editing, and publication of reviews, abstracts, indices, handbooks, bibliographies, and related matter pertaining to scientific works and scientific developments.

(b) Grants under subsection (a) in support of any single periodical publication may not be made for more than three years, except in those cases in which the Secretary determines that further support is necessary to carry out the purposes of subsection (a).

(July 1, 1944, ch. 373, title IV, § 476, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 863.)

§ 286b–8. Grant payments, records, and audit

(a) Payments under grants made under sections 286b–3, 286b–4, 286b–5, 286b–6, and 286b–7 of this title may be made in advance or by way of reimbursement and in such installments as the Secretary shall prescribe by regulation after consultation with the Board.

(b)(1) Each recipient of a grant under this subpart shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to any grant received under this subpart.

(July 1, 1944, ch. 373, title IV, § 477, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 863.)

SUBPART 3—NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

§ 286c. Purpose, establishment, functions, and funding of National Center for Biotechnology Information

(a) Establishment

In order to focus and expand the collection, storage, retrieval, and dissemination of the results of biotechnology research by information systems, and to support and enhance the development of new information technologies to aid in the understanding of the molecular processes that control health and disease, there is established the National Center for Biotechnology Information (hereinafter in this section referred to as the ''Center'') in the National Library of Medicine.

(b) Functions

The Secretary, through the Center and subject to section 286(d) of this title, shall—

(1) design, develop, implement, and manage automated systems for the collection, storage, retrieval, analysis, and dissemination of knowledge concerning human molecular biology, biochemistry, and genetics;

(2) perform research into advanced methods of computer-based information processing capable of representing and analyzing the vast number of biologically important molecules and compounds;

(3) enable persons engaged in biotechnology research and medical care to use systems developed under paragraph (1) and methods described in paragraph (2); and

(4) coordinate, as much as is practicable, efforts to gather biotechnology information on an international basis.

(July 1, 1944, ch. 373, title IV, § 478, as added Pub. L. 100–607, title I, § 105, Nov. 4, 1988, 102 Stat. 3052; amended Pub. L. 103–43, title XIV, § 1402(b), June 10, 1993, 107 Stat. 171.)

Editorial Notes

AMENDMENTS

1993—Subsec. (c). Pub. L. 103–43 struck out subsec. (c) which read as follows: ''For the purpose of performing the duties specified in subsection (b) of this section, there are authorized to be appropriated $8,000,000 for fiscal year 1989 and such sums as may be necessary for fiscal year 1990. Funds appropriated under this subsection shall remain available until expended.''

SUBPART 4—NATIONAL INFORMATION CENTER ON HEALTH SERVICES RESEARCH AND HEALTH CARE TECHNOLOGY

§ 286d. National Information Center

(a) Establishment

There is established within the Library an entity to be known as the National Information Center on Health Services Research and Health Care Technology (in this section referred to as the ''Center'').

(b) Purpose

The purpose of the Center is the collection, storage, analysis, retrieval, and dissemination of information on health services research, clinical practice guidelines, and on health care technology, including the assessment of such technology. Such purpose includes developing and maintaining data bases and developing and implementing methods of carrying out such purpose.

(c) Electronic, convenient format; criteria for inclusion

The Director of the Center shall ensure that information under subsection (b) concerning clinical practice guidelines is collected and maintained electronically and in a convenient format. Such Director shall develop and publish criteria for the inclusion of practice guidelines and technology assessments in the information center database.

(d) Coordination with Director of the Agency for Healthcare Research and Quality

The Secretary, acting through the Center, shall coordinate the activities carried out under this section through the Center with related activities of the Director of the Agency for Healthcare Research and Quality.

(July 1, 1944, ch. 373, title IV, § 478A, as added Pub. L. 103–43, title XIV, § 1421, June 10, 1993, 107 Stat. 171; amended Pub. L. 106–129, § 2(b)(2), Dec. 6, 1999, 113 Stat. 1670.)

Editorial Notes

AMENDMENTS

1999—Subsec. (d). Pub. L. 106–129 substituted ''Director of the Agency for Healthcare Research and Quality'' for ''Administrator for Health Care Policy and Research''.

Statutory Notes and Related Subsidiaries

CONSTRUCTION

Pub. L. 103–43, § 1422(b), June 10, 1993, 107 Stat. 172, provided that: ''The amendments made by section 3 of Public Law 102–410 (106 Stat. 2094) [amending section 299a–1 of this title], by section 1421 of this Act [enacting this section], and by subsection (a) of this section [amending section 299a–1 of this title] may not be construed as terminating the information center on health care technologies and health care technology assessment established under section 904 of the Public Health Service Act [42 U.S.C. 299a–2], as in effect on the day before the date of the enactment of Public Law 102–410 [Oct. 13, 1992]. Such center shall be considered to be the center established in section 478A of the Public Health Service Act [42 U.S.C. 286d], as added by section 1421 of this Act, and shall be subject to the provisions of such section 478A.''

PART E—OTHER AGENCIES OF NIH

SUBPART 1—NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

Editorial Notes

CODIFICATION

Pub. L. 112–74, div. F, title II, § 221(a)(1)(A), Dec. 23, 2011, 125 Stat. 1086, substituted ''advancing translational sciences'' for ''research resources'' in subpart heading.

§ 287. National Center for Advancing Translational Sciences

(a) Purpose

The purpose of the National Center for Advancing Translational Sciences (in this subpart referred to as the ''Center'') is to advance translational sciences, including by—

(1) coordinating and developing resources that leverage basic research in support of translational science; and

(2) developing partnerships and working cooperatively to foster synergy in ways that do not create duplication, redundancy, and competition with industry activities.

(b) Clinical trial activities

(1) In general

The Center may develop and provide infrastructure and resources for all phases of clinical trials research. Except as provided in paragraph (2), the Center may support clinical trials only through the end of phase IIB.

(2) Exception

The Center may support clinical trial activities through the end of phase III for a treatment for a rare disease or condition (as defined in section 360bb of title 21) so long as—

(A) the Center gives public notice for a period of at least 120 days of the Center's intention to support the clinical trial activities in phase III;

(B) no public or private organization provides credible written intent to the Center that the organization has timely plans to further the clinical trial activities or conduct clinical trials of a similar nature beyond phase IIB; and

(C) the Center ensures that support of the clinical trial activities in phase III will not increase the Federal Government's liability beyond the award value of the Center's support.

(c) Biennial report

The Center shall publish a report on a biennial basis that, with respect to all research supported by the Center, includes a complete list of—

(1) the molecules being studied;

(2) clinical trial activities being conducted;

(3) the methods and tools in development;

(4) ongoing partnerships, including—

(A) the rationale for each partnership;

(B) the status of each partnership;

(C) the funding provided by the Center to other entities pursuant to each partnership, and

(D) the activities which have been transferred to industry pursuant to each partnership;

(5) known research activity of other entities that is or will expand upon research activity of the Center;

(6) the methods and tools, if any, that have been developed since the last biennial report was prepared; and

(7) the methods and tools, if any, that have been developed and are being utilized by the Food and Drug Administration to support medical product reviews.

(d) Inclusion of list

The first biennial report submitted under this section after December 13, 2016, shall include a complete list of all of the methods and tools, if any, which have been developed by research supported by the Center.

(e) Rule of construction

Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(July 1, 1944, ch. 373, title IV, § 479, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 864; amended Pub. L. 103–43, title XV, § 1501(2)(B), June 10, 1993, 107 Stat. 172; Pub. L. 112–74, div. F, title II, § 221(a)(1)(C), Dec. 23, 2011, 125 Stat. 1086; Pub. L. 114–255, div. A, title II, §§ 2037, 2042(e), Dec. 13, 2016, 130 Stat. 1063, 1073.)

Editorial Notes

AMENDMENTS

2016—Subsec. (b)(1). Pub. L. 114–255, § 2037(a)(1), substituted ''phase IIB'' for ''phase IIA''.

Subsec. (b)(2). Pub. L. 114–255, § 2037(a)(2)(A), substituted ''phase III'' for ''phase IIB'' in introductory provisions.

Subsec. (b)(2)(A). Pub. L. 114–255, § 2037(a)(2)(B), substituted ''phase III'' for ''phase IIB''.

Subsec. (b)(2)(B). Pub. L. 114–255, § 2037(a)(2)(C), substituted ''phase IIB'' for ''phase IIA''.

Subsec. (b)(2)(C). Pub. L. 114–255, § 2037(a)(2)(D), substituted ''phase III'' for ''phase IIB''.