AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.

(no.) _____

To amend the Public Health Service Act to promote the inclusion of minorities in clinical research, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by Ms. COLLINS (for herself, Ms. WARREN, Mr. KIRK, Ms. BALDWIN, Mr. ALEXANDER, and Mrs. MURRAY)

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Advancing NIH Strategic Planning and Representation in Medical Research Act''.

SEC. 2. NIH STRATEGIC PLAN.

(a) STRATEGIC PLAN.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) in subsection (b)(5), by inserting before the semicolon the following: ", and through the development, implementation, and updating of the strategic plan developed under subsection (m)"; and

(2) by adding at the end the following:

"(m) NIH STRATEGIC PLAN.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Advancing NIH Strategic Planning and Representation in Medical Research Act, and once every 6 years thereafter, the Director of NIH, in consultation with the directors of the national research institutes and national centers, shall develop and submit to the appropriate committees of Congress and post on the Internet website of the National Institutes of Health, a 6-year coordinated strategy (to be known as the 'NIH Strategic Plan') to provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine.

"(2) REQUIREMENTS.—The strategy under paragraph (1) shall—

''(A) identify strategic research priorities and objectives across biomedical research, including—

''(i) an assessment of the state of biomedical and behavioral research, including areas of opportunity with respect to basic, clinical, and translational research;

''(ii) priorities and objectives to advance the treatment, cure, and prevention of health conditions;

''(iii) emerging scientific opportunities, rising public health challenges, and scientific knowledge gaps; and

''(iv) the identification of near-, mid-, and long-term scientific needs;

''(B) consider, in carrying out subparagraph (A)—

''(i) disease burden in the United States;

''(ii) rare diseases and conditions;

''(iii) biological, social, and other determinants of health that contribute to health disparities; and

''(iv) other factors the Director of NIH determines appropriate;

''(C) include multi-institute priorities, including coordination of research among institutes and centers;

''(D) include strategic priorities for funding research through the Common Fund, in accordance with section 402A(c)(1)(C));

''(E) address the agency's proposed and ongoing activities related to training and the biomedical workforce; and

''(F) describe opportunities for collaboration with other agencies and departments, as appropriate.

''(3) USE OF PLANS.—Strategic plans developed and updated by the national research institutes and national centers of the National Institutes of Health shall be prepared regularly and in such a manner that such plans will be informed by the strategic plans developed and updated under this subsection.''.

(b) CONFORMING AMENDMENT.—Section 402A(c)(1)(C) of the Public Health Service Act (42 U.S.C. 282a(c)(1)(C)) is amended by striking ''Not later than June 1, 2007, and every 2 years thereafter,'' and inserting ''As part of the NIH Strategic Plan required under section 402(m),''.

SEC. 3. COLLABORATION TO ENHANCE DIVERSITY IN CLINICAL RESEARCH.

Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) by amending paragraph (4) to read as follows:

''(4) shall assemble accurate data to be used to assess research priorities, including—

''(A) information to better evaluate scientific opportunity, public health burdens, and progress in reducing health disparities; and

''(B) data on study populations of clinical research, funded by or conducted at each national research institute and national center, which—

''(i) specifies the inclusion of—

''(I) women;

''(II) members of minority groups;

''(III) relevant age categories; and

''(IV) other demographic variables determined to be necessary by the Director of NIH;

''(ii) is disaggregated by research area, condition, and disease categories; and

"(iii) is to be made publicly available on the Internet website of the National Institutes of Health;"; and

(2) in paragraph (8)—

(A) in subparagraph (A), by striking "and" at the end; and

(B) by adding at the end the following:

"(C) foster collaboration between clinical research projects funded by the respective national research institutes and national centers that—

"(i) conduct research involving human subjects; and

"(ii) collect similar data; and

"(D) encourage the collaboration described in subparagraph (C) to—

"(i) allow for an increase in the number of subjects studied; and

"(ii) utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities;".

SEC. 4. PROMOTING INCLUSION IN CLINICAL RESEARCH.

(a) STRATEGIC PLAN.—Section 492B(a) of the Public Health Service Act (42 U.S.C. 289a–2(a)) is amended by adding at the end the following:

''(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) CLARIFICATION OF REQUIREMENTS.—Section 492B(c) of the Public Health Service Act (42 U.S.C. 289a–2(c)) is amended—

(1) by striking ''In the case'' and inserting the following:

''(1) IN GENERAL.—In the case''; and

(2) by adding at the end the following:

''(2) REPORTING REQUIREMENTS.—

''(A) IN GENERAL.—For an applicable clinical trial as defined in section 402(j) that is conducted or funded by the National Institutes of Health, the results of any valid analysis described in paragraph (1) shall be submitted to the clinical trial registry data bank created under subsections (i) and (j) of section 402, and the Director of NIH shall encourage, as appropriate, the reporting of such analysis through any additional means determined appropriate by the Director.

''(B) ENSURING REPORTING.—For any new and competing project of clinical research subject to the requirements under this section that receives a grant award beginning not less than 1 year after the date of enactment of the Advancing NIH Strategic Planning and Representation in Medical Research Act for which a valid analysis is provided under paragraph (1) and which is an applicable clinical trial as defined in section 402(j)—

''(i) the entity conducting such clinical research shall report the results of such

valid analysis to the clinical trial registry data bank expanded under 402(j)(3);

''(ii) the Director of NIH shall, as appropriate, consider whether such entity has complied with the reporting requirement described in clause (i) in awarding any future grant to such entity, including pursuant to section 402(j)(5)(A)(ii) when applicable; and

''(iii) the Director of NIH shall encourage the reporting of the results of such valid analysis through any additional means determined appropriate by the Director.''.

(c) REPORTING.—Section 492B(f) of the Public Health Service Act (42 U.S.C. 289a–2(f)) is amended—

(1) by striking ''biennial'' each place such term appears and inserting ''triennial'' in each such place;

(2) by striking ''The advisory council'' and inserting the following:

''(1) IN GENERAL.—The advisory council''; and

(3) by adding at the end the following:

''(2) CONTENTS.—Each triennial report prepared by an advisory council of each national re-

search 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).''.

(d) COORDINATION.—Section 486(c)(2) of the Public Health Service Act (42 U.S.C. 287d(c)(2)) is amended by striking ''designees'' and inserting ''senior-level staff designees''.

SEC. 5. IMPROVING RESEARCH RELATED TO SEXUAL AND GENDER MINORITY POPULATIONS.

(a) IN GENERAL.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

''SEC. 404M. RESEARCH RELATED TO SEXUAL AND GENDER MINORITY POPULATIONS.

''The Director of NIH shall, as appropriate, encourage efforts to improve research related to the health of sexual and gender minority populations, including by—

''(1) facilitating increased participation of sexual and gender minority populations in clinical research supported by the National Institutes of

Health, and reporting on such participation, as applicable;

''(2) facilitating the development of valid and reliable methods for research relevant to sexual and gender minority populations; and

''(3) addressing methodological challenges.''.

(b) REPORTING.—

(1) IN GENERAL.—The Secretary, in collaboration with the Director of the National Institutes of Health, shall as appropriate—

(A) continue to support research for the development of appropriate measures related to reporting health information about sexual and gender minority populations; and

(B) not later than 2 years after the date of enactment of this Act, disseminate and make public such measures.

(2) NATIONAL ACADEMY OF MEDICINE RECOMMENDATIONS.—In developing the measures described in paragraph (1)(A), the Secretary shall take into account recommendations made by the National Academy of Medicine.

SEC. 6. IMPROVING COORDINATION RELATED TO MINORITY HEALTH AND HEALTH DISPARITIES.

Section 464z–3 of the Public Health Service Act (42 U.S.C. 285t) is amended—

(1) by redesignating subsection (h), relating to interagency coordination, that follows subsection (j) as subsection (k); and

(2) in subsection (k) (as so redesignated)—

(A) in the heading, by striking ''INTERAGENCY'' and inserting ''INTRA-NIH'';

(B) by striking ''as the primary Federal officials'' and inserting ''as the primary Federal official'';

(C) by inserting a comma after ''review'';

(D) by striking ''Institutes and Centers of the National Institutes of Health'' and inserting ''national research institutes and national centers''; and

(E) by adding at the end the following: ''The Director of the Institute may foster partnerships between the national research institutes and national centers and may encourage the funding of collaborative research projects to achieve the goals of the National Institutes of Health that are related to minority health and health disparities.''.

SEC. 7. ENHANCING THE RIGOR AND REPRODUCIBILITY OF SCIENTIFIC RESEARCH.

(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall convene a working group under the Advisory Committee to the Director of the National Institutes of Health, appointed under section 222 of the Public Health Service Act (42 U.S.C. 217a), to develop and issue recommendations for a formal policy, which may incorporate or be informed by relevant existing and ongoing activities, to enhance rigor and reproducibility of scientific research funded by the National Institutes of Health.

(b) CONSIDERATIONS.—In developing and issuing the recommendations under subsection (a), the working group established under such subsection shall consider, as appropriate—

(1) preclinical experiment design, including analysis of sex as a biological variable;

(2) clinical experiment design, including—

(A) the diversity of populations studied for clinical research, with respect to biological, social, and other determinants of health that contribute to health disparities;

(B) the circumstances under which summary information regarding biological, social, and other factors that contribute to health disparities should be reported; and

(C) the circumstances under which clinical studies, including clinical trials, should conduct an analysis of the data collected during the study on the basis of biological, social, and other factors that contribute to health disparities;

(3) applicable levels of rigor in statistical methods, methodology, and analysis;

(4) data and information sharing in accordance with applicable privacy laws and regulations; and

(5) any other matter determined relevant by the working group.

(c) POLICIES.—Not later than 18 months after the date of enactment of this Act, the Director of the National Institutes of Health shall consider the recommendations developed by the working group under subsection (a) and develop or update policies as appropriate.

(d) REPORT.—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health, acting through the working group established under subsection (a), shall issue a report to the

Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives regarding recommendations developed under such subsection and any subsequent policy changes implemented, to enhance rigor and reproducibility in scientific research funded by the National Institutes of Health.

(e) 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.

SEC. 8. TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.

(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, 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 (5 U.S.C. App.), 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 designee of such member:

(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 re-

lated 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, 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.

SEC. 9. WOMEN AND MINORITIES IN RESEARCH.

(a) BASIC RESEARCH.—

(1) DEVELOPING POLICIES.—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health (referred to in this section as the ''Director of NIH''), taking into consideration the findings of the working

group established under section 7, shall develop policies for projects of basic research funded by National Institutes of Health to assess—

(A) relevant biological variables including sex, as appropriate; and

(B) how differences between male and female cells, tissues, or animals may be examined and analyzed.

(2) REVISING POLICIES.—The Director of NIH may update or revise the policies developed under paragraph (1) as appropriate.

(3) CONSULTATION AND OUTREACH.—In developing, updating, or revising the policies under this section, the Director of NIH—

(A) shall consult with—

(i) the Office of Research on Women's Health;

(ii) the Office of Laboratory Animal Welfare; and

(iii) appropriate members of the scientific and academic communities; and

(B) shall conduct outreach to solicit feedback from members of the scientific and academic communities on the influence of sex as a variable in basic research, including feedback on

when it is appropriate for projects of basic research involving cells, tissues, or animals to include both male and female cells, tissues, or animals.

(4) ADDITIONAL REQUIREMENTS.—The Director of NIH shall—

(A) ensure that projects of basic research funded by the National Institutes of Health are conducted in accordance with the policies developed, updated, or revised under this section, as applicable; and

(B) encourage that the results of such research, when published or reported, be disaggregated as appropriate with respect to the analysis of any sex differences.

(b) CLINICAL RESEARCH.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Director of NIH, 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 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.