

deavors that study the impact of the organization, financing and management of health services on the quality, cost, access to and outcomes of care. Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions.

(b) Clinical research

As used in this subchapter, the term “clinical research” means patient oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, or epidemiologic or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials.

(July 1, 1944, ch. 373, title IV, § 409, as added Pub. L. 102-321, title I, § 121(b), July 10, 1992, 106 Stat. 358; amended Pub. L. 103-43, title XX, § 2016(a), June 10, 1993, 107 Stat. 218; Pub. L. 106-505, title II, § 206, Nov. 13, 2000, 114 Stat. 2329.)

AMENDMENTS

2000—Pub. L. 106-505 designated existing provisions as subsec. (a), inserted heading, and added subsec. (b).

1993—Pub. L. 103-43 inserted at end “Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions.”

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§ 284e. Research on osteoporosis, Paget’s disease, and related bone disorders

(a) Establishment

The Directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute on Aging, the National Institute of Dental Research, and the National Institute of Diabetes and Digestive and Kidney Diseases, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning osteoporosis, Paget’s disease, and related bone disorders.

(b) Coordination

The Directors referred to in subsection (a) shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and the Interagency Task Force on Aging Research.

(c) Information clearinghouse

(1) In general

In order to assist in carrying out the purpose described in subsection (a), the Director of NIH shall provide for the establishment of an information clearinghouse on osteoporosis and related bone disorders to facilitate and enhance knowledge and understanding on the

part of health professionals, patients, and the public through the effective dissemination of information.

(2) Establishment through grant or contract

For the purpose of carrying out paragraph (1), the Director of NIH shall enter into a grant, cooperative agreement, or contract with a nonprofit private entity involved in activities regarding the prevention and control of osteoporosis and related bone disorders.

(July 1, 1944, ch. 373, title IV, § 409A, as added Pub. L. 103-43, title III, § 302, June 10, 1993, 107 Stat. 151; amended Pub. L. 105-340, title I, § 102, Oct. 31, 1998, 112 Stat. 3192; Pub. L. 109-482, title I, § 103(b)(7), Jan. 15, 2007, 120 Stat. 3687.)

AMENDMENTS

2007—Subsec. (d). Pub. L. 109-482 struck out heading and text of subsec. (d). Text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated \$40,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003.”

1998—Subsec. (d). Pub. L. 105-340 substituted “through 2003” for “and 1996”.

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.

§ 284f. Parkinson’s disease

(a) In general

The Director of NIH shall establish a program for the conduct and support of research and training with respect to Parkinson’s disease (subject to the extent of amounts appropriated to carry out this section).

(b) Inter-institute coordination

(1) In general

The Director of NIH shall provide for the coordination of the program established under subsection (a) among all of the national research institutes conducting Parkinson’s disease research.

(2) Conference

Coordination under paragraph (1) shall include the convening of a research planning conference not less frequently than once every 2 years. Each such conference shall prepare and submit to the Committee on Appropriations and the Committee on Labor and Human Resources of the Senate and the Committee on Appropriations and the Committee on Commerce of the House of Representatives a report concerning the conference.

(c) Morris K. Udall research centers

(1) In general

The Director of NIH is authorized to award Core Center Grants to encourage the development of innovative multidisciplinary research and provide training concerning Parkinson’s disease. The Director is authorized to award not more than 10 Core Center Grants and designate each center funded under such grants as a Morris K. Udall Center for Research on Parkinson’s Disease.

(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 [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”) shall, subject to the availability of appropriations, expand, inten-

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