

(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

Pub. L. 103-43, title I, §133, June 10, 1993, 107 Stat. 135, provided that: "Section 492B of the Public Health Service Act, as added by section 131 of this Act [42 U.S.C. 289a-2], 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

Pub. L. 103-43, title I, § 165, June 10, 1993, 107 Stat. 143, 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 [42 U.S.C. 289b, 289b-1].

“(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) 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 ef-