

(2) Requirements**(A) In general**

With respect to Parkinson's disease, each center assisted under this subsection shall—

- (i) use the facilities of a single institution or a consortium of cooperating institutions, and meet such qualifications as may be prescribed by the Director of the NIH; and
- (ii) conduct basic and clinical research.

(B) Discretionary requirements

With respect to Parkinson's disease, each center assisted under this subsection may—

- (i) conduct training programs for scientists and health professionals;
- (ii) conduct programs to provide information and continuing education to health professionals;
- (iii) conduct programs for the dissemination of information to the public;
- (iv) separately or in collaboration with other centers, establish a nationwide data system derived from patient populations with Parkinson's disease, and where possible, comparing relevant data involving general populations;
- (v) separately or in collaboration with other centers, establish a Parkinson's Disease Information Clearinghouse to facilitate and enhance knowledge and understanding of Parkinson's disease; and
- (vi) separately or in collaboration with other centers, establish a national education program that fosters a national focus on Parkinson's disease and the care of those with Parkinson's disease.

(3) Stipends regarding training programs

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

(4) Duration of support

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

(d) Morris K. Udall Awards for Excellence in Parkinson's Disease Research

The Director of NIH is authorized to establish a grant program to support investigators with a proven record of excellence and innovation in Parkinson's disease research and who demonstrate potential for significant future breakthroughs in the understanding of the pathogenesis,¹ diagnosis, and treatment of Parkinson's disease. Grants under this subsection shall be available for a period of not to exceed 5 years.

(July 1, 1944, ch. 373, title IV, § 409B, as added Pub. L. 105-78, title VI, § 603(c), Nov. 13, 1997, 111

Stat. 1520; amended Pub. L. 109-482, title I, § 103(b)(8), Jan. 15, 2007, 120 Stat. 3687.)

AMENDMENTS

2007—Subsec. (a). Pub. L. 109-482, § 103(b)(8)(A), substituted “to carry out this section” for “under subsection (e) of this section”.

Subsec. (e). Pub. L. 109-482, § 103(b)(8)(B), struck out heading and text of subsec. (e). Text read as follows: “For the purpose of carrying out this section and section 241 of this title and this subchapter with respect to research focused on Parkinson's disease, there are authorized to be appropriated up to \$100,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 and 2000.”

CHANGE OF NAME

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.

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.

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.

ADDITIONAL GRANTS

Pub. L. 108-199, div. E, title II, § 217, Jan. 23, 2004, 118 Stat. 255, provided that: “Notwithstanding section 409B(c) of the Public Health Service Act [subsec. (c) of this section] regarding a limitation on the number of such grants, funds appropriated in this Act [div. E of Pub. L. 108-199, see Tables for classification] and Acts in fiscal years thereafter may be expended by the Director of the National Institutes of Health to award Core Center Grants to encourage the development of innovative multidisciplinary research and provide training concerning Parkinson's disease. Each center funded under such grants shall be designated as a Morris K. Udall Center for Research on Parkinson's Disease.”

Similar provisions were contained in Pub. L. 108-7, div. G, title II, § 218, Feb. 20, 2003, 117 Stat. 326.

FINDING AND PURPOSE

Section 603(b) of Pub. L. 105-78 provided that:

“(1) FINDING.—Congress finds that to take full advantage of the tremendous potential for finding a cure or effective treatment, the Federal investment in Parkinson's disease must be expanded, as well as the coordination strengthened among the National Institutes of Health research institutes.

“(2) PURPOSE.—It is the purpose of this section [enacting this section] to provide for the expansion and coordination of research regarding Parkinson's disease, and to improve care and assistance for afflicted individuals and their family caregivers.”

§ 284g. Expansion, intensification, and coordination of activities of National Institutes of Health with respect to research on autism spectrum disorder**(a) In general****(1) Expansion of activities**

The Director of NIH (in this section referred to as the “Director”) shall, subject to the availability of appropriations, expand, intensify, and coordinate the activities of the Na-

¹ So in original. Probably should be “pathogenesis.”

tional Institutes of Health with respect to research on autism spectrum disorder, including basic and clinical research in fields including pathology, developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, and toxicology. Such research shall investigate the cause (including possible environmental causes), diagnosis or rule out, early detection, prevention, services, supports, intervention, and treatment of autism spectrum disorder.

(2) Consolidation

The Director may consolidate program activities under this section if such consolidation would improve program efficiencies and outcomes.

(3) Administration of program; collaboration among agencies

The Director shall carry out this section acting through the Director of the National Institute of Mental Health and in collaboration with any other agencies that the Director determines appropriate.

(b) Centers of excellence

(1) In general

The Director shall under subsection (a)(1) of this section make awards of grants and contracts 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 autism spectrum disorder.

(2) Research

Each center under paragraph (1) shall conduct basic and clinical research into autism spectrum disorder. Such research should include investigations into the cause, diagnosis, early detection, prevention, control, and treatment of autism spectrum disorder. The centers, as a group, shall conduct research including the fields of developmental neurobiology, genetics, and psychopharmacology.

(3) Services for patients

(A) In general

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

(B) Referrals and costs

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

(C) Availability and access

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

(4) Organization of centers

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

(5) Number of centers; duration of support

(A) In general

The Director shall provide for the establishment of not less than five centers under paragraph (1).

(B) Duration

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 one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(c) Facilitation of research

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

(d) Public input

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

(July 1, 1944, ch. 373, title IV, §409C, as added Pub. L. 106-310, div. A, title I, §101, Oct. 17, 2000, 114 Stat. 1105; amended Pub. L. 109-416, §§2(a), 4(b), Dec. 19, 2006, 120 Stat. 2821, 2830; Pub. L. 109-482, title I, §§103(b)(9), 104(b)(1)(D), Jan. 15, 2007, 120 Stat. 3687, 3693.)

PRIOR PROVISIONS

Another section 409C of act July 1, 1944, was renumbered section 409G and is classified to section 284k of this title.

AMENDMENTS

2007—Subsec. (b)(4) to (6). Pub. L. 109-482, §104(b)(1)(D), redesignated pars. (5) and (6) as (4) and (5), respectively, and struck out heading and text of former par. (4). Text read as follows: “The Director shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers, and may require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director.”

Subsec. (e). Pub. L. 109-482, §103(b)(9), which directed the striking of subsec. (e), could not be executed because of prior amendment by Pub. L. 109-416. See 2006 Amendment note below.

2006—Pub. L. 109-416, §2(a)(1), substituted “autism spectrum disorder” for “autism” in section catchline.

Subsec. (a), Pub. L. 109-416, §2(a)(3), added pars. (1) and (2), redesignated former par. (2) as (3), and struck out heading and text of former par. (1). Text read as follows: “The Director of NIH (in this section referred to as the ‘Director’) shall expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism.”

Subsec. (b)(1), (2), Pub. L. 109-416, §2(a)(2), substituted “autism spectrum disorder” for “autism” in par. (1) and in two places in par. (2).

Subsecs. (c), (d), Pub. L. 109-416, §2(a)(2), substituted “autism spectrum disorder” for “autism”.

Subsec. (e), Pub. L. 109-416, §4(b), struck out heading and text of subsec. (e). Text read as follows: “There are authorized to be appropriated such sums as may be necessary to carry out this section. Amounts appropriated under this subsection are in addition to any other amounts appropriated for such purpose.”

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.

§ 284h. Pediatric Research Initiative

(a) Establishment

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

(b) Purpose

The purpose of the Initiative is to provide funds to enable the Director of NIH—

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

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

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

(c) Duties

In carrying out subsection (b) of this section, the Director of NIH shall—

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

(2) have broad discretion in the allocation of any Initiative assistance among the Institutes, among types of grants, and between basic and clinical research so long as the assistance is directly related to the illnesses and conditions of children; and

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

(d) Transfer of funds

The Director of NIH may transfer amounts appropriated under this section to any of the Institutes for a fiscal year to carry out the purposes of the Initiative under this section.

(July 1, 1944, ch. 373, title IV, §409D, as added Pub. L. 106-310, div. A, title X, §1001, Oct. 17, 2000, 114 Stat. 1127; amended Pub. L. 109-482, title I, §103(b)(10), Jan. 15, 2007, 120 Stat. 3687; Pub. L. 110-154, §1(b)(4), Dec. 21, 2007, 121 Stat. 1827.)

CODIFICATION

Another section 409D of act July 1, 1944, was renumbered section 409H and is classified to section 284l of this title.

AMENDMENTS

2007—Subsec. (c)(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”.

Subsecs. (d), (e), Pub. L. 109-482 redesignated subsec. (e) as (d) and struck out heading and text of former subsec. (d). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated \$50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005.”

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.

§ 284i. Autoimmune diseases

(a) Expansion, intensification, and coordination of activities

(1) In general

The Director of NIH shall expand, intensify, and coordinate research and other activities of the National Institutes of Health with respect to autoimmune diseases.

(2) Allocations by Director of NIH

With respect to amounts appropriated to carry out this section for a fiscal year, the Director of NIH shall allocate the amounts among the national research institutes that are carrying out paragraph (1).

(3) Definition

The term “autoimmune disease” includes, for purposes of this section such diseases or disorders with evidence of autoimmune pathogenesis¹ as the Secretary determines to be appropriate.

(b) Coordinating Committee

(1) In general

The Secretary shall ensure that the Autoimmune Diseases Coordinating Committee (re-

¹ So in original. Probably should be “pathogenesis”.