

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

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

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

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

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

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

(b) Submission to Congressional committees

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

(c) Periodic review and revision

The Director of NIH shall periodically review, and as appropriate, make revisions in the plan required under subsection (a). A description of any revision made in the plan shall be included in the first biennial report under section 283 of this title that is submitted after the revision is made.

(d) Dissemination of information

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

(e) Interagency Coordinating Committee on the Use of Animals in Research

(1) The Director of NIH shall establish within the National Institutes of Health a committee to be known as the Interagency Coordinating Committee on the Use of Animals in Research (in this subsection referred to as the “Committee”).

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

(3) The Committee shall be composed of—

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

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

(July 1, 1944, ch. 373, title IV, §404C, as added Pub. L. 103-43, title II, §205(a), June 10, 1993, 107 Stat. 146; amended Pub. L. 112-74, div. F, title II, §221(d)(2), Dec. 23, 2011, 125 Stat. 1090.)

AMENDMENTS

2011—Subsec. (e)(3)(A). Pub. L. 112-74 struck out “and the Director of the Center for Research Resources” after “institutes”.

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.

§ 283f. Requirements regarding surveys of sexual behavior

With respect to any survey of human sexual behavior proposed to be conducted or supported through the National Institutes of Health, the survey may not be carried out unless—

(1) the proposal has undergone review in accordance with any applicable requirements of sections 289 and 289a of this title; and

(2) the Secretary, in accordance with section 289a-1 of this title, makes a determination that the information expected to be obtained through the survey will assist—

(A) in reducing the incidence of sexually transmitted diseases, the incidence of infection with the human immunodeficiency virus, or the incidence of any other infectious disease; or

(B) in improving reproductive health or other conditions of health.

(July 1, 1944, ch. 373, title IV, §404D, as added Pub. L. 103-43, title II, §207, June 10, 1993, 107 Stat. 148.)

PROHIBITION AGAINST SHARP ADULT SEX SURVEY AND AMERICAN TEENAGE SEX SURVEY

Pub. L. 103-43, title XX, §2015, June 10, 1993, 107 Stat. 217, provided that: “The Secretary of Health and Human Services may not during fiscal year 1993 or any subsequent fiscal year conduct or support the SHARP survey of adult sexual behavior or the American Teenage Study of adolescent sexual behavior. This section becomes effective on the date of the enactment of this Act [June 10, 1993].”

§ 283g. Muscular dystrophy; initiative through Director of National Institutes of Health

(a) Expansion, intensification, and coordination of activities

(1) In general

The Director of NIH, in coordination with the Directors of the National Institute of Neurological Disorders and Stroke, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Heart, Lung, and Blood Institute, and the other national research institutes as appropriate, shall expand

and intensify programs of such Institutes with respect to research and related activities concerning various forms of muscular dystrophy, including Duchenne, Becker, congenital muscular dystrophy, limb-girdle muscular dystrophy, myotonic, facioscapulohumeral muscular dystrophy (referred to in this section as “FSHD”) and other forms of muscular dystrophy.

(2) Coordination

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

(3) Allocations by Director of NIH

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

(b) Centers of excellence

(1) In general

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

(2) Research

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

(3) Coordination of centers

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

(4) Organization of centers

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

(5) Duration of support

Support for a center established under paragraph (1) may be provided under this section for a period of not to exceed 5 years. Such period may be extended for 1 or more additional periods not exceeding 5 years if the operations

of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director of NIH and if such group has recommended to the Director that such period should be extended.

(c) Facilitation of research

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

(d) Coordinating Committee

(1) In general

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

(2) Composition

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

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

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

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

(3) Chair

(A) In general

With respect to muscular dystrophy, the Chair of the Coordinating Committee shall serve as the principal advisor to the Secretary, the Assistant Secretary for Health, and the Director of NIH, and shall provide advice to the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and to the heads of other relevant agencies. The Coordinating

¹ See References in Text note below.

Committee shall select the Chair for a term not to exceed 2 years.

(B) Appointment

The Chair of the Committee shall be appointed by and be directly responsible to the Secretary.

(4) Administrative support; terms of service; other provisions

The following shall apply with respect to the Coordinating Committee:

(A) The Coordinating Committee shall receive necessary and appropriate administrative support from the Department of Health and Human Services.

(B) The Coordinating Committee shall meet as appropriate as determined by the Secretary, in consultation with the chair,² but shall meet no fewer than two times per calendar year.

(e) Plan for HHS activities

(1) In general

Not later than 1 year after December 18, 2001, the Coordinating Committee shall develop a plan for conducting and supporting research and education on muscular dystrophy through the agencies represented on the Coordinating Committee pursuant to subsection (d)(2)(A) and shall periodically review and revise the plan. The plan shall—

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

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

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

(2) Certain elements of plan

The plan under paragraph (1) shall, with respect to each form of muscular dystrophy, provide for the following as appropriate:

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

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

(C) The development of improved screening techniques.

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

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

(f) Public input

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

(g) Clinical research

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

(July 1, 1944, ch. 373, title IV, §404E, as added Pub. L. 107-84, §3, Dec. 18, 2001, 115 Stat. 824; amended Pub. L. 109-482, title I, §§103(b)(4), 104(b)(1)(A), Jan. 15, 2007, 120 Stat. 3687, 3692; Pub. L. 110-154, §1(b)(3), Dec. 21, 2007, 121 Stat. 1827; Pub. L. 110-361, §2, Oct. 8, 2008, 122 Stat. 4010; Pub. L. 113-166, §2, Sept. 26, 2014, 128 Stat. 1879.)

REFERENCES IN TEXT

Section 6 of the MD-CARE Act, referred to in subsec. (a)(2), is section 6 of Pub. L. 107-84, which was formerly set out as a note under section 247b-18 of this title and does not relate to establishment of a coordinating committee. However, subsec. (d) of this section contains provisions relating to the establishment of the Muscular Dystrophy Coordinating Committee.

PRIOR PROVISIONS

A prior section 283g, act July 1, 1944, ch. 373, title IV, §404E, as added Pub. L. 103-43, title II, §209, June 10, 1993, 107 Stat. 149, related to Office of Alternative Medicine, prior to repeal by Pub. L. 105-277, div. A, §101(f) [title VI, §601(1)], Oct. 21, 1998, 112 Stat. 2681-337, 2681-387.

AMENDMENTS

2014—Subsec. (a)(1). Pub. L. 113-166, §2(1), substituted “Musculoskeletal” for “Muscockeletal” and inserted “Becker, congenital muscular dystrophy, limb-girdle muscular dystrophy,” after “Duchenne.”

Subsec. (b)(2). Pub. L. 113-166, §2(2)(A), substituted “cardiac and pulmonary function, and pharmacological” for “genetics, pharmacological”.

Subsec. (b)(3). Pub. L. 113-166, §2(2)(B), inserted “and sharing of data” after “regular communication”.

Subsec. (d)(2). Pub. L. 113-166, §2(3)(A)(i), substituted “18” for “15” in introductory provisions.

Subsec. (d)(2)(A). Pub. L. 113-166, §2(3)(A)(ii), substituted “, the Food and Drug Administration, and the Administration for Community Living” for “and the Food and Drug Administration” and “including the Department of Education and the Social Security Administration” for “such as the Department of Education” and inserted “and adults” after “children”.

Subsec. (d)(4)(B). Pub. L. 113-166, §2(3)(B), inserted “, but shall meet no fewer than two times per calendar year” before period at end.

Subsec. (e)(1). Pub. L. 113-166, §2(4)(A)(i), substituted “through the agencies represented on the Coordinating Committee pursuant to subsection (d)(2)(A)” for “through the national research institutes” in introductory provisions.

Subsec. (e)(1)(A). Pub. L. 113-166, §2(4)(A)(ii), inserted “public services,” after “psychosocial,” and “, studies to demonstrate the cost-effectiveness of providing inde-

²So in original. Probably should be capitalized.

pendent living resources and support to patients with various forms of muscular dystrophy, and studies to determine optimal clinical care interventions for adults with various forms of muscular dystrophy” after “including studies of the impact of such diseases in rural and underserved communities”.

Subsec. (e)(2)(D). Pub. L. 113-166, §2(4)(B), inserted “and new clinical interventions to improve the health of those with muscular dystrophy” after “including new biological agents”.

2008—Subsec. (a)(1). Pub. L. 110-361, §2(b)(1), inserted “the National Heart, Lung, and Blood Institute,” after “the Eunice Kennedy Shriver National Institute of Child Health and Human Development.”.

Subsec. (b)(1). Pub. L. 110-361, §2(b)(2), inserted at end “Such centers of excellence shall be known as the ‘Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers.’”

Subsec. (f). Pub. L. 110-361, §2(a), redesignated subsec. (g) as (f) and struck out former subsec. (f) which related to reports.

Subsec. (g). Pub. L. 110-361, §2(a), (b)(3), added subsec. (g) and redesignated former subsec. (g) as (f).

2007—Pub. L. 109-482, §104(b)(1)(A)(ii), which directed amendment of subsec. (b) by striking subsec. (f) and redesignating subsec. (g) as (f), could not literally be executed and was not executed in view of amendments by Pub. L. 110-361. See 2008 Amendment notes above.

Subsec. (a)(1). Pub. L. 110-154 substituted “Eunice Kennedy Shriver National Institute of Child Health and Human Development” for “National Institute of Child Health and Human Development”.

Subsec. (b)(3). Pub. L. 109-482, §104(b)(1)(A)(i), amended heading and text of par. (3) generally. Text read as follows: “The Director of NIH—

“(A) shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers; and

“(B) shall require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director.”

Subsec. (h). Pub. L. 109-482, §103(b)(4), struck out heading and text of subsec. (h). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2002 through 2006. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriations that is available for conducting or supporting through the National Institutes of Health research and other activities with respect to muscular dystrophy.”

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.

§§ 283h, 283i. Transferred

CODIFICATION

Section 283h, act July 1, 1944, ch. 373, title IV, §404F, as added Pub. L. 107-280, §3, Nov. 6, 2002, 116 Stat. 1989; amended Pub. L. 109-482, title I, §§103(b)(5), 104(b)(1)(B), Jan. 15, 2007, 120 Stat. 3687, 3693, which related to the Office of Rare Diseases, was renumbered section 481 of act July 1, 1944, by Pub. L. 112-74, div. F, title II, §221(c)(2)(A)(i), Dec. 23, 2011, 125 Stat. 1089, and transferred to section 287a-1 of this title.

Section 283i, act July 1, 1944, ch. 373, title IV, §404G, as added Pub. L. 107-280, §4, Nov. 6, 2002, 116 Stat. 1990; amended Pub. L. 109-482, title I, §103(b)(6), Jan. 15, 2007, 120 Stat. 3687, which related to rare disease regional centers of excellence, was renumbered section 481A of act July 1, 1944, by Pub. L. 112-74, div. F, title II, §221(c)(3), Dec. 23, 2011, 125 Stat. 1089, and transferred to section 287a-2 of this title.

§ 283j. Repealed. Pub. L. 114-255, div. A, title II, § 2042(f)(1), Dec. 13, 2016, 130 Stat. 1073

Section, July 1, 1944, ch. 373, title IV, §404H, as added Pub. L. 109-416, §2(b), Dec. 19, 2006, 120 Stat. 2821, required review and report on centers of excellence funded under this subchapter.

§ 283k. Biomedical and behavioral research facilities

(a) Modernization and construction of facilities

(1) In general

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

(2) Construction and cost of construction

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

(b) Scientific and technical review boards for merit-based review of proposals

(1) In general: approval as precondition to grants

(A) Establishment

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

(B) Requirement

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

(2) Duties

(A) Advice

The Board shall provide advice to the Director of NIH and the Council of Councils established under section 282(l) of this title (in this section referred to as the “Council”) in carrying out this section.

(B) Determination of merit

In carrying out subparagraph (A), the Board shall make a determination of the merit of each application submitted for a grant under subsection (a), after consideration of the requirements established in subsection (c), and shall report the results of the determination to the Director of NIH and the Council. Such determinations shall be conducted in a manner consistent with procedures established under section 289a of this title.

(C) Amount

In carrying out subparagraph (A), the Board shall, in the case of applications rec-