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 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) 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**

**(1) In general**

The advisory council of each national research institute shall prepare triennial 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 triennial report under section 283 of this title.

**(2) Contents**

Each triennial report prepared by an advisory council of each national research institute as described in paragraph (1) shall include each of the following:

(A) The number of women included as subjects, and the proportion of subjects that are women, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease, and accounting for single-sex studies.

(B) The number of members of minority groups included as subjects, and the proportion of subjects that are members of minority groups, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease and accounting for single-race and single-ethnicity studies.

(C) For the applicable reporting period, the number of projects of clinical research that include women and members of minority groups and that—

(i) have been completed during such reporting period; and

(ii) are being carried out during such reporting period and have not been completed.

(D) The number of studies completed during the applicable reporting period for which reporting has been submitted in accordance with subsection (c)(2)(A).

**(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), 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; amended Pub. L. 114–255, div. A, title II, §§ 2031(c), 2038(b), 2053, Dec. 13, 2016, 130 Stat. 1056, 1065, 1076.)

**Editorial Notes**

AMENDMENTS

2016—Subsec. (a)(3). Pub. L. 114–255, § 2031(c), added par. (3).

Subsec. (c). Pub. L. 114–255, § 2053, designated existing provisions as par. (1), inserted heading, and added par. (2).

Subsec. (f). Pub. L. 114–255, § 2038(b), designated existing provisions as par. (1), inserted heading, substituted ''triennial'' for ''biennial'' in two places, and added par. (2).

**Statutory Notes and Related Subsidiaries**

CLINICAL RESEARCH

Pub. L. 114–255, div. A, title II, § 2038(h), Dec. 13, 2016, 130 Stat. 1067, provided that:

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Dec. 13, 2016], the Director of the National Institutes of Health, in consultation with the Director of the Office of Research on Women's Health and the Director of the National Institute on Minority Health and Health Disparities, shall update the guidelines established under section 492B(d) of [the] Public Health Service Act (42 U.S.C. 289a–2(d)) in accordance with paragraph (2).

''(2) REQUIREMENTS.—The updated guidelines described in paragraph (1) shall—

''(A) reflect the science regarding sex differences;

''(B) improve adherence to the requirements under section 492B of the Public Health Service Act (42 U.S.C. 289a–2), including the reporting requirements under subsection (f) of such section; and

''(C) clarify the circumstances under which studies should be designed to support the conduct of analyses to detect significant differences in the intervention effect due to demographic factors related to section 492B of the Public Health Service Act, including in the absence of prior studies that demonstrate a difference in study outcomes on the basis of such factors and considering the effects of the absence of such analyses on the availability of data related to demographic differences.''

TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN

Pub. L. 114–255, div. A, title II, § 2041, Dec. 13, 2016, 130 Stat. 1070, provided that:

''(a) TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.—

''(1) ESTABLISHMENT.—Not later than 90 days after the date of enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall establish a task force, in accordance with the Federal Advisory Committee Act ([former] 5 U.S.C. App.) [see 5 U.S.C. 1001 et seq.], to be known as the 'Task Force on Research Specific to Pregnant Women and Lactating Women' (in this section referred to as the 'Task Force').

''(2) DUTIES.—The Task Force shall provide advice and guidance to the Secretary regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.

''(3) MEMBERSHIP.—

''(A) FEDERAL MEMBERS.—The Task Force shall be composed of each of the following Federal members, or the designees of such members:

''(i) The Director of the Centers for Disease Control and Prevention.

''(ii) The Director of the National Institutes of Health, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the directors of such other appropriate national research institutes.

''(iii) The Commissioner of Food and Drugs.

''(iv) The Director of the Office on Women's Health.

''(v) The Director of the National Vaccine Program Office.

''(vi) The head of any other research-related agency or department not described in clauses (i) through (v) that the Secretary determines appropriate, which may include the Department of Veterans Affairs and the Department of Defense.

''(B) NON-FEDERAL MEMBERS.—The Task Force shall be composed of each of the following non-Federal members, including—

''(i) representatives from relevant medical societies with subject matter expertise on pregnant women, lactating women, or children;

''(ii) nonprofit organizations with expertise related to the health of women and children;

''(iii) relevant industry representatives; and

''(iv) other representatives, as appropriate.

''(C) LIMITATIONS.—The non-Federal members described in subparagraph (B) shall—

''(i) compose not more than one-half, and not less than one-third, of the total membership of the Task Force; and

''(ii) be appointed by the Secretary.

''(4) TERMINATION.—

''(A) IN GENERAL.—Subject to subparagraph (B), the Task Force shall terminate on the date that is 2 years after the date on which the Task Force is established under paragraph (1).

''(B) EXTENSION.—The Secretary may extend the operation of the Task Force for one additional 2-year period following the 2-year period described in subparagraph (A), if the Secretary determines that the extension is appropriate for carrying out the purpose of this section.

''(5) MEETINGS.—The Task Force shall meet not less than 2 times each year and shall convene public meetings, as appropriate, to fulfill its duties under paragraph (2).

''(6) TASK FORCE REPORT TO CONGRESS.—Not later than 18 months after the date on which the Task Force is established under paragraph (1), the Task Force shall prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that includes each of the following:

''(A) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies.

''(B) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research.

''(C) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women.

''(D) Identification of Federal activities, including—

''(i) the state of research on pregnancy and lactation;

''(ii) recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;

''(iii) dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and

''(iv) existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities.

''(E) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.

''(b) CONFIDENTIALITY.—Nothing in this section shall authorize the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

''(c) UPDATING PROTECTIONS FOR PREGNANT WOMEN AND LACTATING WOMEN IN RESEARCH.—

''(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act [Dec. 13, 2016], the Secretary, considering any recommendations of the Task Force available at such time and in consultation with the heads of relevant agencies of the Department of Health and Human Services, shall, as appropriate, update regulations and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research.

''(2) CRITERIA FOR EXCLUDING PREGNANT OR LACTATING WOMEN.—In updating any regulations or guidance described in paragraph (1), the Secretary shall consider any appropriate criteria to be used by institutional review boards and individuals reviewing grant proposals for excluding pregnant women or lactating women as a study population requiring additional protections from participating in human subject research.''

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