''(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 [42 U.S.C. 289b] 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 [42 U.S.C. 289b] as amended by sections 161 and 163 of this Act, except as indicated otherwise in subsection (b).

''(2) The term 'section 493A of the Public Health Service Act' means such section [42 U.S.C. 289b–1] as added by section 164 of this Act.

''(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), 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) 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) that applies for assistance under this chapter for any project described in subsection (b) 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) to identify financial interests (as defined under subsection (a)) 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).

(e) Response

In any case in which the Secretary determines that an entity has failed to comply with subsection (c) regarding a project of research described in subsection (b), 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)) 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 6101 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.)

CODIFICATION

In par. (2), ''section 6101 of title 41'' substituted for ''section 3709 of the Revised Statutes (41 U.S.C. 5)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

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., 285*o* 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).

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

(1) Guidelines of the Secretary under subsection (a)(3) 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).

(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) 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) 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.