

(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.

(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 com-

mittees 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

AMENDMENTS

1993—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.)

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;

¹ See References in Text note below.

“(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

¹ See References in Text note below.

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 conduct research, the Secretary may not approve or fund any application that is subject to review under section 289(a) of this title by an Institutional Review Board unless the application has undergone review in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting such review.

(B) In the case of research that is subject to review under procedures established by the Secretary for the protection of human subjects in clinical research conducted by the National Institutes of Health, the Secretary may not authorize the conduct of the research unless the research has, pursuant to such procedures, been recommended for approval.

(2) Peer review

In the case of any proposal for the National Institutes of Health to conduct or support research, the Secretary may not approve or fund any proposal that is subject to technical and scientific peer review under section 289a of this title unless the proposal has undergone such review in accordance with such section and has been recommended for approval by a majority of the members of the entity conducting such review, and unless a majority of the voting members of the appropriate advisory council under section 284a of this title, or as applicable, of the advisory council under section 282(k) of this title, has recommended the proposal for approval.

(b) Ethical review of research

(1) Procedures regarding withholding of funds

If research has been recommended for approval for purposes of subsection (a) of this section, the Secretary may not withhold funds for the research because of ethical considerations unless—

(A) the Secretary convenes an advisory board in accordance with paragraph (5) to study such considerations; and

(B)(i) the majority of the advisory board recommends that, because of such consider-

ations, the Secretary withhold funds for the research; or

(ii) the majority of such board recommends that the Secretary not withhold funds for the research because of such considerations, but the Secretary finds, on the basis of the report submitted under paragraph (5)(B)(ii), that the recommendation is arbitrary and capricious.

(2) Rules of construction

Paragraph (1) may not be construed as prohibiting the Secretary from withholding funds for research on the basis of—

(A) the inadequacy of the qualifications of the entities that would be involved with the conduct of the research (including the entity that would directly receive the funds from the Secretary), subject to the condition that, with respect to the process of review through which the research was recommended for approval for purposes of subsection (a) of this section, all findings regarding such qualifications made in such process are conclusive; or

(B) the priorities established by the Secretary for the allocation of funds among projects of research that have been so recommended.

(3) Applicability

The limitation established in paragraph (1) regarding the authority to withhold funds because of ethical considerations shall apply without regard to whether the withholding of funds on such basis is characterized as a disapproval, a moratorium, a prohibition, or other characterization.

(4) Preliminary matters regarding use of procedures

(A) If the Secretary makes a determination that an advisory board should be convened for purposes of paragraph (1), the Secretary shall, through a statement published in the Federal Register, announce the intention of the Secretary to convene such a board.

(B) A statement issued under subparagraph (A) shall include a request that interested individuals submit to the Secretary recommendations specifying the particular individuals who should be appointed to the advisory board involved. The Secretary shall consider such recommendations in making appointments to the board.

(C) The Secretary may not make appointments to an advisory board under paragraph (1) until the expiration of the 30-day period beginning on the date on which the statement required in subparagraph (A) is made with respect to the board.

(5) Ethics advisory boards

(A) Any advisory board convened for purposes of paragraph (1) shall be known as an ethics advisory board (in this paragraph referred to as an “ethics board”).

(B)(i) An ethics board shall advise, consult with, and make recommendations to the Secretary regarding the ethics of the project of biomedical or behavioral research with respect to which the board has been convened.

(ii) Not later than 180 days after the date on which the statement required in paragraph (4)(A) is made with respect to an ethics board, the board shall submit to the Secretary, and to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report describing the findings of the board regarding the project of research involved and making a recommendation under clause (i) of whether the Secretary should or should not withhold funds for the project. The report shall include the information considered in making the findings.

(C) An ethics board shall be composed of no fewer than 14, and no more than 20, individuals who are not officers or employees of the United States. The Secretary shall make appointments to the board from among individuals with special qualifications and competence to provide advice and recommendations regarding ethical matters in biomedical and behavioral research. Of the members of the board—

- (i) no fewer than 1 shall be an attorney;
- (ii) no fewer than 1 shall be an ethicist;
- (iii) no fewer than 1 shall be a practicing physician;
- (iv) no fewer than 1 shall be a theologian; and
- (v) no fewer than one-third, and no more than one-half, shall be scientists with substantial accomplishments in biomedical or behavioral research.

(D) The term of service as a member of an ethics board shall be for the life of the board. If such a member does not serve the full term of such service, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(E) A member of an ethics board shall be subject to removal from the board by the Secretary for neglect of duty or malfeasance or for other good cause shown.

(F) The Secretary shall designate an individual from among the members of an ethics board to serve as the chair of the board.

(G) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall conduct inquiries and hold public hearings.

(H) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall have access to all relevant information possessed by the Department of Health and Human Services, or available to the Secretary from other agencies.

(I) Members of an ethics board shall receive compensation for each day engaged in carrying out the duties of the board, including time engaged in traveling for purposes of such duties. Such compensation may not be provided in an amount in excess of the maximum rate of basic pay payable for GS-18 of the General Schedule.

(J) The Secretary, acting through the Director of the National Institutes of Health, shall provide to each ethics board reasonable staff and assistance to carry out the duties of the board.

(K) An ethics board shall terminate 30 days after the date on which the report required in subparagraph (B)(ii) is submitted to the Secretary and the congressional committees specified in such subparagraph.

(6) "Ethical considerations" defined

For purposes of this subsection, the term "ethical considerations" means considerations as to whether the nature of the research involved is such that it is unethical to conduct or support the research.

(July 1, 1944, ch. 373, title IV, §492A, as added Pub. L. 103-43, title I, §101, June 10, 1993, 107 Stat. 126; amended Pub. L. 109-482, title I, §102(e), Jan. 15, 2007, 120 Stat. 3684.)

AMENDMENTS

2007—Subsec. (a)(2). Pub. L. 109-482 inserted before period at end “, and unless a majority of the voting members of the appropriate advisory council under section 284a of this title, or as applicable, of the advisory council under section 282(k) of this title, has recommended the proposal for approval”.

CHANGE OF NAME

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.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104-14, set out as a note preceding section 21 of Title 2, The Congress. 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.

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.

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

§ 289a-2. Inclusion of women and minorities in clinical research

(a) Requirement of inclusion

(1) In general

In conducting or supporting clinical research for purposes of this subchapter, the Director of NIH shall, subject to subsection (b) of this section, ensure that—

- (A) women are included as subjects in each project of such research; and
- (B) members of minority groups are included as subjects in such research.

(2) Outreach regarding participation as subjects

The Director of NIH, in consultation with the Director of the Office of Research on Wom-

en's Health and the Director of the Office of Research on Minority Health, shall conduct or support outreach programs for the recruitment of women and members of minority groups as subjects in projects of clinical research.

(b) Inapplicability of requirement

The requirement established in subsection (a) of this section regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

- (1) is inappropriate with respect to the health of the subjects;
- (2) is inappropriate with respect to the purpose of the research; or
- (3) is inappropriate under such other circumstances as the Director of NIH may designate.

(c) Design of clinical trials

In the case of any clinical trial in which women or members of minority groups will under subsection (a) of this section be included as subjects, the Director of NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

(d) Guidelines

(1) In general

Subject to paragraph (2), the Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall establish guidelines regarding the requirements of this section. The guidelines shall include guidelines regarding—

- (A) the circumstances under which the inclusion of women and minorities as subjects in projects of clinical research is inappropriate for purposes of subsection (b) of this section;
- (B) the manner in which clinical trials are required to be designed and carried out for purposes of subsection (c) of this section; and
- (C) the operation of outreach programs under subsection (a) of this section.

(2) Certain provisions

With respect to the circumstances under which the inclusion of women or members of minority groups (as the case may be) as subjects in a project of clinical research is inappropriate for purposes of subsection (b) of this section, the following applies to guidelines under paragraph (1):

- (A)(i) In the case of a clinical trial, the guidelines shall provide that the costs of such inclusion in the trial is not a permissible consideration in determining whether such inclusion is inappropriate.
- (ii) In the case of other projects of clinical research, the guidelines shall provide that the costs of such inclusion in the project is not a permissible consideration in determining whether such inclusion is inappropriate

unless the data regarding women or members of minority groups, respectively, that would be obtained in such project (in the event that such inclusion were required) have been or are being obtained through other means that provide data of comparable quality.

(B) In the case of a clinical trial, the guidelines may provide that such inclusion in the trial is not required if there is substantial scientific data demonstrating that there is no significant difference between—

- (i) the effects that the variables to be studied in the trial have on women or members of minority groups, respectively; and
- (ii) the effects that the variables have on the individuals who would serve as subjects in the trial in the event that such inclusion were not required.

(e) Date certain for guidelines; applicability

(1) Date certain

The guidelines required in subsection (d) of this section shall be established and published in the Federal Register not later than 180 days after June 10, 1993.

(2) Applicability

For fiscal year 1995 and subsequent fiscal years, the Director of NIH may not approve any proposal of clinical research to be conducted or supported by any agency of the National Institutes of Health unless the proposal specifies the manner in which the research will comply with this section.

(f) Reports by advisory councils

The advisory council of each national research institute shall prepare biennial reports describing the manner in which the institute has complied with this section. Each such report shall be submitted to the Director of the institute involved for inclusion in the biennial report under section 283 of this title.

(g) Definitions

For purposes of this section:

- (1) The term "project of clinical research" includes a clinical trial.
- (2) The term "minority group" includes subpopulations of minority groups. The Director of NIH shall, through the guidelines established under subsection (d) of this section, define the terms "minority group" and "subpopulation" for purposes of the preceding sentence.

(July 1, 1944, ch. 373, title IV, §492B, as added Pub. L. 103-43, title I, §131, June 10, 1993, 107 Stat. 133.)

INAPPLICABILITY TO CURRENT PROJECTS

Section 133 of Pub. L. 103-43 provided that: "Section 492B of the Public Health Service Act, as added by section 131 of this Act [this section], shall not apply with respect to projects of clinical research for which initial funding was provided prior to the date of the enactment of this Act [June 10, 1993]. With respect to the inclusion of women and minorities as subjects in clinical research conducted or supported by the National Institutes of Health, any policies of the Secretary of Health and Human Services regarding such inclusion that are in effect on the day before the date of the enactment of

this Act shall continue to apply to the projects referred to in the preceding sentence.”

§ 289b. Office of Research Integrity

(a) In general

(1) Establishment of Office

Not later than 90 days after June 10, 1993, the Secretary shall establish an office to be known as the Office of Research Integrity (referred to in this section as the “Office”), which shall be established as an independent entity in the Department of Health and Human Services.

(2) Appointment of Director

The Office shall be headed by a Director, who shall be appointed by the Secretary, be experienced and specially trained in the conduct of research, and have experience in the conduct of investigations of research misconduct. The Secretary shall carry out this section acting through the Director of the Office. The Director shall report to the Secretary.

(3) Definitions

(A) The Secretary shall by regulation establish a definition for the term “research misconduct” for purposes of this section.

(B) For purposes of this section, the term “financial assistance” means a grant, contract, or cooperative agreement.

(b) Existence of administrative processes as condition of funding for research

The Secretary shall by regulation require that each entity that applies for financial assistance under this chapter for any project or program that involves the conduct of biomedical or behavioral research submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity;

(2) an agreement that the entity will report to the Director any investigation of alleged research misconduct in connection with projects for which funds have been made available under this chapter that appears substantial; and

(3) an agreement that the entity will comply with regulations issued under this section.

(c) Process for response of Director

The Secretary shall by regulation establish a process to be followed by the Director for the prompt and appropriate—

(1) response to information provided to the Director respecting research misconduct in connection with projects for which funds have been made available under this chapter;

(2) receipt of reports by the Director of such information from recipients of funds under this chapter;

(3) conduct of investigations, when appropriate; and

(4) taking of other actions, including appropriate remedies, with respect to such misconduct.

(d) Monitoring by Director

The Secretary shall by regulation establish procedures for the Director to monitor administrative processes and investigations that have been established or carried out under this section.

(e) Protection of whistleblowers

(1) In general

In the case of any entity required to establish administrative processes under subsection (b) of this section, the Secretary shall by regulation establish standards for preventing, and for responding to the occurrence of retaliation by such entity, its officials or agents, against an employee in the terms and conditions of employment in response to the employee having in good faith—

(A) made an allegation that the entity, its officials or agents, has engaged in or failed to adequately respond to an allegation of research misconduct; or

(B) cooperated with an investigation of such an allegation.

(2) Monitoring by Secretary

The Secretary shall by regulation establish procedures for the Director to monitor the implementation of the standards established by an entity under paragraph (1) for the purpose of determining whether the procedures have been established, and are being utilized, in accordance with the standards established under such paragraph.

(3) Noncompliance

The Secretary shall by regulation establish remedies for noncompliance by an entity, its officials or agents, which has engaged in retaliation in violation of the standards established under paragraph (1). Such remedies may include termination of funding provided by the Secretary for such project or recovery of funding being provided by the Secretary for such project, or other actions as appropriate.

(July 1, 1944, ch. 373, title IV, §493, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 874; amended Pub. L. 103-43, title I, §§161, 163, June 10, 1993, 107 Stat. 140, 142.)

CODIFICATION

June 10, 1993, referred to in subsec. (a)(1), was in the original “the date of enactment of this section” which was translated as meaning the date of enactment of Pub. L. 103-43, which amended this section generally, to reflect the probable intent of Congress.

AMENDMENTS

1993—Pub. L. 103-43, §161, amended section generally. Prior to amendment, section read as follows:

“(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 submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that such entity—

“(1) has established (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of scientific fraud in connection with biomedical and behavioral research conducted at or sponsored by such entity; and

“(2) will report to the Secretary any investigation of alleged scientific fraud which appears substantial.
“(b) The Director of NIH shall establish a process for the prompt and appropriate response to information provided the Director of NIH respecting scientific fraud in connection with projects 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 fraud.”

Subsec. (e). Pub. L. 103-43, §163, added subsec. (e).

REGULATIONS

Section 165 of Pub. L. 103-43 provided that:

“(a) ISSUANCE OF FINAL RULES.—

“(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act [June 10, 1993], the Secretary shall, subject to paragraph (2), issue the final rule for each regulation required in section 493 or 493A of the Public Health Service Act [this section and section 289b-1 of this title].

“(2) DEFINITION OF RESEARCH MISCONDUCT.—Not later than 90 days after the date on which the report required in section 162(e) [107 Stat. 142] is submitted to the Secretary, the Secretary shall issue the final rule for the regulations required in section 493 of the Public Health Service Act with respect to the definition of the term ‘research misconduct’.

“(b) APPLICABILITY TO ONGOING INVESTIGATIONS.—The final rule issued pursuant to subsection (a) for investigations under section 493 of the Public Health Service Act [this section] does not apply to investigations commenced before the date of the enactment of this Act [June 10, 1993] under authority of such section as in effect before such date.

“(c) DEFINITIONS.—For purposes of this section:

“(1) The term ‘section 493 of the Public Health Service Act’ means such section as amended by sections 161 and 163 of this Act [this section], except as indicated otherwise in subsection (b).

“(2) The term ‘section 493A of the Public Health Service Act’ means such section as added by section 164 of this Act [section 289b-1 of this title].

“(3) The term ‘Secretary’ means the Secretary of Health and Human Services.”

§ 289b-1. Protection against financial conflicts of interest in certain projects of research

(a) Issuance of regulations

The Secretary shall by regulation define the specific circumstances that constitute the existence of a financial interest in a project on the part of an entity or individual that will, or may be reasonably expected to, create a bias in favor of obtaining results in such project that are consistent with such financial interest. Such definition shall apply uniformly to each entity or individual conducting a research project under this chapter. In the case of any entity or individual receiving assistance from the Secretary for a project of research described in subsection (b) of this section, the Secretary shall by regulation establish standards for responding to, including managing, reducing, or eliminating, the existence of such a financial interest. The entity may adopt individualized procedures for implementing the standards.

(b) Relevant projects

A project of research referred to in subsection (a) of this section is a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment and for which such entity is receiving assistance from the Secretary.

(c) Identifying and reporting to Secretary

The Secretary shall by regulation require that each entity described in subsection (a) of this section that applies for assistance under this chapter for any project described in subsection (b) of this section submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect an administrative process under subsection (a) of this section to identify financial interests (as defined under subsection (a) of this section) that exist regarding the project; and

(2) an agreement that the entity will report to the Secretary such interests identified by the entity and how any such interests identified by the entity will be managed or eliminated in order that the project in question will be protected from bias that may stem from such interests; and

(3) an agreement that the entity will comply with regulations issued under this section.

(d) Monitoring of process

The Secretary shall monitor the establishment and conduct of the administrative process established by an entity pursuant to subsection (a) of this section.

(e) Response

In any case in which the Secretary determines that an entity has failed to comply with subsection (c) of this section regarding a project of research described in subsection (b) of this section, the Secretary—

(1) shall require that, as a condition of receiving assistance, the entity disclose the existence of a financial interest (as defined under subsection (a) of this section) in each public presentation of the results of such project; and

(2) may take such other actions as the Secretary determines to be appropriate.

(f) Definitions

For purposes of this section:

(1) The term “financial interest” includes the receipt of consulting fees or honoraria and the ownership of stock or equity.

(2) The term “assistance”, with respect to conducting a project of research, means a grant, contract, or cooperative agreement.

(July 1, 1944, ch. 373, title IV, §493A, as added Pub. L. 103-43, title I, §164, June 10, 1993, 107 Stat. 142.)

REGULATIONS

Final rule for regulations required in this section to be issued not later than 180 days after June 10, 1993, see section 165 of Pub. L. 103-43, set out as a note under section 289b of this title.

§ 289c. Research on public health emergencies

If the Secretary determines, after consultation with the Director of NIH, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control and Prevention, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of NIH—

(1) shall expedite the review by advisory councils under section 284a of this title and by peer review groups under section 289a of this title of applications for grants for research on such disease or disorder or proposals for contracts for such research;

(2) shall exercise the authority in section 5 of title 41 respecting public exigencies to waive the advertising requirements of such section in the case of proposals for contracts for such research;

(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; and

(4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatment of such disease or disorder that has been developed in research assisted under this section.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.

(July 1, 1944, ch. 373, title IV, § 494, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 875; amended Pub. L. 102-531, title III, § 312(d)(9), Oct. 27, 1992, 106 Stat. 3504; Pub. L. 109-482, title I, § 104(b)(1)(P), Jan. 15, 2007, 120 Stat. 3693.)

AMENDMENTS

2007—Pub. L. 109-482 struck out subsec. (a) designation before “If the Secretary” and subsec. (b) which read as follows: “Not later than 90 days after the end of a fiscal year, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on actions taken under subsection (a) of this section in such fiscal year.”

1992—Subsec. (a). Pub. L. 102-531 substituted “Centers for Disease Control and Prevention” for “Centers for Disease Control”.

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.

§ 289c-1. Collaborative use of certain health services research funds

The Secretary shall ensure that amounts made available under subparts 14, 15 and 16 of part C for health services research relating to alcohol abuse and alcoholism, drug abuse and mental health be used collaboratively, as appropriate, and in consultation with the Agency for Healthcare Research and Quality.

(July 1, 1944, ch. 373, title IV, § 494A, as added Pub. L. 102-321, title I, § 125, July 10, 1992, 106 Stat. 366; amended Pub. L. 103-43, title XX, § 2016(c), June 10, 1993, 107 Stat. 218; Pub. L. 104-66, title I, § 1062(b), Dec. 21, 1995, 109 Stat. 720; Pub. L. 105-362, title VI, § 601(a)(1)(F), Nov. 10, 1998, 112 Stat. 3285; Pub. L. 106-129, § 2(b)(2), Dec. 6, 1999, 113 Stat. 1670.)

REFERENCES IN TEXT

Subparts 14, 15 and 16 of part C, referred to in text, are classified to sections 285n et seq., 285o et seq., and 285p et seq., respectively, of this title.

AMENDMENTS

1999—Pub. L. 106-129, which directed the substitution of “Agency for Healthcare Research and Quality” for “Agency for Health Care Policy and Research”, was executed by making the substitution for “Agency for Health Care Policy Research”, to reflect the probable intent of Congress.

1998—Pub. L. 105-362 struck out heading and designation of subsec. (a) and heading and text of subsec. (b). Text of subsec. (b) read as follows: “Not later than December 30, 1993, and each December 30 thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report concerning the activities carried out with the amounts referred to in subsection (a) of this section.”

1995—Subsec. (b). Pub. L. 104-66 substituted “December 30, 1993, and each December 30 thereafter” for “September 30, 1993, and annually thereafter”.

1993—Subsec. (b). Pub. L. 103-43 substituted “September 30, 1993” for “May 3, 1993”.

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.

§ 289d. Animals in research

(a) Establishment of guidelines

The Secretary, acting through the Director of NIH, shall establish guidelines for the following:

(1) The proper care of animals to be used in biomedical and behavioral research.

(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall require—

(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

(3) The organization and operation of animal care committees in accordance with subsection (b) of this section.

(b) Animal care committees; establishment; membership; functions

(1) Guidelines of the Secretary under subsection (a)(3) of this section shall require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this chapter (including the National Institutes of Health and the national research institutes) to assure compliance with the guidelines established under subsection (a) of this section.

(2) Each animal care committee shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than three members, and shall include at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

(3) Each animal care committee of a research entity shall—

(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semi-annually to

evaluate compliance with applicable guidelines established under subsection (a) of this section for appropriate animal care and treatment;

(B) keep appropriate records of reviews conducted under subparagraph (A); and

(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) of this section or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

Reports filed under subparagraph (C) shall include any minority views filed by members of the committee.

(c) Assurances required in application or contract proposal; reasons for use of animals; notice and comment requirements for promulgation of regulations

The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in its application or contract proposal, submitted after the expiration of the twelve-month period beginning on November 20, 1985—

(1) assurances satisfactory to the Director of NIH that—

(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) of this section and has an animal care committee which meets the requirements of subsection (b) of this section; and

(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress; and

(2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract.

Notwithstanding subsection (a)(2) of section 553 of title 5, regulations under this subsection shall be promulgated in accordance with the notice and comment requirements of such section.

(d) Failure to meet guidelines; suspension or revocation of grant or contract

If the Director of NIH determines that—

(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this subchapter do not meet applicable guidelines established under subsection (a) of this section;

(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

(3) no action has been taken by the entity to correct such conditions;

the Director of NIH shall suspend or revoke such grant or contract under such conditions as the Director determines appropriate.

(e) Disclosure of trade secrets or privileged or confidential information

No guideline or regulation promulgated under subsection (a) or (c) of this section may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential.

(July 1, 1944, ch. 373, title IV, § 495, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 875.)

PROHIBITION ON FUNDING OF PROJECTS INVOLVING USE OF CHIMPANZEES OBTAINED FROM THE WILD

Pub. L. 102-394, title II, § 213, Oct. 6, 1992, 106 Stat. 1812, provided that: "No funds appropriated under this Act or subsequent Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts shall be used by the National Institutes of Health, or any other Federal agency, or recipient of Federal funds on any project that entails the capture or procurement of chimpanzees obtained from the wild. For purposes of this section, the term 'recipient of Federal funds' includes private citizens, corporations, or other research institutions located outside of the United States that are recipients of Federal funds."

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 102-170, title II, § 213, Nov. 26, 1991, 105 Stat. 1127.

Pub. L. 101-517, title II, § 211, Nov. 5, 1990, 104 Stat. 2209.

Pub. L. 101-166, title II, § 214, Nov. 21, 1989, 103 Stat. 1178.

PLAN FOR RESEARCH INVOLVING ANIMALS

Section 4 of Pub. L. 99-158 directed Director of National Institutes of Health to establish, not later than Oct. 1, 1986, a plan for research into methods of biomedical research and experimentation which reduces the use of animals in research or which produce less pain and distress in animals to develop methods found to be valid and reliable, to train scientists in use of such methods, to disseminate information on such methods and to establish an Interagency Coordinating Committee to assist in development of the plan, prior to repeal by Pub. L. 103-43, title II, § 205(b), June 10, 1993, 107 Stat. 148. See section 283e of this title.

§ 289e. Use of appropriations

(a) Appropriations to carry out the purposes of this subchapter, unless otherwise expressly provided, may be expended in the District of Columbia for—

(1) personal services;

(2) stenographic recording and translating services;

(3) travel expenses (including the expenses of attendance at meetings when specifically authorized by the Secretary);

(4) rental;

(5) supplies and equipment;

(6) purchase and exchange of medical books, books of reference, directories, periodicals, newspapers, and press clippings;

(7) purchase, operation, and maintenance of passenger motor vehicles;

(8) printing and binding (in addition to that otherwise provided by law); and

(9) all other necessary expenses in carrying out this subchapter.

Such appropriations may be expended by contract if deemed necessary, without regard to section 5 of title 41.

(b)(1) None of the amounts appropriated under this chapter for the purposes of this subchapter may be obligated for the construction of facilities (including the acquisition of land) unless a provision of this subchapter establishes express authority for such purpose and unless the Act making appropriations under such provision specifies that the amounts appropriated are available for such purpose.

(2) Any grants, cooperative agreements, or contracts authorized in this subchapter for the construction of facilities may be awarded only on a competitive basis.

(July 1, 1944, ch. 373, title IV, § 496, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 877; amended Pub. L. 101-190, § 8, Nov. 29, 1989, 103 Stat. 1695; Pub. L. 103-43, title XX, § 2008(b)(15), June 10, 1993, 107 Stat. 211.)

AMENDMENTS

1993—Subsec. (a). Pub. L. 103-43 substituted “Appropriations to carry out the purposes of this subchapter” for “Such appropriations”.

1989—Subsec. (a). Pub. L. 101-190 designated existing provisions as subsec. (a), struck out first sentence which read as follows: “Appropriations to carry out the purposes of this subchapter shall be available for the acquisition of land or the erection of buildings only if so specified.”, and added subsec. (b).

CONSTRUCTION OF BIOMEDICAL FACILITIES FOR DEVELOPMENT AND BREEDING OF SPECIALIZED STRAINS OF MICE

Sections 1 to 7 of Pub. L. 101-190, as amended by Pub. L. 101-374, § 4(a), (c)(1), Aug. 15, 1990, 104 Stat. 458, 459, authorized a reservation of funds for making a grant to construct facilities for development and breeding of specialized strains of mice for use in biomedical research, provided for a competitive grant award process, required applicant for the grant to agree to a twenty-year transferable obligation, restricted grant applicant to public or nonprofit private status, with assurances of sufficient financial resources, set forth other grant requirements, and specified consequences of failure to comply with agreements and violation of the twenty-year obligation.

§ 289f. Gifts and donations; memorials

The Secretary may, in accordance with section 238 of this title, accept conditional gifts for the National Institutes of Health or a national research institute or for the acquisition of grounds or for the erection, equipment, or maintenance of facilities for the National Institutes of Health or a national research institute. Donations of \$50,000 or over for the National Institutes of Health or a national research institute for carrying out the purposes of this subchapter may be acknowledged by the establishment within the National Institutes of Health or a national research institute of suitable memorials to the donors.

(July 1, 1944, ch. 373, title IV, § 497, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 877; amended Pub. L. 99-660, title III, § 311(b)(1), Nov. 14, 1986, 100 Stat. 3779; Pub. L. 100-607, title II, § 204(3), Nov. 4, 1988, 102 Stat. 3079; Pub. L. 100-690, title II, § 2620(b)(2), Nov. 18, 1988, 102 Stat. 4244; Pub. L. 101-381, title I, § 102(5), Aug. 18, 1990, 104 Stat.

586; Pub. L. 103-43, title XX, § 2010(b)(6), June 10, 1993, 107 Stat. 214.)

AMENDMENTS

1993—Pub. L. 103-43 substituted “section 238” for “section 300aaa”.

1990—Pub. L. 101-381 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

1988—Pub. L. 100-690 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

Pub. L. 100-607 substituted “300aaa” for “300cc”.

1986—Pub. L. 99-660 substituted “section 300cc of this title” for “section 300aa of this title”.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-690 effective immediately after enactment of Pub. L. 100-607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100-690, set out as a note under section 242m of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99-660 effective Dec. 22, 1987, see section 323 of Pub. L. 99-660, as amended, set out as an Effective Date note under section 300aa-1 of this title.

§ 289g. Fetal research

(a) Conduct or support by Secretary; restrictions

The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—

(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

(b) Risk standard for fetuses intended to be aborted and fetuses intended to be carried to term to be same

In administering the regulations for the protection of human research subjects which—

(1) apply to research conducted or supported by the Secretary;

(2) involve living human fetuses in utero; and

(3) are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations;

or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

(July 1, 1944, ch. 373, title IV, § 498, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 877; amended Pub. L. 100-607, title I, §§ 156, 157(b), Nov. 4, 1988, 102 Stat. 3059; Pub. L. 103-43, title I, § 121(b)(1), June 10, 1993, 107 Stat. 133.)

AMENDMENTS

1993—Subsec. (c). Pub. L. 103-43 struck out subsec. (c) which directed Biomedical Ethics Advisory Committee

to conduct a study of the nature, advisability, and biomedical and ethical implications of exercising any waiver of the risk standard published in section 46.102(g) of part 46 of title 45 of the Code of Federal Regulations and to report its finding to the Biomedical Ethics Board not later than 24 months after Nov. 4, 1988, which report was to be then transmitted to specified Congressional committees.

1988—Subsec. (c)(1). Pub. L. 100-607, §157(b), substituted “24 months after November 4, 1988” for “thirty months after November 20, 1985”.

Subsec. (c)(2). Pub. L. 100-607, §156(1), substituted “24-month period beginning on November 4, 1988” for “thirty-six month period beginning on November 20, 1985”.

Subsec. (c)(3). Pub. L. 100-607, §156(2), substituted “1990” for “1988”.

NULLIFICATION OF CERTAIN PROVISIONS

Section 121(c) of Pub. L. 103-43 provided that: “The provisions of Executive Order 12806 (57 Fed. Reg. 21589 (May 21, 1992)) [formerly set out below] shall not have any legal effect. The provisions of section 204(d) of part 46 of title 45 of the Code of Federal Regulations (45 CFR 46.204(d)) shall not have any legal effect.”

EXECUTIVE ORDER NO. 12806. ESTABLISHMENT OF FETAL TISSUE BANK

Ex. Ord. No. 12806, May 19, 1992, 57 F.R. 21589, which established a human fetal tissue bank, was nullified by Pub. L. 103-43, title I, §121(c), June 10, 1993, 107 Stat. 133, set out above.

FEDERAL FUNDING OF FETAL TISSUE TRANSPLANTATION RESEARCH

Memorandum of President of the United States, Jan. 22, 1993, 58 F.R. 7457, provided:

Memorandum for the Secretary of Health and Human Services

On March 22, 1988, the Assistant Secretary for Health of Health and Human Services (“HHS”) imposed a temporary moratorium on Federal funding of research involving transplantation of fetal tissue from induced abortions. Contrary to the recommendations of a National Institutes of Health advisory panel, on November 2, 1989, the Secretary of Health and Human Services extended the moratorium indefinitely. This moratorium has significantly hampered the development of possible treatments for individuals afflicted with serious diseases and disorders, such as Parkinson’s disease, Alzheimer’s disease, diabetes, and leukemia. Accordingly, I hereby direct that you immediately lift the moratorium.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

WILLIAM J. CLINTON.

§ 289g-1. Research on transplantation of fetal tissue

(a) Establishment of program

(1) In general

The Secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes.

(2) Source of tissue

Human fetal tissue may be used in research carried out under paragraph (1) regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.

(b) Informed consent of donor

(1) In general

In research carried out under subsection (a) of this section, human fetal tissue may be used only if the woman providing the tissue

makes a statement, made in writing and signed by the woman, declaring that—

(A) the woman donates the fetal tissue for use in research described in subsection (a) of this section;

(B) the donation is made without any restriction regarding the identity of individuals who may be the recipients of transplantations of the tissue; and

(C) the woman has not been informed of the identity of any such individuals.

(2) Additional statement

In research carried out under subsection (a) of this section, human fetal tissue may be used only if the attending physician with respect to obtaining the tissue from the woman involved makes a statement, made in writing and signed by the physician, declaring that—

(A) in the case of tissue obtained pursuant to an induced abortion—

(i) the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for a donation of the tissue for use in such research;

(ii) no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; and

(iii) the abortion was performed in accordance with applicable State law;

(B) the tissue has been donated by the woman in accordance with paragraph (1); and

(C) full disclosure has been provided to the woman with regard to—

(i) such physician’s interest, if any, in the research to be conducted with the tissue; and

(ii) any known medical risks to the woman or risks to her privacy that might be associated with the donation of the tissue and that are in addition to risks of such type that are associated with the woman’s medical care.

(c) Informed consent of researcher and donee

In research carried out under subsection (a) of this section, human fetal tissue may be used only if the individual with the principal responsibility for conducting the research involved makes a statement, made in writing and signed by the individual, declaring that the individual—

(1) is aware that—

(A) the tissue is human fetal tissue;

(B) the tissue may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and

(C) the tissue was donated for research purposes;

(2) has provided such information to other individuals with responsibilities regarding the research;

(3) will require, prior to obtaining the consent of an individual to be a recipient of a transplantation of the tissue, written acknowledgment of receipt of such information by such recipient; and

(4) has had no part in any decisions as to the timing, method, or procedures used to termi-

nate the pregnancy made solely for the purposes of the research.

(d) Availability of statements for audit

(1) In general

In research carried out under subsection (a) of this section, human fetal tissue may be used only if the head of the agency or other entity conducting the research involved certifies to the Secretary that the statements required under subsections (b)(2) and (c) of this section will be available for audit by the Secretary.

(2) Confidentiality of audit

Any audit conducted by the Secretary pursuant to paragraph (1) shall be conducted in a confidential manner to protect the privacy rights of the individuals and entities involved in such research, including such individuals and entities involved in the donation, transfer, receipt, or transplantation of human fetal tissue. With respect to any material or information obtained pursuant to such audit, the Secretary shall—

(A) use such material or information only for the purposes of verifying compliance with the requirements of this section;

(B) not disclose or publish such material or information, except where required by Federal law, in which case such material or information shall be coded in a manner such that the identities of such individuals and entities are protected; and

(C) not maintain such material or information after completion of such audit, except where necessary for the purposes of such audit.

(e) Applicability of State and local law

(1) Research conducted by recipients of assistance

The Secretary may not provide support for research under subsection (a) of this section unless the applicant for the financial assistance involved agrees to conduct the research in accordance with applicable State law.

(2) Research conducted by Secretary

The Secretary may conduct research under subsection (a) of this section only in accordance with applicable State and local law.

(f) Report

The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this section during the preceding fiscal year, including a description of whether and to what extent research under subsection (a) of this section has been conducted in accordance with this section.

(g) “Human fetal tissue” defined

For purposes of this section, the term “human fetal tissue” means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.

(July 1, 1944, ch. 373, title IV, §498A, as added Pub. L. 103-43, title I, §111, June 10, 1993, 107 Stat. 129.)

CHANGE OF NAME

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.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104-14, set out as a note preceding section 21 of Title 2, The Congress. 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.

NULLIFICATION OF MORATORIUM

Section 113 of Pub. L. 103-43 provided that:

“(a) IN GENERAL.—Except as provided in subsection (c), no official of the executive branch may impose a policy that the Department of Health and Human Services is prohibited from conducting or supporting any research on the transplantation of human fetal tissue for therapeutic purposes. Such research shall be carried out in accordance with section 498A of the Public Health Service Act [this section] (as added by section 111 of this Act), without regard to any such policy that may have been in effect prior to the date of the enactment of this Act [June 10, 1993].

“(b) PROHIBITION AGAINST WITHHOLDING OF FUNDS IN CASES OF TECHNICAL AND SCIENTIFIC MERIT.—

“(1) IN GENERAL.—Subject to subsection (b)(2) of section 492A of the Public Health Service Act [section 289a-1(b)(2) of this title] (as added by section 101 of this Act), in the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may not withhold funds for the research if—

“(A) the research has been approved for purposes of subsection (a) of such section 492A;

“(B) the research will be carried out in accordance with section 498A of such Act [this section] (as added by section 111 of this Act); and

“(C) there are reasonable assurances that the research will not utilize any human fetal tissue that has been obtained in violation of section 498B(a) of such Act [section 289g-2(a) of this title] (as added by section 112 of this Act).

“(2) STANDING APPROVAL REGARDING ETHICAL STATUS.—In the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the issuance in December 1988 of the Report of the Human Fetal Tissue Transplantation Research Panel shall be deemed to be a report—

“(A) issued by an ethics advisory board pursuant to section 492A(b)(5)(B)(ii) of the Public Health Service Act (as added by section 101 of this Act); and

“(B) finding, on a basis that is neither arbitrary nor capricious, that the nature of the research is such that it is not unethical to conduct or support the research.

“(c) AUTHORITY FOR WITHHOLDING FUNDS FROM RESEARCH.—In the case of any research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may withhold funds for the research if any of the conditions specified in any of subparagraphs (A) through (C) of subsection (b)(1) are not met with respect to the research.

“(d) DEFINITION.—For purposes of this section, the term ‘human fetal tissue’ has the meaning given such term in section 498A(f) of the Public Health Service Act [subsec. (f) of this section] (as added by section 111 of this Act).”

REPORT BY GENERAL ACCOUNTING OFFICE ON ADEQUACY OF REQUIREMENTS

Section 114 of Pub. L. 103-43 provided that, with respect to research on the transplantation of human fetal tissue for therapeutic purposes, the Comptroller General of the United States was to conduct an audit for the purpose of determining whether and to what extent such research conducted or supported by Secretary of Health and Human Services had been conducted in accordance with this section and whether and to what extent there have been violations of section 289g-2 of this title and directed the Comptroller General to complete the audit and report the findings to Congress, not later than May 19, 1995.

§ 289g-2. Prohibitions regarding human fetal tissue**(a) Purchase of tissue**

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.

(b) Solicitation or acceptance of tissue as directed donation for use in transplantation

It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, the tissue will be or is obtained pursuant to an induced abortion, and—

(1) the donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual;

(2) the donated tissue will be transplanted into a relative of the donating individual; or

(3) the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.

(c) Solicitation or acceptance of tissue from fetuses gestated for research purposes

It shall be unlawful for any person or entity involved or engaged in interstate commerce to—

(1) solicit or knowingly acquire, receive, or accept a donation of human fetal tissue knowing that a human pregnancy was deliberately initiated to provide such tissue; or

(2) knowingly acquire, receive, or accept tissue or cells obtained from a human embryo or fetus that was gestated in the uterus of a nonhuman animal.

(d) Criminal penalties for violations**(1) In general**

Any person who violates subsection (a), (b), or (c) shall be fined in accordance with title 18, subject to paragraph (2), or imprisoned for not more than 10 years, or both.

(2) Penalties applicable to persons receiving consideration

With respect to the imposition of a fine under paragraph (1), if the person involved violates subsection (a) or (b)(3), a fine shall be imposed in an amount not less than twice the amount of the valuable consideration received.

(e) Definitions

For purposes of this section:

(1) The term “human fetal tissue” has the meaning given such term in section 289g-1(g) of this title.

(2) The term “interstate commerce” has the meaning given such term in section 321(b) of title 21.

(3) The term “valuable consideration” does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

(July 1, 1944, ch. 373, title IV, §498B, as added Pub. L. 103-43, title I, §112, June 10, 1993, 107 Stat. 131; amended Pub. L. 109-242, §2, July 19, 2006, 120 Stat. 570.)

AMENDMENTS

2006—Subsec. (c). Pub. L. 109-242, §2(2), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 109-242, §2(1), (3), redesignated subsec. (c) as (d) and substituted “(a), (b), or (c)” for “(a) or (b)” in par. (1). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 109-242, §2(1), (4), redesignated subsec. (d) as (e) and substituted “section 289g-1(g)” for “section 289g-1(f)” in par. (1).

§ 289g-3. Breast implant research**(a) In general**

The Director of NIH may conduct or support research to examine the long-term health implications of silicone breast implants, both gel and saline filled. Such research studies may include the following:

(1) Developing and examining techniques to measure concentrations of silicone in body fluids and tissues.

(2) Surveillance of recipients of silicone breast implants, including long-term outcomes and local complications.

(b) Definition

For purposes of this section, the term “breast implant” means a breast prosthesis that is implanted to augment or reconstruct the female breast.

(July 1, 1944, ch. 373, title IV, §498C, as added Pub. L. 107-250, title II, §215(b), Oct. 26, 2002, 116 Stat. 1615.)

BREAST IMPLANTS; STUDY BY COMPTROLLER GENERAL

Pub. L. 107-250, title II, §214, Oct. 26, 2002, 116 Stat. 1615, provided that:

“(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study to determine the following with respect to breast implants:

“(1) The content of information typically provided by health professionals to women who consult with such professionals on the issue of whether to undergo breast implant surgery.

“(2) Whether such information is provided by physicians or other health professionals, and whether the information is provided verbally or in writing, and at what point in the process of determining whether to undergo surgery is such information provided.

“(3) Whether the information presented, as a whole, provides a complete and accurate discussion of the risks and benefits of breast implants, and the extent to which women who receive such information understand the risks and benefits.

“(4) The number of adverse events that have been reported, and whether such events have been adequately investigated.

“(5) With respect to women who participate as subjects in research being carried out regarding the safety and effectiveness of breast implants:

“(A) The content of information provided to the women during the process of obtaining the informed consent of the women to be subjects, and the extent to which such information is updated.

“(B) Whether such process provides written explanations of the criteria for being subjects in the research.

“(C) The point at which, in the planning or conduct of the research, the women are provided information regarding the provision of informed consent to be subjects.

“(b) REPORT.—The Comptroller General shall submit to the Congress a report describing the findings of the study.

“(c) DEFINITION.—For purposes of this section, the term ‘breast implant’ means a breast prosthesis that is implanted to augment or reconstruct the female breast.”

§ 289h. Repealed. Pub. L. 103-43, title I, § 121(b)(2), June 10, 1993, 107 Stat. 133

Section, act July 1, 1944, ch. 373, title IV, § 499, as added Nov. 20, 1985, Pub. L. 99-158, § 2, 99 Stat. 878, related to construction of subchapter.

§ 290. National Institutes of Health Management Fund; establishment; advancements; availability; final adjustments of advances

For the purpose of facilitating the economical and efficient conduct of operations in the National Institutes of Health which are financed by two or more appropriations where the costs of operation are not readily susceptible of distribution as charges to such appropriations, there is established the National Institutes of Health Management Fund. Such amounts as the Director of the National Institutes of Health may determine to represent a reasonable distribution of estimated costs among the various appropriations involved may be advanced each year to this fund and shall be available for expenditure for such costs under such regulations as may be prescribed by said Director, including the operation of facilities for the sale of meals to employees and others at rates to be determined by said Director to be sufficient to cover the reasonable value of the meals served and the proceeds thereof shall be deposited to the credit of this fund: *Provided*, That funds advanced to this fund shall be available only in the fiscal year in which they are advanced: *Provided further*, That final adjustments of advances in accordance with actual costs shall be effected wherever practicable with the appropriations from which such funds are advanced.

(Pub. L. 85-67, title II, § 201, June 29, 1957, 71 Stat. 220; Pub. L. 87-290, title II, § 201, Sept. 22, 1961, 75 Stat. 603.)

CODIFICATION

Section was enacted as a part of the Department of Health, Education, and Welfare Appropriation Act, 1958, and not as a part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1961—Pub. L. 87-290 substituted “reasonable value of the meals served” for “cost of such operation”.

§ 290a. Victims of fire

(a) Research on burns, burn injuries, and rehabilitation

The Secretary of Health and Human Services shall establish, within the National Institutes of Health and in cooperation with the Director, an expanded program of research on burns, treatment of burn injuries, and rehabilitation of victims of fires. The National Institutes of Health shall—

(1) sponsor and encourage the establishment throughout the Nation of twenty-five additional burn centers, which shall comprise separate hospital facilities providing specialized burn treatment and including research and teaching programs and twenty-five additional burn units, which shall comprise specialized facilities in general hospitals used only for burn victims;

(2) provide training and continuing support of specialists to staff the new burn centers and burn units;

(3) sponsor and encourage the establishment of ninety burn programs in general hospitals which comprise staffs of burn injury specialists;

(4) provide special training in emergency care for burn victims;

(5) augment sponsorship of research on burns and burn treatment;

(6) administer and support a systematic program of research concerning smoke inhalation injuries; and

(7) sponsor and support other research and training programs in the treatment and rehabilitation of burn injury victims.

(b) Authorization of appropriations

For purposes of this section, there are authorized to be appropriated not to exceed \$5,000,000 for the fiscal year ending June 30, 1975 and not to exceed \$8,000,000 for the fiscal year ending June 30, 1976.

(Pub. L. 93-498, § 19, Oct. 29, 1974, 88 Stat. 1547; Pub. L. 96-88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 106-503, title I, § 110(a)(2)(B)(vii), Nov. 13, 2000, 114 Stat. 2302.)

CODIFICATION

Section was enacted as part of the Federal Fire Prevention and Control Act of 1974 (which is classified principally to chapter 49 (§ 2201 et seq.) of Title 15), and not as a part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2000—Subsec. (a). Pub. L. 106-503 substituted “in cooperation with the Director” for “in cooperation with the Secretary”.

CHANGE OF NAME

“Secretary of Health and Human Services” substituted for “Secretary of Health, Education, and Welfare” in subsec. (a) pursuant to section 509(b) of Pub. L. 96-88 which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of all functions, personnel, assets, components, authorities, grant programs, and liabilities of the Federal Emergency Management Agency, including the functions of the Under Secretary for Federal Emer-

gency Management relating thereto, to the Federal Emergency Management Agency, see section 315(a)(1) of Title 6, Domestic Security.

For transfer of functions, personnel, assets, and liabilities of the Federal Emergency Management Agency, including the functions of the Director of the Federal Emergency Management Agency relating thereto, to the Secretary of Homeland Security, and for treatment of related references, see former section 313(1) and sections 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

DEFINITIONS

For definition of terms used in this section, see section 2203 of Title 15, Commerce and Trade.

PART I—FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

AMENDMENTS

1998—Pub. L. 105-392, title IV, § 418(1), Nov. 13, 1998, 112 Stat. 3591, substituted “Foundation for the National Institutes of Health” for “National Foundation for Biomedical Research” in part heading.

1993—Pub. L. 103-43, title I, § 141(a)(2), June 10, 1993, 107 Stat. 136, redesignated part H “National Foundation for Biomedical Research” as I.

§ 290b. Establishment and duties of Foundation

(a) In general

The Secretary shall, acting through the Director of NIH, establish a nonprofit corporation to be known as the Foundation for the National Institutes of Health (hereafter in this section referred to as the “Foundation”). The Foundation shall not be an agency or instrumentality of the United States Government.

(b) Purpose of Foundation

The purpose of the Foundation shall be to support the National Institutes of Health in its mission (including collection of funds for pediatric pharmacologic research), and to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations.

(c) Certain activities of Foundation

(1) In general

In carrying out subsection (b) of this section, the Foundation may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of the following activities with respect to the purpose described in such subsection:

(A) A program to provide and administer endowed positions that are associated with the research program of the National Institutes of Health. Such endowments may be expended for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the endowed positions.

(B) A program to provide and administer fellowships and grants to research personnel in order to work and study in association with the National Institutes of Health. Such fellowships and grants may include stipends, travel, health insurance benefits and other appropriate expenses. The recipients of fel-

lowships shall be selected by the donors and the Foundation upon the recommendation of the National Institutes of Health employees in the laboratory where the fellow would serve, and shall be subject to the agreement of the Director of the National Institutes of Health and the Executive Director of the Foundation.

(C) A program to collect funds for pediatric pharmacologic research and studies for which the Secretary issues a certification in the affirmative under section 355a(n)(1)(A) of title 21.¹

(D) Supplementary programs to provide for—

(i) scientists of other countries to serve in research capacities in the United States in association with the National Institutes of Health or elsewhere, or opportunities for employees of the National Institutes of Health or other public health officials in the United States to serve in such capacities in other countries, or both;

(ii) the conduct and support of studies, projects, and research, which may include stipends, travel and other support for personnel in collaboration with national and international non-profit and for-profit organizations;

(iii) the conduct and support of forums, meetings, conferences, courses, and training workshops that may include undergraduate, graduate, post-graduate, and post-doctoral accredited courses and the maintenance of accreditation of such courses by the Foundation at the State and national level for college or continuing education credits or for degrees;

(iv) programs to support and encourage teachers and students of science at all levels of education and programs for the general public which promote the understanding of science;

(v) programs for writing, editing, printing, publishing, and vending of books and other materials; and

(vi) the conduct of other activities to carry out and support the purpose described in subsection (b) of this section.

(2) Fees

The Foundation may assess fees for the provision of professional, administrative and management services by the Foundation in amounts determined reasonable and appropriate by the Executive Director.

(3) Authority of Foundation

The Foundation shall be the sole entity responsible for carrying out the activities described in this subsection.

(d) Board of Directors

(1) Composition

(A) The Foundation shall have a Board of Directors (hereafter referred to in this section as the “Board”), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

¹So in original. The closing parenthesis probably should not appear.