

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 Women'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

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