

## CODIFICATION

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), 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) National Pediatric Research Network****(1) Network**

In carrying out the Initiative, the Director of NIH, in collaboration with the national research institutes and national centers that carry out activities involving pediatric research, shall support a National Pediatric Research Network in order to more effectively support pediatric research and optimize the use of Federal resources. Such National Pediatric Research Network may be comprised of, as appropriate—

(A) the pediatric research consortia receiving awards under paragraph (2); or

(B) other consortia, centers, or networks focused on pediatric research that are recognized by the Director of NIH and established pursuant to the authorities vested in the National Institutes of Health by other sections of this chapter.

**(2) Pediatric research consortia****(A) In general**

The Director of NIH shall award funding, including through grants, contracts, or other mechanisms, to public or private non-profit entities for providing support for pediatric research consortia, including with respect to—

(i) basic, clinical, behavioral, or translational research to meet unmet needs for pediatric research; and

(ii) training researchers in pediatric research techniques in order to address unmet pediatric research needs.

**(B) Research**

The Director of NIH shall, as appropriate, ensure that—

(i) each consortium receiving an award under subparagraph (A) conducts or supports at least one category of research described in subparagraph (A)(i) and collectively such consortia conduct or support such categories of research; and

(ii) one or more such consortia provide training described in subparagraph (A)(ii).

**(C) Organization of consortium**

Each consortium receiving an award under subparagraph (A) shall—

- (i) be formed from a collaboration of cooperating institutions;
- (ii) be coordinated by a lead institution or institutions;
- (iii) agree to disseminate scientific findings, including from clinical trials, rapidly and efficiently, as appropriate, to—
  - (I) other consortia;
  - (II) the National Institutes of Health;
  - (III) the Food and Drug Administration;
  - (IV) and<sup>1</sup> other relevant agencies; and
- (iv) meet such requirements as may be prescribed by the Director of NIH.

**(D) Supplement, not supplant**

Any support received by a consortium under subparagraph (A) shall be used to supplement, and not supplant, other public or private support for activities authorized to be supported under this paragraph.

**(E) Duration of support**

Support of a consortium under subparagraph (A) shall be for a period of not to exceed 5 years. Such period may be extended at the discretion of the Director of NIH.

**(3) Coordination of consortia activities**

The Director of NIH shall, as appropriate—

- (A) provide for the coordination of activities (including the exchange of information and regular communication) among the consortia established pursuant to paragraph (2); and
- (B) require the periodic preparation and submission to the Director of reports on the activities of each such consortium.

**(4) Assistance with registries**

Each consortium receiving an award under paragraph (2)(A) may provide assistance, as appropriate, to the Centers for Disease Control and Prevention for activities related to patient registries and other surveillance systems upon request by the Director of the Centers for Disease Control and Prevention.

**(e) Research on pediatric rare diseases or conditions**

In making awards under subsection (d)(2) for pediatric research consortia, the Director of NIH shall ensure that an appropriate number of such awards are awarded to such consortia that agree to—

- (1) consider pediatric rare diseases or conditions, or those related to birth defects; and
- (2) conduct or coordinate one or more multisite clinical trials of therapies for, or approaches to, the prevention, diagnosis, or treatment of one or more pediatric rare diseases or conditions.

**(f) Transfer of funds**

The Director of NIH may transfer amounts appropriated under this section to any of the Insti-

<sup>1</sup> So in original. The word “and” probably should appear at end of subcl. (III).

tutes 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; Pub. L. 113-55, title II, § 202, Nov. 27, 2013, 127 Stat. 644; Pub. L. 114-255, div. A, title II, § 2071, Dec. 13, 2016, 130 Stat. 1083.)

**CODIFICATION**

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

**AMENDMENTS**

2016—Subsec. (d)(1). Pub. L. 114-255, § 2071(1), substituted “in collaboration with the national research institutes and national centers that carry out activities involving pediatric research, shall support” for “in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and in collaboration with other appropriate national research institutes and national centers that carry out activities involving pediatric research, may provide for the establishment of” in introductory provisions.

Subsec. (d)(2)(A), (E). Pub. L. 114-255, § 2071(2), substituted “shall” for “may” in introductory provisions of par. (2)(A) and in first sentence of par. (2)(E).

2013—Subsecs. (d) to (f). Pub. L. 113-55 added subsecs. (d) and (e) and redesignated former subsec. (d) as (f).

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 pathogenesis<sup>1</sup> as the Secretary determines to be appropriate.

<sup>1</sup> So in original. Probably should be “pathogenesis”.