

Calendar No. 430114TH CONGRESS
2D SESSION**S. 2745**

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

IN THE SENATE OF THE UNITED STATES

APRIL 5, 2016

Ms. COLLINS (for herself, Ms. WARREN, Mr. KIRK, Ms. BALDWIN, Mr. ALEXANDER, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 18, 2016

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Advancing NIH Stra-
3 tegic Planning and Representation in Medical Research
4 Act”.

5 **SEC. 2. NIH STRATEGIC PLAN.**

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

8 (1) in subsection (b)(5), by inserting before the
9 semicolon the following: “, and through the develop-
10 ment, implementation, and updating of the strategic
11 plan developed under subsection (m)”;

12 (2) by adding at the end the following:

13 “(m) NIH STRATEGIC PLAN.—

14 “(1) IN GENERAL.—Not later than 2 years
15 after the date of enactment of the Advancing NIH
16 Strategic Planning and Representation in Medical
17 Research Act, and once every 6 years thereafter, the
18 Director of NIH, in consultation with the directors
19 of the national research institutes and national cen-
20 ters, shall develop and submit to the appropriate
21 committees of Congress and post on the Internet
22 website of the National Institutes of Health, a 6-
23 year coordinated strategy (to be known as the ‘NIH
24 Strategic Plan’) to provide direction to the bio-
25 medical research investments made by the National
26 Institutes of Health, to facilitate collaboration across

1 the institutes and centers, to leverage scientific op-
2 portunity, and to advance biomedicine.

3 “(2) REQUIREMENTS.—The strategy under
4 paragraph (1) shall—

5 “(A) identify strategic research priorities
6 and objectives across biomedical research, in-
7 cluding—

8 “(i) an assessment of the state of bio-
9 medical and behavioral research, including
10 areas of opportunity with respect to basic,
11 clinical, and translational research;

12 “(ii) priorities and objectives to ad-
13 vance the treatment, cure, and prevention
14 of health conditions;

15 “(iii) emerging scientific opportuni-
16 ties, rising public health challenges, and
17 scientific knowledge gaps; and

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

20 “(B) consider, in carrying out subpara-
21 graph (A)—

22 “(i) disease burden in the United
23 States;

24 “(ii) rare diseases and conditions;

1 “(iii) biological, social, and other de-
2 terminants of health that contribute to
3 health disparities; and

4 “(iv) other factors the Director of
5 NIH determines appropriate;

6 “(C) include multi-institute priorities, in-
7 cluding coordination of research among insti-
8 tutes and centers;

9 “(D) include strategic priorities for fund-
10 ing research through the Common Fund, in ac-
11 cordance with section 402A(e)(1)(C);

12 “(E) address the agency’s proposed and
13 ongoing activities related to training and the
14 biomedical workforce; and

15 “(F) describe opportunities for collabora-
16 tion with other agencies and departments, as
17 appropriate.

18 “(3) USE OF PLANS.—Strategic plans developed
19 and updated by the national research institutes and
20 national centers of the National Institutes of Health
21 shall be prepared regularly and in such a manner
22 that such plans will be informed by the strategic
23 plans developed and updated under this sub-
24 section.”.

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

7 **SEC. 3. COLLABORATION TO ENHANCE DIVERSITY IN CLIN-**
 8 **ICAL RESEARCH.**

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

11 (1) by amending paragraph (4) to read as fol-
 12 lows:

13 “~~(4)~~ shall assemble accurate data to be used to
 14 assess research priorities, including—

15 “~~(A)~~ information to better evaluate sci-
 16 entific opportunity, public health burdens, and
 17 progress in reducing health disparities; and

18 “~~(B)~~ data on study populations of clinical
 19 research, funded by or conducted at each na-
 20 tional research institute and national center,
 21 which—

22 “~~(i)~~ specifies the inclusion of—

23 “~~(I)~~ women;

24 “~~(II)~~ members of minority
 25 groups;

1 “(III) relevant age categories;
2 and

3 “(IV) other demographic vari-
4 ables determined to be necessary by
5 the Director of NIH;

6 “(ii) is disaggregated by research
7 area, condition, and disease categories; and

8 “(iii) is to be made publicly available
9 on the Internet website of the National In-
10 stitutes of Health;” and

11 (2) in paragraph (8)—

12 (A) in subparagraph (A), by striking
13 “and” at the end; and

14 (B) by adding at the end the following:

15 “(C) foster collaboration between clinical
16 research projects funded by the respective na-
17 tional research institutes and national centers
18 that—

19 “(i) conduct research involving human
20 subjects; and

21 “(ii) collect similar data; and

22 “(D) encourage the collaboration described
23 in subparagraph (C) to—

24 “(i) allow for an increase in the num-
25 ber of subjects studied; and

1 “(ii) utilize diverse study populations,
2 with special consideration to biological, so-
3 cial, and other determinants of health that
4 contribute to health disparities;”.

5 **SEC. 4. PROMOTING INCLUSION IN CLINICAL RESEARCH.**

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

9 “(3) STRATEGIC PLANNING.—

10 “(A) IN GENERAL.—The directors of the
11 national institutes and national centers shall
12 consult at least once annually with the Director
13 of the National Institute on Minority Health
14 and Health Disparities and the Director of the
15 Office of Research on Women’s Health regard-
16 ing objectives of the national institutes and na-
17 tional centers to ensure that future activities by
18 such institutes and centers take into account
19 women and minorities and are focused on re-
20 ducing health disparities.

21 “(B) STRATEGIC PLANS.—Any strategic
22 plan issued by a national institute or national
23 center shall include details on the objectives de-
24 scribed in subparagraph (A).”.

1 (b) CLARIFICATION OF REQUIREMENTS.—Section
2 492B(e) of the Public Health Service Act (42 U.S.C.
3 ~~289a-2(c)~~) is amended—

4 (1) by striking “In the case” and inserting the
5 following:

6 “(1) IN GENERAL.—In the case”; and

7 (2) by adding at the end the following:

8 “(2) REPORTING REQUIREMENTS.—For any
9 new and competing project of clinical research sub-
10 ject to the requirements under this section that re-
11 ceives a grant award 1 year after the date of enact-
12 ment of the Advancing NIH Strategic Planning and
13 Representation in Medical Research Act, or any date
14 thereafter, for which a valid analysis is provided
15 under paragraph (1)—

16 “(A) and which is an applicable clinical
17 trial as defined in section 402(j), the entity con-
18 ducting such clinical research shall submit the
19 results of such valid analysis to the clinical trial
20 registry data bank expanded under section
21 402(j)(3), and the Director of NIH shall, as ap-
22 propriate, consider whether such entity has
23 complied with the reporting requirement de-
24 scribed in this subparagraph in awarding any

1 future grant to such entity, including pursuant
2 to section 402(j)(5)(A)(ii) when applicable; and

3 “(B) the Director of NIH shall encourage
4 the reporting of the results of such valid anal-
5 ysis described in paragraph (1) through any ad-
6 ditional means determined appropriate by the
7 Director.”.

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

10 (1) by striking “biennial” each place such term
11 appears and inserting “triennial” in each such place;

12 (2) by striking “The advisory council” and in-
13 serting the following:

14 “(1) IN GENERAL.—The advisory council”; and

15 (3) by adding at the end the following:

16 “(2) CONTENTS.—Each triennial report pre-
17 pared by an advisory council of each national re-
18 search institute as described in paragraph (1) shall
19 include each of the following:

20 “(A) The number of women included as
21 subjects, and the proportion of subjects that are
22 women, in any project of clinical research con-
23 ducted during the applicable reporting period,
24 disaggregated by categories of research area,

1 condition, or disease, and accounting for single-
2 sex studies.

3 “(B) The number of members of minority
4 groups included as subjects, and the proportion
5 of subjects that are members of minority
6 groups, in any project of clinical research con-
7 ducted during the applicable reporting period,
8 disaggregated by categories of research area,
9 condition, or disease and accounting for single-
10 race and single-ethnicity studies.

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

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

17 “(ii) are being carried out during such
18 reporting period and have not been com-
19 pleted.

20 “(D) The number of studies completed
21 during the applicable reporting period for which
22 reporting has been submitted in accordance
23 with subsection (e)(2)(A).”.

24 (d) COORDINATION.—Section 486(e)(2) of the Public
25 Health Service Act (42 U.S.C. 287d(e)(2)) is amended by

1 striking “designees” and inserting “senior-level staff des-
2 ignees”.

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

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

8 **“SEC. 404M. RESEARCH RELATED TO SEXUAL AND GENDER**
9 **MINORITY POPULATIONS.**

10 “The Director of NIH shall, as appropriate, encour-
11 age efforts to improve research related to the health of
12 sexual and gender minority populations, including by—

13 “(1) facilitating increased participation of sex-
14 ual and gender minority populations in clinical re-
15 search supported by the National Institutes of
16 Health, and reporting on such participation, as ap-
17 plicable;

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

21 “(3) addressing methodological challenges.”.

22 (b) REPORTING.—

23 (1) IN GENERAL.—The Secretary, in collabora-
24 tion with the Director of the National Institutes of
25 Health, shall as appropriate—

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

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

8 (2) NATIONAL ACADEMY OF MEDICINE REC-
9 COMMENDATIONS.—In developing the measures de-
10 scribed in paragraph (1)(A), the Secretary shall take
11 into account recommendations made by the National
12 Academy of Medicine.

13 **SEC. 6. IMPROVING COORDINATION RELATED TO MINOR-**
14 **ITY HEALTH AND HEALTH DISPARITIES.**

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

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

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

21 (A) in the heading, by striking “INTER-
22 AGENCY” and inserting “INTRA-NIH”;

23 (B) by striking “as the primary Federal
24 officials” and inserting “as the primary Federal
25 official”;

1 (C) by inserting a comma after “review”;

2 (D) by striking “Institutes and Centers of
3 the National Institutes of Health” and inserting
4 “national research institutes and national cen-
5 ters”; and

6 (E) by adding at the end the following:

7 “The Director of the Institute may foster part-
8 nerships between the national research insti-
9 tutes and national centers and may encourage
10 the funding of collaborative research projects to
11 achieve the goals of the National Institutes of
12 Health that are related to minority health and
13 health disparities.”.

14 **SEC. 7. ENHANCING THE RIGOR AND REPRODUCIBILITY OF**
15 **SCIENTIFIC RESEARCH.**

16 (a) **ESTABLISHMENT.**—Not later than 1 year after
17 the date of enactment of this Act, the Secretary of Health
18 and Human Services, acting through the Director of the
19 National Institutes of Health, shall convene a working
20 group under the Advisory Committee to the Director of
21 the National Institutes of Health, appointed under section
22 222 of the Public Health Service Act (42 U.S.C. 217a),
23 to develop and issue recommendations for a formal policy,
24 which may incorporate or be informed by relevant existing
25 and ongoing activities, to enhance rigor and reproduc-

1 ability of scientific research funded by the National Insti-
2 tutes of Health.

3 (b) CONSIDERATIONS.—In developing and issuing the
4 recommendations under subsection (a), the working group
5 established under such subsection shall consider, as appro-
6 priate—

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

9 (2) clinical experiment design, including—

10 (A) the diversity of populations studied for
11 clinical research, with respect to biological, so-
12 cial, and other determinants of health that con-
13 tribute to health disparities;

14 (B) the circumstances under which sum-
15 mary information regarding biological, social,
16 and other factors that contribute to health dis-
17 parities should be reported; and

18 (C) the circumstances under which clinical
19 studies, including clinical trials, should conduct
20 an analysis of the data collected during the
21 study on the basis of biological, social, and
22 other factors that contribute to health dispari-
23 ties;

24 (3) applicable levels of rigor in statistical meth-
25 ods, methodology, and analysis;

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

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

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

10 (d) REPORT.—Not later than 2 years after the date
11 of enactment of this Act, the Director of the National In-
12 stitutes of Health, acting through the working group es-
13 tablished under subsection (a), shall issue a report to the
14 Secretary of Health and Human Services, the Committee
15 on Health, Education, Labor, and Pensions of the Senate,
16 and the Committee on Energy and Commerce of the
17 House of Representatives regarding recommendations de-
18 veloped under such subsection and any subsequent policy
19 changes implemented, to enhance rigor and reproducibility
20 in scientific research funded by the National Institutes of
21 Health.

22 (e) CONFIDENTIALITY.—Nothing in this section shall
23 authorize the Secretary of Health and Human Services to
24 disclose any information that is a trade secret, or other
25 privileged or confidential information, described in section

1 552(b)(4) of title 5, United States Code, or section 1905
2 of title 18, United States Code.

3 **SEC. 8. TASK FORCE ON RESEARCH SPECIFIC TO PREG-**
4 **NANT WOMEN AND LACTATING WOMEN.**

5 (a) **TASK FORCE ON RESEARCH SPECIFIC TO PREG-**
6 **NANT WOMEN AND LACTATING WOMEN.—**

7 (1) **ESTABLISHMENT.**—Not later than 90 days
8 after the date of enactment of this Act, the Sec-
9 retary of Health and Human Services (referred to in
10 this section as the “Secretary”) shall establish a
11 task force, in accordance with the Federal Advisory
12 Committee Act (5 U.S.C. App.), to be known as the
13 “Task Force on Research Specific to Pregnant
14 Women and Lactating Women” (in this section re-
15 ferred to as the “Task Force”).

16 (2) **DUTIES.**—The Task Force shall provide ad-
17 vice and guidance to the Secretary regarding Fed-
18 eral activities related to identifying and addressing
19 gaps in knowledge and research regarding safe and
20 effective therapies for pregnant women and lactating
21 women, including the development of such therapies
22 and the collaboration on and coordination of such
23 activities.

24 (3) **MEMBERSHIP.**—

1 (A) FEDERAL MEMBERS.—The Task Force
2 shall be composed of each of the following Fed-
3 eral members, or the designee of such member:

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

6 (ii) The Director of the National In-
7 stitutes of Health; the Director of the Eu-
8 nice Kennedy Shriver National Institute of
9 Child Health and Human Development,
10 and the directors of such other appropriate
11 national research institutes.

12 (iii) The Commissioner of Food and
13 Drugs.

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

16 (v) The Director of the National Vac-
17 cine Program Office.

18 (vi) The head of any other research-
19 related agency or department not described
20 in clauses (i) through (v) that the Sec-
21 retary determines appropriate, which may
22 include the Department of Veterans Af-
23 fairs and the Department of Defense.

1 (B) ~~NON-FEDERAL MEMBERS.~~—The Task
2 Force shall be composed of each of the fol-
3 lowing non-Federal members, including—

4 (i) representatives from relevant med-
5 ical societies with subject matter expertise
6 on pregnant women, lactating women, or
7 children;

8 (ii) nonprofit organizations with ex-
9 pertise related to the health of women and
10 children;

11 (iii) relevant industry representatives;
12 and

13 (iv) other representatives, as appro-
14 priate.

15 (C) ~~LIMITATIONS.~~—The non-Federal mem-
16 bers described in subparagraph (B) shall—

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

20 (ii) be appointed by the Secretary.

21 (4) ~~TERMINATION.~~—

22 (A) ~~IN GENERAL.~~—Subject to subpara-
23 graph (B), the Task Force shall terminate on
24 the date that is 2 years after the date on which

1 the Task Force is established under paragraph
2 (1).

3 (B) EXTENSION.—The Secretary may ex-
4 tend the operation of the Task Force for one
5 additional 2-year period following the 2-year pe-
6 riod described in subparagraph (A); if the Sec-
7 retary determines that the extension is appro-
8 priate for carrying out the purpose of this sec-
9 tion.

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

14 (6) TASK FORCE REPORT TO CONGRESS.—Not
15 later than 18 months after the date on which the
16 Task Force is established under paragraph (1), the
17 Task Force shall prepare and submit to the Sec-
18 retary, the Committee on Health, Education, Labor,
19 and Pensions of the Senate, and the Committee on
20 Energy and Commerce of the House of Representa-
21 tives a report that includes each of the following:

22 (A) A plan to identify and address gaps in
23 knowledge and research regarding safe and ef-
24 fective therapies for pregnant women and lac-

1 tating women, including the development of
2 such therapies.

3 (B) Ethical issues surrounding the inclu-
4 sion of pregnant women and lactating women in
5 clinical research.

6 (C) Effective communication strategies
7 with health care providers and the public on in-
8 formation relevant to pregnant women and lac-
9 tating women.

10 (D) Identification of Federal activities, in-
11 cluding—

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

14 (ii) recommendations for the coordina-
15 tion of, and collaboration on research re-
16 lated to pregnant women and lactating
17 women;

18 (iii) dissemination of research findings
19 and information relevant to pregnant
20 women and lactating women to providers
21 and the public; and

22 (iv) existing Federal efforts and pro-
23 grams to improve the scientific under-
24 standing of the health impacts on pregnant
25 women, lactating women and, related birth

1 and pediatric outcomes, including with re-
2 spect to pharmacokinetics, pharmacody-
3 namies, and toxicities.

4 ~~(E)~~ Recommendations to improve the de-
5 velopment of safe and effective therapies for
6 pregnant women and lactating women.

7 ~~(b) CONFIDENTIALITY.~~—Nothing in this section shall
8 authorize the Secretary of Health and Human Services to
9 disclose any information that is a trade secret, or other
10 privileged or confidential information, described in section
11 552(b)(4) of title 5, United States Code, or section 1905
12 of title 18, United States Code.

13 ~~(c) UPDATING PROTECTIONS FOR PREGNANT~~
14 ~~WOMEN AND LACTATING WOMEN IN RESEARCH.~~—

15 ~~(1) IN GENERAL.~~—Not later than 2 years after
16 the date of enactment of this Act, the Secretary,
17 considering any recommendations of the Task Force
18 available at such time and in consultation with the
19 heads of relevant agencies of the Department of
20 Health and Human Services, shall, as appropriate,
21 update regulations and guidance, as applicable, re-
22 garding the inclusion of pregnant women and lac-
23 tating women in clinical research.

24 ~~(2) CRITERIA FOR EXCLUDING PREGNANT OR~~
25 ~~LACTATING WOMEN.~~—In updating any regulations or

1 guidance described in paragraph (1), the Secretary
2 shall consider any appropriate criteria to be used by
3 institutional review boards and individuals reviewing
4 grant proposals for excluding pregnant women or
5 lactating women as a study population requiring ad-
6 ditional protections from participating in human
7 subject research.

8 **SEC. 9. WOMEN AND MINORITIES IN RESEARCH.**

9 (a) **BASIC RESEARCH.**—

10 (1) **DEVELOPING POLICIES.**—Not later than 2
11 years after the date of enactment of this Act, the
12 Director of the National Institutes of Health (re-
13 ferred to in this section as the “Director of NIH”),
14 taking into consideration the findings of the working
15 group established under section 7, shall develop poli-
16 cies for projects of basic research funded by Na-
17 tional Institutes of Health to assess—

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

20 (B) how differences between male and fe-
21 male cells, tissues, or animals may be examined
22 and analyzed.

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

1 ~~(3) CONSULTATION AND OUTREACH.—~~In devel-
2 oping, updating, or revising the policies under this
3 section, the Director of NIH—

4 ~~(A)~~ shall consult with—

5 ~~(i)~~ the Office of Research on Women’s
6 Health;

7 ~~(ii)~~ the Office of Laboratory Animal
8 Welfare; and

9 ~~(iii)~~ appropriate members of the sci-
10 entific and academic communities; and

11 ~~(B)~~ shall conduct outreach to solicit feed-
12 back from members of the scientific and aca-
13 demic communities on the influence of sex as a
14 variable in basic research, including feedback on
15 when it is appropriate for projects of basic re-
16 search involving cells, tissues, or animals to in-
17 clude both male and female cells, tissues, or
18 animals.

19 ~~(4) ADDITIONAL REQUIREMENTS.—~~The Direc-
20 tor of NIH shall—

21 ~~(A)~~ ensure that projects of basic research
22 funded by the National Institutes of Health are
23 conducted in accordance with the policies devel-
24 oped, updated, or revised under this section, as
25 applicable; and

1 (~~B~~) encourage that the results of such re-
2 search, when published or reported, be
3 disaggregated as appropriate with respect to
4 the analysis of any sex differences.

5 (~~b~~) ~~CLINICAL RESEARCH.~~—

6 (~~1~~) ~~IN GENERAL.~~—Not later than 1 year after
7 the date of enactment of this Act, the Director of
8 NIH, in consultation with the Director of the Office
9 of Research on Women’s Health and the Director of
10 the National Institute on Minority Health and
11 Health Disparities, shall update the guidelines estab-
12 lished under section 492B(d) of Public Health Serv-
13 ice Act (~~42 U.S.C. 289a–2(d)~~) in accordance with
14 paragraph (~~2~~).

15 (~~2~~) ~~REQUIREMENTS.~~—The updated guidelines
16 described in paragraph (~~1~~) shall—

17 (~~A~~) reflect the science regarding sex dif-
18 ferences;

19 (~~B~~) improve adherence to the requirements
20 under section 492B of the Public Health Serv-
21 ice Act (~~42 U.S.C. 289a–2~~), including the re-
22 porting requirements under subsection (~~f~~) of
23 such section; and

24 (~~C~~) clarify the circumstances under which
25 studies should be designed to support the con-

1 duct of analyses to detect significant differences
 2 in the intervention effect due to demographic
 3 factors related to section 492B of the Public
 4 Health Service Act, including in the absence of
 5 prior studies that demonstrate a difference in
 6 study outcomes on the basis of such factors and
 7 considering the effects of the absence of such
 8 analyses on the availability of data related to
 9 demographic differences.

10 **SECTION 1. SHORT TITLE.**

11 *This Act may be cited as the “Advancing NIH Stra-*
 12 *tegic Planning and Representation in Medical Research*
 13 *Act”.*

14 **SEC. 2. NIH STRATEGIC PLAN.**

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21 (2) *by adding at the end the following:*

22 “(m) *NIH STRATEGIC PLAN.*—

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 24 *the date of enactment of the Advancing NIH Strategic*
 25 *Planning and Representation in Medical Research*

1 *Act, and once every 6 years thereafter, the Director of*
2 *NIH, in consultation with the directors of the na-*
3 *tional research institutes and national centers, shall*
4 *develop and submit to the appropriate committees of*
5 *Congress and post on the Internet website of the Na-*
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7 *strategy (to be known as the ‘NIH Strategic Plan’) to*
8 *provide direction to the biomedical research invest-*
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10 *facilitate collaboration across the institutes and cen-*
11 *ters, to leverage scientific opportunity, and to ad-*
12 *vance biomedicine.*

13 “(2) *REQUIREMENTS.*—*The strategy under para-*
14 *graph (1) shall—*

15 “(A) *identify strategic research priorities*
16 *and objectives across biomedical research, includ-*
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18 “(i) *an assessment of the state of bio-*
19 *medical and behavioral research, including*
20 *areas of opportunity with respect to basic,*
21 *clinical, and translational research;*

22 “(ii) *priorities and objectives to ad-*
23 *vance the treatment, cure, and prevention of*
24 *health conditions;*

1 “(iii) emerging scientific opportunities,
2 rising public health challenges, and sci-
3 entific knowledge gaps; and

4 “(iv) the identification of near-, mid-,
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6 “(B) consider, in carrying out subpara-
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11 “(iii) biological, social, and other de-
12 terminants of health that contribute to
13 health disparities; and

14 “(iv) other factors the Director of NIH
15 determines appropriate;

16 “(C) include multi-institute priorities, in-
17 cluding coordination of research among insti-
18 tutes and centers;

19 “(D) include strategic priorities for funding
20 research through the Common Fund, in accord-
21 ance with section 402A(c)(1)(C));

22 “(E) address the agency’s proposed and on-
23 going activities related to training and the bio-
24 medical workforce; and

1 “(F) describe opportunities for collaboration
2 with other agencies and departments, as appro-
3 priate.

4 “(3) *USE OF PLANS.*—Strategic plans developed
5 and updated by the national research institutes and
6 national centers of the National Institutes of Health
7 shall be prepared regularly and in such a manner
8 that such plans will be informed by the strategic
9 plans developed and updated under this subsection.”.

10 (b) **CONFORMING AMENDMENT.**—Section
11 402A(c)(1)(C) of the Public Health Service Act (42 U.S.C.
12 282a(c)(1)(C)) is amended by striking “Not later than June
13 1, 2007, and every 2 years thereafter,” and inserting “As
14 part of the NIH Strategic Plan required under section
15 402(m),”.

16 **SEC. 3. COLLABORATION TO ENHANCE DIVERSITY IN CLIN-**
17 **ICAL RESEARCH.**

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

20 (1) by amending paragraph (4) to read as fol-
21 lows:

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

1 “(A) information to better evaluate sci-
2 entific opportunity, public health burdens, and
3 progress in reducing health disparities; and

4 “(B) data on study populations of clinical
5 research, funded by or conducted at each na-
6 tional research institute and national center,
7 which—

8 “(i) specifies the inclusion of—

9 “(I) women;

10 “(II) members of minority groups;

11 “(III) relevant age categories; and

12 “(IV) other demographic variables

13 determined to be necessary by the Di-
14 rector of NIH;

15 “(ii) is disaggregated by research area,
16 condition, and disease categories; and

17 “(iii) is to be made publicly available
18 on the Internet website of the National In-
19 stitutes of Health;”;

20 (2) in paragraph (8)—

21 (A) in subparagraph (A), by striking “and”
22 at the end; and

23 (B) by adding at the end the following:

1 “(C) foster collaboration between clinical re-
 2 search projects funded by the respective national
 3 research institutes and national centers that—

4 “(i) conduct research involving human
 5 subjects; and

6 “(ii) collect similar data; and

7 “(D) encourage the collaboration described
 8 in subparagraph (C) to—

9 “(i) allow for an increase in the num-
 10 ber of subjects studied; and

11 “(ii) utilize diverse study populations,
 12 with special consideration to biological, so-
 13 cial, and other determinants of health that
 14 contribute to health disparities;”.

15 **SEC. 4. PROMOTING INCLUSION IN CLINICAL RESEARCH.**

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

19 “(3) *STRATEGIC PLANNING.*—

20 “(A) *IN GENERAL.*—The directors of the na-
 21 tional institutes and national centers shall con-
 22 sult at least once annually with the Director of
 23 the National Institute on Minority Health and
 24 Health Disparities and the Director of the Office
 25 of Research on Women’s Health regarding objec-

1 *tives of the national institutes and national cen-*
2 *ters to ensure that future activities by such insti-*
3 *tutes and centers take into account women and*
4 *minorities and are focused on reducing health*
5 *disparities.*

6 “(B) *STRATEGIC PLANS.*—*Any strategic*
7 *plan issued by a national institute or national*
8 *center shall include details on the objectives de-*
9 *scribed in subparagraph (A).”.*

10 (b) *CLARIFICATION OF REQUIREMENTS.*—*Section*
11 *492B(c) of the Public Health Service Act (42 U.S.C. 289a-*
12 *2(c)) is amended—*

13 (1) *by striking “In the case” and inserting the*
14 *following:*

15 “(1) *IN GENERAL.*—*In the case”;* and

16 (2) *by adding at the end the following:*

17 “(2) *REPORTING REQUIREMENTS.*—*For any new*
18 *and competing project of clinical research subject to*
19 *the requirements under this section that receives a*
20 *grant award 1 year after the date of enactment of the*
21 *Advancing NIH Strategic Planning and Representa-*
22 *tion in Medical Research Act, or any date thereafter,*
23 *for which a valid analysis is provided under para-*
24 *graph (1)—*

1 “(A) and which is an applicable clinical
2 trial as defined in section 402(j), the entity con-
3 ducting such clinical research shall submit the
4 results of such valid analysis to the clinical trial
5 registry data bank expanded under 402(j)(3),
6 and the Director of NIH shall, as appropriate,
7 consider whether such entity has complied with
8 the reporting requirement described in this sub-
9 paragraph in awarding any future grant to such
10 entity, including pursuant to section
11 402(j)(5)(A)(ii) when applicable; and

12 “(B) the Director of NIH shall encourage
13 the reporting of the results of such valid analysis
14 described in paragraph (1) through any addi-
15 tional means determined appropriate by the Di-
16 rector.”.

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

19 (1) by striking “biennial” each place such term
20 appears and inserting “triennial” in each such place;

21 (2) by striking “The advisory council” and in-
22 serting the following:

23 “(1) *IN GENERAL.*—The advisory council”; and

24 (3) by adding at the end the following:

1 “(2) *CONTENTS.*—*Each triennial report pre-*
2 *pared by an advisory council of each national re-*
3 *search institute as described in paragraph (1) shall*
4 *include each of the following:*

5 “(A) *The number of women included as sub-*
6 *jects, and the proportion of subjects that are*
7 *women, in any project of clinical research con-*
8 *ducted during the applicable reporting period,*
9 *disaggregated by categories of research area, con-*
10 *dition, or disease, and accounting for single-sex*
11 *studies.*

12 “(B) *The number of members of minority*
13 *groups included as subjects, and the proportion*
14 *of subjects that are members of minority groups,*
15 *in any project of clinical research conducted dur-*
16 *ing the applicable reporting period,*
17 *disaggregated by categories of research area, con-*
18 *dition, or disease and accounting for single-race*
19 *and single-ethnicity studies.*

20 “(C) *For the applicable reporting period,*
21 *the number of projects of clinical research that*
22 *include women and members of minority groups*
23 *and that—*

24 “(i) *have been completed during such*
25 *reporting period; and*

1 “(ii) are being carried out during such
2 reporting period and have not been com-
3 pleted.

4 “(D) The number of studies completed dur-
5 ing the applicable reporting period for which re-
6 porting has been submitted in accordance with
7 subsection (c)(2)(A).”.

8 (d) *COORDINATION.*—Section 486(c)(2) of the Public
9 Health Service Act (42 U.S.C. 287d(c)(2)) is amended by
10 striking “designees” and inserting “senior-level staff des-
11 ignees”.

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

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

17 **“SEC. 404M. RESEARCH RELATED TO SEXUAL AND GENDER**
18 **MINORITY POPULATIONS.**

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

22 “(1) facilitating increased participation of sex-
23 ual and gender minority populations in clinical re-
24 search supported by the National Institutes of Health,
25 and reporting on such participation, as applicable;

1 “(2) *facilitating the development of valid and re-*
2 *liable methods for research relevant to sexual and gen-*
3 *der minority populations; and*

4 “(3) *addressing methodological challenges.*”.

5 **(b) REPORTING.—**

6 **(1) IN GENERAL.—***The Secretary, in collabora-*
7 *tion with the Director of the National Institutes of*
8 *Health, shall as appropriate—*

9 **(A)** *continue to support research for the de-*
10 *velopment of appropriate measures related to re-*
11 *porting health information about sexual and*
12 *gender minority populations; and*

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

16 **(2) NATIONAL ACADEMY OF MEDICINE REC-**
17 **COMMENDATIONS.—***In developing the measures de-*
18 *scribed in paragraph (1)(A), the Secretary shall take*
19 *into account recommendations made by the National*
20 *Academy of Medicine.*

21 **SEC. 6. IMPROVING COORDINATION RELATED TO MINORITY**

22 **HEALTH AND HEALTH DISPARITIES.**

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

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

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

5 (A) *in the subsection heading, by striking*
6 *“INTERAGENCY” and inserting “INTRA-NIH”;*

7 (B) *by striking “as the primary Federal of-*
8 *ficials” and inserting “as the primary Federal*
9 *official”;*

10 (C) *by inserting a comma after “review”;*

11 (D) *by striking “Institutes and Centers of*
12 *the National Institutes of Health” and inserting*
13 *“national research institutes and national cen-*
14 *ters”;* and

15 (E) *by adding at the end the following:*

16 *“The Director of the Institute may foster part-*
17 *nerships between the national research institutes*
18 *and national centers and may encourage the*
19 *funding of collaborative research projects to*
20 *achieve the goals of the National Institutes of*
21 *Health that are related to minority health and*
22 *health disparities.”.*

1 **SEC. 7. ENHANCING THE RIGOR AND REPRODUCIBILITY OF**
2 **SCIENTIFIC RESEARCH.**

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

14 (b) *CONSIDERATIONS.*—In developing and issuing the
15 recommendations under subsection (a), the working group
16 established under such subsection shall consider, as appro-
17 priate—

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

20 (2) *clinical experiment design, including—*

21 (A) *the diversity of populations studied for*
22 *clinical research, with respect to biological, so-*
23 *cial, and other determinants of health that con-*
24 *tribute to health disparities;*

25 (B) *the circumstances under which sum-*
26 *mary information regarding biological, social,*

1 *and other factors that contribute to health dis-*
2 *parities should be reported; and*

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

8 *(3) applicable levels of rigor in statistical meth-*
9 *ods, methodology, and analysis;*

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

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

14 *(c) POLICIES.—Not later than 18 months after the date*
15 *of enactment of this Act, the Director of the National Insti-*
16 *tutes of Health shall consider the recommendations devel-*
17 *oped by the working group under subsection (a) and develop*
18 *or update policies as appropriate.*

19 *(d) REPORT.—Not later than 2 years after the date*
20 *of enactment of this Act, the Director of the National Insti-*
21 *tutes of Health, acting through the working group estab-*
22 *lished under subsection (a), shall issue a report to the Sec-*
23 *retary of Health and Human Services, the Committee on*
24 *Health, Education, Labor, and Pensions of the Senate, and*
25 *the Committee on Energy and Commerce of the House of*

1 *Representatives regarding recommendations developed*
 2 *under such subsection and any subsequent policy changes*
 3 *implemented, to enhance rigor and reproducibility in sci-*
 4 *entific research funded by the National Institutes of Health.*

5 *(e) CONFIDENTIALITY.—Nothing in this section shall*
 6 *authorize the Secretary of Health and Human Services to*
 7 *disclose any information that is a trade secret, or other*
 8 *privileged or confidential information, described in section*
 9 *552(b)(4) of title 5, United States Code, or section 1905*
 10 *of title 18, United States Code.*

11 **SEC. 8. TASK FORCE ON RESEARCH SPECIFIC TO PREG-**
 12 **NANT WOMEN AND LACTATING WOMEN.**

13 *(a) TASK FORCE ON RESEARCH SPECIFIC TO PREG-*
 14 *NANT WOMEN AND LACTATING WOMEN.—*

15 *(1) ESTABLISHMENT.—Not later than 90 days*
 16 *after the date of enactment of this Act, the Secretary*
 17 *of Health and Human Services (referred to in this*
 18 *section as the “Secretary”) shall establish a task force,*
 19 *in accordance with the Federal Advisory Committee*
 20 *Act (5 U.S.C. App.), to be known as the “Task Force*
 21 *on Research Specific to Pregnant Women and Lac-*
 22 *tating Women” (in this section referred to as the*
 23 *“Task Force”).*

24 *(2) DUTIES.—The Task Force shall provide ad-*
 25 *vice and guidance to the Secretary regarding Federal*

1 *activities related to identifying and addressing gaps*
2 *in knowledge and research regarding safe and effective*
3 *therapies for pregnant women and lactating women,*
4 *including the development of such therapies and the*
5 *collaboration on and coordination of such activities.*

6 (3) *MEMBERSHIP.*—

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

10 (i) *The Director of the Centers for Dis-*
11 *ease Control and Prevention.*

12 (ii) *The Director of the National Insti-*
13 *tutes of Health, the Director of the Eunice*
14 *Kennedy Shriver National Institute of*
15 *Child Health and Human Development,*
16 *and the directors of such other appropriate*
17 *national research institutes.*

18 (iii) *The Commissioner of Food and*
19 *Drugs.*

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

22 (v) *The Director of the National Vac-*
23 *cine Program Office.*

24 (vi) *The head of any other research-re-*
25 *lated agency or department not described in*

1 *clauses (i) through (v) that the Secretary*
2 *determines appropriate, which may include*
3 *the Department of Veterans Affairs and the*
4 *Department of Defense.*

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

8 *(i) representatives from relevant med-*
9 *ical societies with subject matter expertise*
10 *on pregnant women, lactating women, or*
11 *children;*

12 *(ii) nonprofit organizations with ex-*
13 *pertise related to the health of women and*
14 *children;*

15 *(iii) relevant industry representatives;*
16 *and*

17 *(iv) other representatives, as appro-*
18 *priate.*

19 *(C) LIMITATIONS.—The non-Federal mem-*
20 *bers described in subparagraph (B) shall—*

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

24 *(ii) be appointed by the Secretary.*

25 *(4) TERMINATION.—*

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

5 (B) *EXTENSION.*—The Secretary may ex-
6 tend the operation of the Task Force for one ad-
7 ditional 2-year period following the 2-year pe-
8 riod described in subparagraph (A), if the Sec-
9 retary determines that the extension is appro-
10 priate for carrying out the purpose of this sec-
11 tion.

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

16 (6) *TASK FORCE REPORT TO CONGRESS.*—Not
17 later than 18 months after the date on which the Task
18 Force is established under paragraph (1), the Task
19 Force shall prepare and submit to the Secretary, the
20 Committee on Health, Education, Labor, and Pen-
21 sions of the Senate, and the Committee on Energy
22 and Commerce of the House of Representatives a re-
23 port that includes each of the following:

24 (A) A plan to identify and address gaps in
25 knowledge and research regarding safe and effec-

1 *tive therapies for pregnant women and lactating*
2 *women, including the development of such thera-*
3 *pies.*

4 *(B) Ethical issues surrounding the inclu-*
5 *sion of pregnant women and lactating women in*
6 *clinical research.*

7 *(C) Effective communication strategies with*
8 *health care providers and the public on informa-*
9 *tion relevant to pregnant women and lactating*
10 *women.*

11 *(D) Identification of Federal activities, in-*
12 *cluding—*

13 *(i) the state of research on pregnancy*
14 *and lactation;*

15 *(ii) recommendations for the coordina-*
16 *tion of, and collaboration on research re-*
17 *lated to pregnant women and lactating*
18 *women;*

19 *(iii) dissemination of research findings*
20 *and information relevant to pregnant*
21 *women and lactating women to providers*
22 *and the public; and*

23 *(iv) existing Federal efforts and pro-*
24 *grams to improve the scientific under-*
25 *standing of the health impacts on pregnant*

1 *women, lactating women, and related birth*
2 *and pediatric outcomes, including with re-*
3 *spect to pharmacokinetics,*
4 *pharmacodynamics, and toxicities.*

5 *(E) Recommendations to improve the devel-*
6 *opment of safe and effective therapies for preg-*
7 *nant women and lactating women.*

8 *(b) CONFIDENTIALITY.—Nothing in this section shall*
9 *authorize the Secretary of Health and Human Services to*
10 *disclose any information that is a trade secret, or other*
11 *privileged or confidential information, described in section*
12 *552(b)(4) of title 5, United States Code, or section 1905*
13 *of title 18, United States Code.*

14 *(c) UPDATING PROTECTIONS FOR PREGNANT WOMEN*
15 *AND LACTATING WOMEN IN RESEARCH.—*

16 *(1) IN GENERAL.—Not later than 2 years after*
17 *the date of enactment of this Act, the Secretary, con-*
18 *sidering any recommendations of the Task Force*
19 *available at such time and in consultation with the*
20 *heads of relevant agencies of the Department of*
21 *Health and Human Services, shall, as appropriate,*
22 *update regulations and guidance, as applicable, re-*
23 *garding the inclusion of pregnant women and lac-*
24 *tating women in clinical research.*

1 (2) *CRITERIA FOR EXCLUDING PREGNANT OR*
2 *LACTATING WOMEN.*—*In updating any regulations or*
3 *guidance described in paragraph (1), the Secretary*
4 *shall consider any appropriate criteria to be used by*
5 *institutional review boards and individuals reviewing*
6 *grant proposals for excluding pregnant women or lac-*
7 *tating women as a study population requiring addi-*
8 *tional protections from participating in human sub-*
9 *ject research.*

10 **SEC. 9. WOMEN AND MINORITIES IN RESEARCH.**

11 (a) *BASIC RESEARCH.*—

12 (1) *DEVELOPING POLICIES.*—*Not later than 2*
13 *years after the date of enactment of this Act, the Di-*
14 *rector of the National Institutes of Health (referred to*
15 *in this section as the “Director of NIH”), taking into*
16 *consideration the findings of the working group estab-*
17 *lished under section 7, shall develop policies for*
18 *projects of basic research funded by National Insti-*
19 *tutes of Health to assess—*

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

22 (B) *how differences between male and fe-*
23 *male cells, tissues, or animals may be examined*
24 *and analyzed.*

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

4 (3) *CONSULTATION AND OUTREACH.*—*In devel-*
5 *oping, updating, or revising the policies under this*
6 *section, the Director of NIH—*

7 (A) *shall consult with—*

8 (i) *the Office of Research on Women’s*
9 *Health;*

10 (ii) *the Office of Laboratory Animal*
11 *Welfare; and*

12 (iii) *appropriate members of the sci-*
13 *entific and academic communities; and*

14 (B) *shall conduct outreach to solicit feed-*
15 *back from members of the scientific and aca-*
16 *ademic communities on the influence of sex as a*
17 *variable in basic research, including feedback on*
18 *when it is appropriate for projects of basic re-*
19 *search involving cells, tissues, or animals to in-*
20 *clude both male and female cells, tissues, or ani-*
21 *mals.*

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

24 (A) *ensure that projects of basic research*
25 *funded by the National Institutes of Health are*

1 *conducted in accordance with the policies devel-*
2 *oped, updated, or revised under this section, as*
3 *applicable; and*

4 *(B) encourage that the results of such re-*
5 *search, when published or reported, be*
6 *disaggregated as appropriate with respect to the*
7 *analysis of any sex differences.*

8 *(b) CLINICAL RESEARCH.—*

9 *(1) IN GENERAL.—Not later than 1 year after*
10 *the date of enactment of this Act, the Director of NIH,*
11 *in consultation with the Director of the Office of Re-*
12 *search on Women’s Health and the Director of the*
13 *National Institute on Minority Health and Health*
14 *Disparities, shall update the guidelines established*
15 *under section 492B(d) of Public Health Service Act*
16 *(42 U.S.C. 289a–2(d)) in accordance with paragraph*
17 *(2).*

18 *(2) REQUIREMENTS.—The updated guidelines*
19 *described in paragraph (1) shall—*

20 *(A) reflect the science regarding sex dif-*
21 *ferences;*

22 *(B) improve adherence to the requirements*
23 *under section 492B of the Public Health Service*
24 *Act (42 U.S.C. 289a–2), including the reporting*

1 *requirements under subsection (f) of such section;*
2 *and*

3 *(C) clarify the circumstances under which*
4 *studies should be designed to support the conduct*
5 *of analyses to detect significant differences in the*
6 *intervention effect due to demographic factors re-*
7 *lated to section 492B of the Public Health Serv-*
8 *ice Act, including in the absence of prior studies*
9 *that demonstrate a difference in study outcomes*
10 *on the basis of such factors and considering the*
11 *effects of the absence of such analyses on the*
12 *availability of data related to demographic dif-*
13 *ferences.*

Calendar No. 430

114TH CONGRESS
2^D SESSION

S. 2745

A BILL

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

APRIL 18, 2016

Reported with an amendment