(5)(A), inserted before period at end “, and define the duties of the officers and employees”.

Subsec. (i)(5), (6). Pub. L. 103-43, §1701(5)(B), (C), redesignated par. (6) as (5) and struck out former par. (5) which read as follows: “prescribe by its Board its by-laws, that shall be consistent with law, and that shall provide for the manner in which—

“(A) its officers, employees, and agents are selected;

“(B) its property is acquired, held, and transferred;

“(C) its general operations are to be conducted; and

“(D) the privileges granted by law are exercised and enjoyed;”.

Subsec. (i)(7). Pub. L. 103-43, §1701(5)(C), (D), redesignated par. (8) as (7) and substituted “part” for “subtitle”. Former par. (7) redesignated (6).

Subsec. (i)(8). Pub. L. 103-43, §1701(5)(C), (E), redesignated par. (9) as (8) and substituted “establish a process for the selection of candidates for positions under subsection (c)” for “establish a mechanism for the selection of candidates, subject to the approval of the Director of the National Institutes of Health, for the endowed scientific positions within the organizational structure of the intramural research programs of the National Institutes of Health and candidates for participation in the National Institutes of Health Scholars program”.

Subsec. (i)(9), (10). Pub. L. 103-43, §1701(5)(C), redesignated pars. (10) and (11) as (9) and (10), respectively. Former par. (9) redesignated (8).

Subsec. (i)(11). Pub. L. 103-43, §1701(5)(C), (F), redesignated par. (12) as (11) and inserted “solicit” before “accept”. Former par. (11) redesignated (10).

Subsec. (i)(12), (13). Pub. L. 103-43, §1701(5)(C), redesignated pars. (13) and (14) as (12) and (13), respectively. Former par. (12) redesignated (11).

Subsec. (i)(14). Pub. L. 103-43, §1701(5)(G), (H), added par. (14). Former par. (14) redesignated (13).

Subsec. (i)(15). Pub. L. 103-43, §1701(5)(I), substituted “part” for “subtitle”.

Subsec. (j). Pub. L. 103-43, §1701(2), redesignated subsec. (h) as (j).

Subsecs. (k), (l). Pub. L. 103-43, §1701(6), added subsecs. (k) and (l).

Subsec. (m). Pub. L. 103-43, §1701(7), amended heading and text of subsec. (m) generally. Prior to amendment, text read as follows:

“(1) AUTHORIZATION OF APPROPRIATIONS.—Subject to paragraph (2), for the purpose of carrying out this part, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1995.

“(2) LIMITATIONS.—

“(A) Amounts appropriated under paragraph (1) or made available under subparagraph (C) may not be provided to the fund established under subsection (b)(1)(A) of this section.

“(B) For the first fiscal year for which amounts are appropriated under paragraph (1), \$200,000 is authorized to be appropriated.

“(C) With respect to the first fiscal year for which amounts are appropriated under paragraph (1), the Secretary may, from amounts appropriated for such fiscal year for the programs of the Department of Health and Human Services, make available not more than \$200,000 for carrying out this part, subject to subparagraph (A).”

Pub. L. 103-43, §1701(2), redesignated subsec. (i) as (m).

Subsec. (n). Pub. L. 103-43, §1701(8), added subsec. (n). 1992—Subsec. (g)(9). Pub. L. 102-321 struck out “or the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration” after “Director of the National Institutes of Health” and “and the Alcohol, Drug Abuse, and Mental Health Administration” after “research programs of the National Institutes of Health”.

1991—Subsec. (c)(1)(C). Pub. L. 102-170, §216(1), substituted “11” for “9”.

Subsec. (c)(1)(C)(iii). Pub. L. 102-170, §216(2), substituted “5” for “3”.

Statutory Notes and Related Subsidiaries

CHANGE OF NAME

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

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

EFFECTIVE DATE OF 2007 AMENDMENT

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

EFFECTIVE DATE OF 1992 AMENDMENT

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

PART J—ADVANCED RESEARCH PROJECTS AGENCY—HEALTH

§ 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 December 29, 2022, the Secretary shall transfer all functions, personnel, missions, activities, authorities, and funds of the Advanced Research Projects Agency for Health as in existence on December 29, 2022, 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 December 29, 2022, 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 December 29, 2022, 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 over-