Statutory Notes and Related Subsidiaries

ORDERLY TRANSITION

Pub. L. 117–328, div. FF, title II, § 2313(b), Dec. 29, 2022, 136 Stat. 5762, provided that: ''The Secretary of Health and Human Services shall take such steps as are necessary to provide for the orderly transition to the authority of the National Science Advisory Board for Biosecurity established under section 404O of the Public Health Service Act [42 U.S.C. 283r], as added by subsection (a), from any authority of the Board described in section 205 of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417) [set out below], as in effect on the day before the date of enactment of this Act [Dec. 29, 2022].''

APPLICATION

Pub. L. 117–328, div. FF, title II, § 2313(c), Dec. 29, 2022, 136 Stat. 5763, provided that: ''The requirements under section 404O of the Public Health Service Act [42 U.S.C. 283r], as added by subsection (a), related to the mission, activities, or functions of the National Science Advisory Board for Biosecurity shall not apply until the completion of any work undertaken by such Board before the date of enactment of this Act [Dec. 29, 2022].''

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY: PROVISION OF ADVICE, GUIDANCE, OR RECOMMENDATIONS

Pub. L. 109–417, title II, § 205, Dec. 19, 2006, 120 Stat. 2851, provided that: ''The National Science Advisory Board for Biosecurity shall, when requested by the Secretary of Health and Human Services, provide to relevant Federal departments and agencies, advice, guidance, or recommendations concerning—

''(1) a core curriculum and training requirements for workers in maximum containment biological laboratories; and

''(2) periodic evaluations of maximum containment biological laboratory capacity nationwide and assessments of the future need for increased laboratory capacity.''

PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

§ 284. Directors of national research institutes

(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 December 13, 2016, shall be deemed to be appointed for a 5-year term under this subsection beginning on such date.

(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) Duties and authority; grants, contracts, and cooperative agreements

(1) In carrying out the purposes of section 241 of this title with respect to human diseases or disorders or other aspects of human health for which the national research institutes were established, the Secretary, acting through the Director of each national research institute—

(A) shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to—

(i) the maintenance of health,

(ii) the detection, diagnosis, treatment, and prevention of human diseases and disorders,

(iii) the rehabilitation of individuals with human diseases, disorders, and disabilities, and

(iv) the expansion of knowledge of the processes underlying human diseases, disorders, and disabilities, the processes underlying the normal and pathological functioning of the body and its organ systems, and the processes underlying the interactions between the human organism and the environment;

(B) may, subject to the peer review prescribed under section 289a(b) of this title and

any advisory council review under section 284a(a)(3)(A)(i) of this title, conduct the research, investigations, experiments, demonstrations, and studies referred to in subparagraph (A);

(C) 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 288 of this title, 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 of title 10 shall apply with respect to contracts entered into under this subsection and section 282(b) of this title.

(2) Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements. The Secretary, acting through the Director of each national research institute—

(A) may enter into a contract for research, training, or demonstrations only if the contract has been recommended after technical and scientific peer review required by regulations under section 289a of this title;

(B) may make grants and cooperative agreements under paragraph (1) for research, training, or demonstrations, except that—

(i) if the direct cost of the grant or cooperative agreement to be made does not exceed $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 289a of this title, and

(ii) if the direct cost of the grant or cooperative agreement to be made exceeds $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 289a of this title and is recommended under section 284a(a)(3)(A)(ii) of this title by the advisory council for the national research institute involved; and

(C) shall, subject to section 300cc–40c(d)(2) of this title, receive from the President and the Office of Management and Budget directly all funds appropriated by the Congress for obligation and expenditure by the Institute.

(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 282(m) of this title;

(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) Coordination with other public and private entities; cooperation with other national research institutes; appointment of additional peer review groups

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 282(b)(16) of this title; 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.

Chapter 10 of title 5 shall not apply to the duration of a peer review group appointed under paragraph (3).

(July 1, 1944, ch. 373, title IV, § 405, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 826; amended Pub. L. 100–607, title I, § 116, Nov. 4, 1988, 102 Stat. 3053; Pub. L. 100–690, title II, § 2613(c), Nov. 18, 1988, 102 Stat. 4239; Pub. L. 103–43, title III, § 301(a)(1), (b), June 10, 1993, 107 Stat. 150; Pub. L. 109–482, title I, § 102(f)(1)(B), Jan. 15, 2007, 120 Stat. 3685; Pub. L. 114–255, div. A, title II, §§ 2033(a), (b), 2036(c), Dec. 13, 2016, 130 Stat. 1057, 1058, 1063; Pub. L. 117–81, div. A, title XVII, § 1702(j)(1)(B), Dec. 27, 2021, 135 Stat. 2159; Pub. L. 117–286, § 4(a)(232), Dec. 27, 2022, 136 Stat. 4331.)

Editorial Notes

AMENDMENTS

2022—Subsec. (c). Pub. L. 117–286 substituted ''Chapter 10 of title 5'' for ''The Federal Advisory Committee Act'' in concluding provisions.

2021—Subsec. (b)(1). Pub. L. 117–81 substituted ''section 3861'' for ''section 2354'' in concluding provisions.

2016—Subsec. (a). Pub. L. 114–255, § 2033(a), amended subsec. (a) generally. Prior to amendment, text read as follows: ''The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes shall be appointed by the Secretary. Each Director of a national research institute shall report directly to the Director of NIH.''

Subsec. (b)(1)(C) to (M). Pub. L. 114–255, § 2036(c), added par. (C) and redesignated former pars. (C) to (L) as (D) to (M), respectively.

Subsec. (b)(3). Pub. L. 114–255, § 2033(b), added par. (3).

2007—Subsec. (c)(3)(A). Pub. L. 109–482 substituted ''section 282(b)(16)'' for ''section 282(b)(6)''.

1993—Subsec. (b)(2)(C). Pub. L. 103–43, § 301(a)(1), added subpar. (C).

Subsec. (c). Pub. L. 103–43, § 301(b)(2), inserted concluding provisions relating to Federal Advisory Committee Act.

Subsec. (c)(3). Pub. L. 103–43, § 301(b)(1), amended par. (3) generally. Prior to amendment, par. (3) read as follows: ''may, in consultation with the advisory council for the Institute and the approval of the Director of NIH, establish and appoint technical and scientific peer review groups in addition to those established and appointed under section 282(b)(6) of this title; and''.

1988—Subsec. (b)(1). Pub. L. 100–607, § 116(1), struck out ''the'' after ''with respect to'' in introductory provisions.

Subsec. (c)(3). Pub. L. 100–690 substituted ''establish and appoint'' and ''established and appointed'' for ''establish'' and ''established'', respectively.

Pub. L. 100–607, § 116(2)(A), amended par. (3) generally. Prior to amendment, par. (3) read as follows: ''may, with the approval of the advisory council for the institute and the Director of NIH, appoint technical and scientific peer review groups in addition to those appointed under section 282(b)(6) of this title.''

Subsec. (c)(4). Pub. L. 100–607, § 116(2)(C), added par. (4).

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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 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

FEDERAL RESEARCH

Pub. L. 117–215, title IV, § 401, Dec. 2, 2022, 136 Stat. 2265, provided that:

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Dec. 2, 2022], the Secretary of Health and Human Services, in coordination with the Director of the National Institutes of Health and the heads of other relevant Federal agencies, shall submit to the Caucus on International Narcotics Control, the Committee on the Judiciary, and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce and the Committee on the Judiciary of the House of Representatives a report on—

''(1) the potential therapeutic effects of cannabidiol or marijuana on serious medical conditions, including intractable epilepsy;

''(2) the potential effects of marijuana, including—

''(A) the effect of increasing delta-9-tetrahydrocannabinol levels on the human body and developing adolescent brains; and

''(B) the effect of various delta-9-tetrahydrocannabinol levels on cognitive abilities, such as those that are required to operate motor vehicles or other heavy equipment; and

''(3) the barriers associated with researching marijuana or cannabidiol in States that have legalized the use of such substances, which shall include—

''(A) recommendations as to how such barriers might be overcome, including whether public-private partnerships or Federal-State research partnerships may or should be implemented to provide researchers with access to additional strains of marijuana and cannabidiol; and

''(B) recommendations as to what safeguards must be in place to verify—

''(i) the levels of tetrahydrocannabinol, cannabidiol, or other cannabinoids contained in products obtained from such States is accurate; and

''(ii) that such products do not contain harmful or toxic components.

''(b) ACTIVITIES.—To the extent practicable, the Secretary of Health and Human Services, either directly or through awarding grants, contacts, or cooperative agreements, shall expand and coordinate the activities of the National Institutes of Health and other relevant Federal agencies to better determine the effects of cannabidiol and marijuana, as outlined in the report submitted under paragraphs (1) and (2) of subsection (a).''

[For definitions of terms as used in section 401 of Pub. L. 117–215, set out above, see section 2(a) of Pub. L. 117–215, set out as a note under section 801 of Title 21, Food and Drugs.]

ENHANCING THE CLINICAL AND TRANSLATIONAL SCIENCE AWARD

Pub. L. 109–482, title I, § 106, Jan. 15, 2007, 120 Stat. 3696, provided that:

''(a) IN GENERAL.—In administering the Clinical and Translational Science Award, the Director of NIH shall establish a mechanism to preserve independent funding and infrastructure for pediatric clinical research centers by—

''(1) allowing the appointment of a secondary principal investigator under a single Clinical and Translational Science Award, such that a pediatric principal investigator may be appointed with direct authority over a separate budget and infrastructure for pediatric clinical research; or

''(2) otherwise securing institutional independence of pediatric clinical research centers with respect to finances, infrastructure, resources, and research agenda.

''(b) REPORT.—As part of the biennial report under section 403 of the Public Health Service Act [42 U.S.C. 283], the Director of NIH shall provide an evaluation and comparison of outcomes and effectiveness of training programs under subsection (a).

''(c) DEFINITION.—For purposes of this section, the term 'Director of NIH' has the meaning given such term in section 401 of the Public Health Service Act [42 U.S.C. 281].''

§ 284a. Advisory councils

(a) Establishment; acceptance of conditional gifts; functions

(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 238 of this title, 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 289a(b)(2) of this title 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 284(b)(2) of this title 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) Membership; compensation

(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 Under Secretary for Health 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) Term of office; reappointment; vacancy

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) Chairman; term of office

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) Meetings

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.