

(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 284i 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 (referred to in this section as the “Coordinating Committee”) coordinates activities across the National Institutes and with other Federal health programs and activities relating to such diseases.

(2) Composition

The Coordinating Committee shall be composed of the directors or their designees of each of the national research institutes involved in research with respect to autoimmune diseases 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 and the Food and Drug Administration.

(3) Chair

(A) In general

With respect to autoimmune diseases, the Chair of the 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 other relevant agencies.

(B) Director of NIH

The Chair of the Committee shall be directly responsible to the Director of NIH.

(c) Plan for NIH activities

(1) In general

Not later than 1 year after October 17, 2000, the Coordinating Committee shall develop a plan for conducting and supporting research and education on autoimmune diseases

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