S.1 - National Institutes of Health Revitalization Act of 1993

Subtitle B--Clinical Research Equity Regarding Women and Minorities

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PART I--WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

SEC. 131. REQUIREMENT OF INCLUSION IN RESEARCH.

Part G of title IV of the Public Health Service Act, as amended by section 101 of this Act, is amended by inserting after section 492A the following section:

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

SEC. 492B. (a) REQUIREMENT OF INCLUSION
(1) IN GENERAL- In conducting or supporting clinical research for purposes of this title, 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.
(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- 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.
(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 the date of the enactment of the National Institutes of Health Revitalization Act of 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 403.
(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.'

SEC. 132. PEER REVIEW.
Section 492 of the Public Health Service Act (42 U.S.C. 289a) is amended by adding at the end the following subsection:
(c)(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 492B.
(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 492B, 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.'

SEC. 133. INAPPLICABILITY TO CURRENT PROJECTS.
Section 492B of the Public Health Service Act, as added by section 131 of this Act, 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. 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.

PART II--OFFICE OF RESEARCH ON WOMEN'S HEALTH
SEC. 141. ESTABLISHMENT.

(a) IN GENERAL- Title IV of the Public Health Service Act, as amended by the preceding provisions of this title, is amended--
(1) by redesignating section 486 as section 485A;
(2) by redesignating parts F through H as parts G through I, respectively; and
(3) by inserting after part E the following part:

Part F--Research on Women's Health
SEC. 486. OFFICE OF RESEARCH ON WOMEN'S HEALTH.

(a) ESTABLISHMENT- There is established within the Office of the Director of NIH an office to be known as the Office of Research on Women's Health (in this part referred to as the `Office'). The Office shall be headed by a director, who shall be appointed by the Director of NIH.
(b) PURPOSE- The Director of the Office shall--
(1) identify projects of research on women's health that should be conducted or supported by the national research institutes;
(2) identify multidisciplinary research relating to research on women's health that should be so conducted or supported;
(3) carry out paragraphs (1) and (2) with respect to the aging process in women, with priority given to menopause;
(4) promote coordination and collaboration among entities conducting research identified under any of paragraphs (1) through (3);
(5) encourage the conduct of such research by entities receiving funds from the national research institutes;
(6) recommend an agenda for conducting and supporting such research;
(7) promote the sufficient allocation of the resources of the national research institutes for

conducting and supporting such research;
(8) assist in the administration of section 492B with respect to the inclusion of women as subjects in clinical research; and
(9) prepare the report required in section 486B.
(c) COORDINATING COMMITTEE-
(1) In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (in this subsection referred to as the `Coordinating Committee').
(2) The Coordinating Committee shall be composed of the Directors of the national research institutes (or the designees of the Directors).
(3) The Director of the Office shall serve as the chair of the Coordinating Committee.
(4) With respect to research on women's health, the Coordinating Committee shall assist the Director of the Office in--
(A) identifying the need for such research, and making an estimate each fiscal year of the funds needed to adequately support the research;
(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities;
(C) supporting the development of methodologies to determine the circumstances in which obtaining data specific to women (including data relating to the age of women and the membership of women in ethnic or racial groups) is an appropriate function of clinical trials of treatments and therapies;
(D) supporting the development and expansion of clinical trials of treatments and therapies for which obtaining such data has been determined to be an appropriate function; and
(E) encouraging the national research institutes to conduct and support such research, including such clinical trials.
(d) ADVISORY COMMITTEE-
(1) In carrying out subsection (b), the Director of the Office shall establish an advisory committee to be known as the Advisory Committee on Research on Women's Health (in this subsection referred to as the `Advisory Committee').
(2) The Advisory Committee shall be composed of no fewer than 12, and not more than 18 individuals, who are not officers or employees of the Federal Government. The Director of the Office shall make appointments to the Advisory Committee from among physicians, practitioners, scientists, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on research on women's health. A majority of the members of the Advisory Committee shall be women.
(3) The Director of the Office shall serve as the chair of the Advisory Committee.
(4) The Advisory Committee shall--
(A) advise the Director of the Office on appropriate research activities to be undertaken by the national research institutes with respect to--
(i) research on women's health;
(ii) research on gender differences in clinical drug trials, including responses to pharmacological drugs;
(iii) research on gender differences in disease etiology, course, and treatment;
(iv) research on obstetrical and gynecological health conditions, diseases, and treatments; and
(v) research on women's health conditions which require a multidisciplinary approach;
(B) report to the Director of the Office on such research;

(C) provide recommendations to such Director regarding activities of the Office (including recommendations on the development of the methodologies described in subsection (c)(4)(C) and recommendations on priorities in carrying out research described in subparagraph (A)); and
(D) assist in monitoring compliance with section 492B regarding the inclusion of women in clinical research.
(5)(A) The Advisory Committee shall prepare a biennial report describing the activities of the Committee, including findings made by the Committee regarding--
(i) compliance with section 492B;
(ii) the extent of expenditures made for research on women's health by the agencies of the National Institutes of Health; and
(iii) the level of funding needed for such research.
(B) The report required in subparagraph (A) shall be submitted to the Director of NIH for inclusion in the report required in section 403.
(e) REPRESENTATION OF WOMEN AMONG RESEARCHERS- The Secretary, acting through the Assistant Secretary for Personnel and in collaboration with the Director of the Office, shall determine the extent to which women are represented among senior physicians and scientists of the national research institutes and among physicians and scientists conducting research with funds provided by such institutes, and as appropriate, carry out activities to increase the extent of such representation.
(f) DEFINITIONS- For purposes of this part:
(1) The term `women's health conditions', with respect to women of all age, ethnic, and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)--
(A) unique to, more serious, or more prevalent in women;
(B) for which the factors of medical risk or types of medical intervention are different for women, or for which it is unknown whether such factors or types are different for women; or
(C) with respect to which there has been insufficient clinical research involving women as subjects or insufficient clinical data on women.
(2) The term `research on women's health' means research on women's health conditions, including research on preventing such conditions.

SEC. 486A. NATIONAL DATA SYSTEM AND CLEARINGHOUSE ON RESEARCH ON WOMEN'S HEALTH.

(a) DATA SYSTEM-
(1) The Director of NIH, in consultation with the Director of the Office and the Director of the National Library of Medicine, shall establish a data system for the collection, storage, analysis, retrieval, and dissemination of information regarding research on women's health that is conducted or supported by the national research institutes. Information from the data system shall be available through information systems available to health care professionals and providers, researchers, and members of the public.
(2) The data system established under paragraph (1) shall include a registry of clinical trials of experimental treatments that have been developed for research on women's health. Such registry shall include information on subject eligibility criteria, sex, age, ethnicity or race, and the location of the trial site or sites. Principal investigators of such clinical trials shall provide this information to the registry within 30 days after it is available. Once a trial has been completed, the principal investigator shall provide the registry with information pertaining to the results,

including potential toxicities or adverse effects associated with the experimental treatment or treatments evaluated.
(b) CLEARINGHOUSE- The Director of NIH, in consultation with the Director of the Office and with the National Library of Medicine, shall establish, maintain, and operate a program to provide information on research and prevention activities of the national research institutes that relate to research on women's health.

SEC. 486B. BIENNIAL REPORT.
(a) IN GENERAL- With respect to research on women's health, the Director of the Office shall, not later than February 1, 1994, and biennially thereafter, prepare a report--
(1) describing and evaluating the progress made during the preceding 2 fiscal years in research and treatment conducted or supported by the National Institutes of Health;
(2) describing and analyzing the professional status of women physicians and scientists of such Institutes, including the identification of problems and barriers regarding advancements;
(3) summarizing and analyzing expenditures made by the agencies of such Institutes (and by such Office) during the preceding 2 fiscal years; and
(4) making such recommendations for legislative and administrative initiatives as the Director of the Office determines to be appropriate.
(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR OF NIH- The Director of the Office shall submit each report prepared under subsection (a) to the Director of NIH for inclusion in the report submitted to the President and the Congress under section 403.'.
(b) REQUIREMENT OF SUFFICIENT ALLOCATION OF RESOURCES OF INSTITUTES- Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended--
(1) in paragraph (10), by striking `and' after the semicolon at the end;
(2) in paragraph (11), by striking the period at the end and inserting `; and'; and
(3) by inserting after paragraph (11) the following paragraph:
(12) after consultation with the Director of the Office of Research on Women's Health, shall ensure that resources of the National Institutes of Health are sufficiently allocated for projects of research on women's health that are identified under section 486(b).'.