ioral 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.)

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''.

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.

PART H—GENERAL PROVISIONS

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 informa-

[1] See References in Text note below.

tion 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.)

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].

''(c) REGULATIONS.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed regulations related to the updating of the Federal Policy for the Protection of Human Subjects (the Common Rule), particularly with respect to informed consent. Not later than 2 years after such date of enactment, the Secretary shall promulgate final regulations based on such proposed regulations.''

STUDY CONCERNING RESEARCH INVOLVING CHILDREN

Pub. L. 107–109, § 12, Jan. 4, 2002, 115 Stat. 1416, provided that:

''(a) CONTRACT WITH INSTITUTE OF MEDICINE.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine for—

''(1) the conduct, in accordance with subsection (b), of a review of—

''(A) Federal regulations in effect on the date of the enactment of this Act [Jan. 4, 2002] relating to research involving children;

''(B) federally prepared or supported reports relating to research involving children; and

''(C) federally supported evidence-based research involving children; and

''(2) the submission to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, not later than two years after the date of enactment of this Act, of a report concerning the review conducted under paragraph (1) that includes recommendations on best practices relating to research involving children.

''(b) AREAS OF REVIEW.—In conducting the review under subsection (a)(1), the Institute of Medicine shall consider the following:

''(1) The written and oral process of obtaining and defining 'assent', 'permission' and 'informed consent' with respect to child clinical research participants and the parents, guardians, and the individuals who may serve as the legally authorized representatives of such children (as defined in subpart A of part 46 of title 45, Code of Federal Regulations).

''(2) The expectations and comprehension of child research participants and the parents, guardians, or legally authorized representatives of such children, for the direct benefits and risks of the child's research involvement, particularly in terms of research versus therapeutic treatment.

''(3) The definition of 'minimal risk' with respect to a healthy child or a child with an illness.

''(4) The appropriateness of the regulations applicable to children of differing ages and maturity levels, including regulations relating to legal status.

''(5) Whether payment (financial or otherwise) may be provided to a child or his or her parent, guardian, or legally authorized representative for the participation of the child in research, and if so, the amount and type of payment that may be made.

''(6) Compliance with the regulations referred to in subsection (a)(1)(A), the monitoring of such compliance (including the role of institutional review boards), and the enforcement actions taken for violations of such regulations.

''(7) The unique roles and responsibilities of institutional review boards in reviewing research involving children, including composition of membership on institutional review boards.

''(c) REQUIREMENTS OF EXPERTISE.—The Institute of Medicine shall conduct the review under subsection (a)(1) and make recommendations under subsection (a)(2) in conjunction with experts in pediatric medicine, pediatric research, and the ethical conduct of research involving children.''

REQUIREMENT FOR ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED IN RESEARCH

Pub. L. 106–310, div. A, title XXVII, §2701, Oct. 17, 2000, 114 Stat. 1167, as amended by Pub. L. 106–505, title X, §1001(a), Nov. 13, 2000, 114 Stat. 2350, provided that: ''Notwithstanding any other provision of law, not later than 6 months after the date of the enactment of this Act [Oct. 17, 2000], the Secretary of Health and Human Services shall require that all research involving children that is conducted, supported, or regulated by the Department of Health and Human Services be in compliance with subpart D of part 46 of title 45, Code of Federal Regulations.''

[Pub. L. 106–505, title X, §1001(b), Nov. 13, 2000, 114 Stat. 2350, provided that: ''The amendment made by subsection (a) [amending section 2701 of Pub. L. 106–310, set out above] takes effect on the date of the enactment of the Children's Health Act of 2000 [Oct. 17, 2000].'']

§ 289a. Peer review requirements

(a) Applications for biomedical and behavioral research grants, cooperative agreements, and contracts; regulations

(1) The Secretary, acting through the Director of NIH, shall by regulation require appropriate technical and scientific peer review of—

(A) applications made for grants and cooperative agreements under this chapter for biomedical and behavioral research; and

(B) applications made for biomedical and behavioral research and development contracts to be administered through the National Institutes of Health.

(2) Regulations promulgated under paragraph (1) shall require that the review of applications made for grants, contracts, and cooperative agreements required by the regulations be conducted—

(A) to the extent practical, in a manner consistent with the system for technical and scientific peer review applicable on November 20, 1985, to grants under this chapter for biomedical and behavioral research, and

(B) to the extent practical, by technical and scientific peer review groups performing such review on or before November 20, 1985,

and shall authorize such review to be conducted by groups appointed under sections 282(b)(16) and 284(c)(3) of this title.

(b) Periodic review of research at National Institutes of Health

The Director of NIH shall establish procedures for periodic technical and scientific peer review of research at the National Institutes of Health. Such procedures shall require that—

(1) the reviewing entity be provided a written description of the research to be reviewed, and

(2) the reviewing entity provide the advisory council of the national research institute involved with such description and the results of the review by the entity,

and shall authorize such review to be conducted by groups appointed under sections 282(b)(6)[1] and 284(c)(3) of this title.

(c) Compliance with requirements for inclusion of women and minorities in clinical research

(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding compliance with section 289a–2 of this title.

(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 289a–2 of this title, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.

(July 1, 1944, ch. 373, title IV, §492, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 874; amended Pub. L. 103–43, title I, §132, June 10, 1993, 107 Stat. 135; Pub. L. 109–482, title I, §102(f)(1)(B), Jan. 15, 2007, 120 Stat. 3685.)

REFERENCES IN TEXT

Section 282(b)(6) of this title, referred to in subsec. (b), was redesignated section 282(b)(16) by Pub. L. 109–482, title I, §102(a)(3), Jan. 15, 2007, 120 Stat. 3681.

AMENDMENTS

2007—Subsec. (a)(2). Pub. L. 109–482 substituted ''sections 282(b)(16)'' for ''sections 282(b)(6)'' in concluding provisions.

1993—Subsec. (c). Pub. L. 103–43 added subsec. (c).

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.

§ 289a–1. Certain provisions regarding review and approval of proposals for research

(a) Review as precondition to research

(1) Protection of human research subjects

(A) In the case of any application submitted to the Secretary for financial assistance to

[1] See References in Text note below.