Stat. 185; amended Pub. L. 105–392, title IV, §410(d), Nov. 13, 1998, 112 Stat. 3589; Pub. L. 106–554, §1(a)(1) [title II, §223], Dec. 21, 2000, 114 Stat. 2763, 2763A–30, related to loan repayment program regarding clinical researchers from disadvantaged backgrounds.

Section 288–5a, July 1, 1944, ch. 373, title IV, §487F, as added Pub. L. 106–505, title II, §205, Nov. 13, 2000, 114 Stat. 2329; amended Pub. L. 109–482, title I, §103(b)(49), Jan. 15, 2007, 120 Stat. 3689, related to loan repayment program regarding clinical researchers. Another section 487F of act July 1, 1944, was classified to section 288–6 of this title, prior to repeal by Pub. L. 114–255.

Section 288–6, July 1, 1944, ch. 373, title IV, §487F, as added Pub. L. 106–310, div. A, title X, §1002(b), Oct. 17, 2000, 114 Stat. 1129; amended Pub. L. 110–85, title V, §503(b), Sept. 27, 2007, 121 Stat. 890, related to pediatric research loan repayment program. Another section 487F of act July 1, 1944, was classified to section 288–5a of this title, prior to repeal by Pub. L. 114–255.

§ 288a. Visiting Scientist Awards

(a) The Secretary may make awards (hereafter in this section referred to as ''Visiting Scientist Awards'') to outstanding scientists who agree to serve as visiting scientists at institutions of postsecondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe.

(July 1, 1944, ch. 373, title IV, §488, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 872.)

§ 288b. Studies respecting biomedical and behavioral research personnel

(a) Scope of undertaking

The Secretary shall, in accordance with subsection (b), arrange for the conduct of a continuing study to—

(1) establish (A) the Nation's overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel;

(2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this chapter, at or through national research institutes under the National Institutes of Health, and (B) other current training programs available for the training of such personnel;

(3) identify the kinds of research positions available to and held by individuals completing such programs;

(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

(b) Arrangement with National Academy of Sciences or other nonprofit private groups or associations

(1) The Secretary shall request the National Academy of Sciences to conduct the study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of such study.

(2) If the National Academy of Sciences is unwilling to conduct such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in subsection (c).[1]

(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of NIH.

(July 1, 1944, ch. 373, title IV, §489, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 872; amended Pub. L. 102–321, title I, §163(b)(5), July 10, 1992, 106 Stat. 376.)

Editorial Notes

REFERENCES IN TEXT

Subsection (c), referred to in subsec. (b)(2), was omitted from the Code. See Codification note below.

CODIFICATION

Subsec. (c) of this section, which required the Secretary to submit a report on results of the study required under subsec. (a) of this section to certain committees of Congress at least once every four years, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, page 96 of House Document No. 103–7.

AMENDMENTS

1992—Subsec. (a)(2). Pub. L. 102–321 struck out ''and institutes under the Alcohol, Drug Abuse, and Mental Health Administration'' after ''National Institutes of Health''.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1992 AMENDMENT

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

[1] See References in Text note below.

PART H—GENERAL PROVISIONS

Editorial Notes

CODIFICATION

Pub. L. 103–43, title I, §141(a)(2), June 10, 1993, 107 Stat. 136, redesignated part G ''General Provisions'' as H. Former part H ''National Foundation for Biomedical Research'' redesignated I.

§ 289. Institutional review boards; ethics guidance program

(a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an ''Institutional Review Board'') to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such violations.

(July 1, 1944, ch. 373, title IV, §491, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 873.)

Statutory Notes and Related Subsidiaries

PROTECTION OF HUMAN RESEARCH SUBJECTS

Pub. L. 114–255, div. A, title III, §3023, Dec. 13, 2016, 130 Stat. 1098, provided that:

''(a) IN GENERAL.—In order to simplify and facilitate compliance by researchers with applicable regulations for the protection of human subjects in research, the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall, to the extent practicable and consistent with other statutory provisions, harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations in accordance with subsection (b).

''(b) AVOIDING REGULATORY DUPLICATION AND UNNECESSARY DELAYS.—The Secretary shall, as appropriate—

''(1) make such modifications to the provisions of the HHS Human Subject Regulations, the FDA Human Subject Regulations, and the vulnerable populations rules as may be necessary—

''(A) to reduce regulatory duplication and unnecessary delays;

''(B) to modernize such provisions in the context of multisite and cooperative research projects; and

''(C) to protect vulnerable populations, incorporate local considerations, and support community engagement through mechanisms such as consultation with local researchers and human research protection programs, in a manner consistent with subparagraph (B); and

''(2) ensure that human subject research that is subject to the HHS Human Subject Regulations and to the FDA Human Subject Regulations may—

''(A) use joint or shared review;

''(B) rely upon the review of—

''(i) an independent institutional review board; or

''(ii) an institutional review board of an entity other than the sponsor of the research; or

''(C) use similar arrangements to avoid duplication of effort.

''(c) CONSULTATION.—In harmonizing or modifying regulations or guidance under this section, the Secretary shall consult with stakeholders (including researchers, academic organizations, hospitals, institutional research boards, pharmaceutical, biotechnology, and medical device developers, clinical research organizations, patient groups, and others).

''(d) TIMING.—The Secretary shall complete the harmonization described in subsection (a) not later than 3 years after the date of enactment of this Act [Dec. 13, 2016].

''(e) PROGRESS REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary shall submit to Congress a report on the progress made toward completing such harmonization.

''(f) DEFINITIONS.—

''(1) HUMAN SUBJECT REGULATIONS.—In this section:

''(A) FDA HUMAN SUBJECT REGULATIONS.—The term 'FDA Human Subject Regulations' means the provisions of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations).

''(B) HHS HUMAN SUBJECT REGULATIONS.—The term 'HHS Human Subject Regulations' means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations).

''(C) VULNERABLE POPULATION RULES.—The term 'vulnerable population rules' means—

''(i) except in the case of research described in clause (ii), the provisions of subparts B through D of part 46, Code of Federal Regulations (or any successor regulations); and

''(ii) in the case of research that is subject to FDA Human Subject Regulations, the provisions applicable to vulnerable populations under part 56 of title 21, Code of Federal Regulations (or any successor regulations) and subpart D of part 50 of such title 21 (or any successor regulations).

''(2) INSTITUTIONAL REVIEW BOARD DEFINED.—In this section, the term 'institutional review board' has the meaning that applies to the term 'institutional review board' under the HHS Human Subject Regulations.''

INFORMED CONSENT FOR NEWBORN SCREENING RESEARCH

Pub. L. 113–240, §12, Dec. 18, 2014, 128 Stat. 2857, provided that:

''(a) IN GENERAL.—Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f)(2) of title 45, Code of Federal Regulations, for purposes of Federally funded research conducted pursuant to the Public Health Service Act [42 U.S.C. 201 et seq.] until such time as updates to the Federal Policy for the Protection of Human Subjects (the Common Rule) are promulgated pursuant to subsection (c). For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply.

''(b) EFFECTIVE DATE.—Subsection (a) shall apply only to newborn dried blood spots used for purposes of Federally funded research that were collected not earlier than 90 days after the date of enactment of this Act [Dec. 18, 2014].