

volved 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 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), 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 considerations, 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), 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

¹ See References in Text note below.

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 Sec-

retary 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), 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.

(3) Strategic planning

(A) In general

The directors of the national institutes and national centers shall consult at least once annually with the Director of the National Institute on Minority Health and Health Disparities and the Director of the Office of Research on Women's Health regarding objectives of the national institutes and national centers to ensure that future activities by such institutes and centers take into account women and minorities and are focused on reducing health disparities.

(B) Strategic plans

Any strategic plan issued by a national institute or national center shall include details on the objectives described in subparagraph (A).

(b) Inapplicability of requirement

The requirement established in subsection (a) 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

(1) In general

In the case of any clinical trial in which women or members of minority groups will

under subsection (a) 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.

(2) Reporting requirements

For any new and competing project of clinical research subject to the requirements under this section that receives a grant award 1 year after December 13, 2016, or any date thereafter, for which a valid analysis is provided under paragraph (1)—

(A) and which is an applicable clinical trial as defined in section 282(j) of this title, the entity conducting such clinical research shall submit the results of such valid analysis to the clinical trial registry data bank expanded under section 282(j)(3) of this title, and the Director of the National Institutes of Health shall, as appropriate, consider whether such entity has complied with the reporting requirement described in this subparagraph in awarding any future grant to such entity, including pursuant to section 282(j)(5)(A)(ii) of this title when applicable; and

(B) the Director of the National Institutes of Health shall encourage the reporting of the results of such valid analysis described in paragraph (1) through any additional means determined appropriate by the Director.

(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);
- (B) the manner in which clinical trials are required to be designed and carried out for purposes of subsection (c); and
- (C) the operation of outreach programs under subsection (a).

(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), 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