§ 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) of this section, 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) of this section 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) of this section.1

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


REFERENCES IN TEXT

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

C O D I F I C A T I O N

Subsec. (c) of this section, which required the Secretary to submit a report on results required under subsec. (a) of this section to certain committees of Congress at least once every four years, was terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 106–55, 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.

A M E N D M E N T S


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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.

P A R T  H — G E N E R A L  P R O V I S I O N S

A M E N D M E N T S


§ 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

1 See References in Text note below.
Secretary of Health and Human Services shall enter
(July 1, 1944, ch. 373, title IV, § 491, as added Pub.
ports of such information from recipients of
shall include procedures for the receiving of re -
made available under this chapter. The process
subjects of research for which funds have been
incidences of violations of the rights of human
members respecting the rights of the human subjects of such
research.
(2) The Secretary shall establish a process for
prompt and appropriate response to information
provided to the Director of NIH respecting
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 re-
ports of such information from recipients of funds under this chapter and taking appropriate
actions with respect to such violations.
(July 1, 1944, ch. 373, title IV, § 491, as added Pub.
INFORMED CONSENT FOR NEWBORN SCREENING
RESEARCH
duced that:
“(a) IN GENERAL.—Research on newborn dried blood
spots shall be considered research carried out on human subjects meeting the definition of section
46.116(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
duced 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 relat-
ing 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 in-
cludes 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
“(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 re-
search 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 participa-
tion 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 compli-
ance (including the role of institutional review
boards), and the enforcement actions taken for viola-
tions of such regulations.
“(7) The unique roles and responsibilities of institu-
tional review boards,
“(b) 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,
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 com-
pliance with subpart D of part 46 of title 45, Code of
Federal Regulations.”
(Pub. L. 106–665, 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 enact-
ment 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 coopera-
tive agreements under this chapter for bio-
medical and behavioral research; and