

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 [42 U.S.C. 284f(c)] 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

Pub. L. 105-78, title VI, §603(b), Nov. 13, 1997, 111 Stat. 1519, 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”), in consultation with relevant Federal departments and agencies, as appropriate, shall—

(A) subject to the availability of appropriations, expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism spectrum disorder, including basic and clinical research—

(i) in fields, such as pathology, developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, toxicology, psychiatry, psychology, developmental behavioral pediatrics, audiology, and gerontology; and

(ii) on interventions to maximize outcomes for individuals with autism spectrum disorder; and

(B) ensure that research referred to in subparagraph (A)—

(i) investigates the causes (including possible environmental causes), diagnosis or ruling out, early and ongoing detection, prevention, services and supports across the lifespan, intervention, and treatment

of autism spectrum disorder and co-occurring conditions, including dissemination and implementation of clinical care, supports, interventions, and treatments;

(ii) examines supports for caregivers; and

(iii) reflects the entire population of individuals with autism spectrum disorder, including those individuals with co-occurring conditions and the full range of needs for supports and services, including such supports and services to ensure the safety, and promote the well-being, of such individuals.

(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) 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 causes, diagnosis, early and ongoing detection, prevention, and treatment of autism spectrum disorder across the lifespan. The centers, as a group, shall conduct research in fields such as developmental neurobiology, genetics, genomics, psychopharmacology, developmental psychology, behavioral psychology, clinical psychology, and gerontology.

(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 appli-

cants which meet the scientific criteria for funding under this section.

(D) Reducing disparities

The Director may consider, as appropriate, the extent to which a center can demonstrate availability and access to clinical services for youth and adults from diverse racial, ethnic, geographic, or linguistic backgrounds 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 seven centers under paragraph (1).

(B) Duration

Support for a center established under paragraph (1) may be provided under this section for a period 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) 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

(1) In general

The Director shall under subsection (a)(1) 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.

(2) Guidance

The Director may provide guidance to centers under subsection (b)(1) on strategies, activities, and opportunities to promote engagement with, and solicit input from, individuals with autism spectrum disorder and their family members, guardians, advocates or authorized representatives, providers, or other appropriate individuals to inform the activities of the center. Such strategies, activities, and opportunities should consider including, as ap-

propriate, individuals, family members, and caregivers of individuals with autism spectrum disorder who represent the entire population of individuals with autism spectrum disorder, including those individuals with co-occurring conditions and the full range of needs for supports and services, including such supports and services to ensure the safety, and promote the well-being, of such individuals, to inform the activities of the center.

(e) Budget estimate

For each of fiscal years 2026 through 2029, the Director shall prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate for the initiatives of the National Institutes of Health pursuant to the strategic plan developed under section 280i-2(b)(5) of this title and updated under section 280i-2(b)(6)(B) of this title, after reasonable opportunity for comment (but without change) by the Secretary and the Interagency Autism Coordinating Committee established under section 280i-2 of this title.

(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; Pub. L. 116-60, § 2, Sept. 30, 2019, 133 Stat. 1110; Pub. L. 118-180, § 2, Dec. 23, 2024, 138 Stat. 2614.)

Editorial Notes

CODIFICATION

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

AMENDMENTS

2024—Subsec. (a)(1). Pub. L. 118-180, § 2(a), made numerous amendments to text and structure of par. (1). Prior to amendment, text read as follows: “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 National 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, toxicology, and interventions to maximize outcomes for individuals with autism spectrum disorder. Such research shall investigate the causes (including possible environmental causes), diagnosis or ruling out, early and ongoing detection, prevention, services across the lifespan, supports, intervention, and treatment of autism spectrum disorder, including dissemination and implementation of clinical care, supports, interventions, and treatments.”

Subsec. (b)(2). Pub. L. 118-180, § 2(b)(1), substituted “in fields such as” for “including the fields of” and “behavioral psychology, clinical psychology, and gerontology” for “behavioral psychology, and clinical psychology”.

Subsec. (b)(5)(A). Pub. L. 118-180, § 2(b)(2), substituted “seven centers” for “five centers”.

Subsec. (b)(5)(B). Pub. L. 118-180, § 2(b)(3), substituted “period not to exceed” for “period of not to exceed”.

Subsec. (d). Pub. L. 118-180, § 2(c), amended subsec. (d) generally. Prior to amendment, text read as follows: “The Director shall under subsection (a)(1) provide for means through which the public can obtain informa-

tion 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.”

Subsec. (e). Pub. L. 118-180, §2(d), added subsec. (e).

2019—Subsec. (a)(1). Pub. L. 116-60, §2(1), substituted “toxicology, and interventions to maximize outcomes for individuals with autism spectrum disorder” for “and toxicology” and “Such research shall investigate the causes (including possible environmental causes), diagnosis or ruling out, early and ongoing detection, prevention, services across the lifespan, supports, intervention, and treatment of autism spectrum disorder, including dissemination and implementation of clinical care, supports, interventions, and treatments.” for “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.”

Subsec. (b)(2). Pub. L. 116-60, §2(2)(A), substituted “causes, diagnosis, early and ongoing detection, prevention, and treatment of autism spectrum disorder across the lifespan” for “cause, diagnosis, early detection, prevention, control, and treatment of autism spectrum disorder” and “neurobiology, genetics, genomics, psychopharmacology, developmental psychology, behavioral psychology, and clinical psychology.” for “neurobiology, genetics, and psychopharmacology.”

Subsec. (b)(3)(D). Pub. L. 116-60, §2(2)(B), added subpar. (D).

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.”

Statutory Notes and Related Subsidiaries

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§ 284h. Pediatric Research Initiative

(a) Establishment

The Secretary shall establish within the Office of the Director of NIH a Pediatric Research Ini-

tiative (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.