

114TH 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.

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## 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

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## 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,*

3 **SECTION 1. SHORT TITLE.**

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

7 **SEC. 2. NIH STRATEGIC PLAN.**

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

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

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

6           “(m) NIH STRATEGIC PLAN.—

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

22          “(2) REQUIREMENTS.—The strategy under  
23          paragraph (1) shall—

1           “(A) identify strategic research priorities  
2           and objectives across biomedical research, in-  
3           cluding—

4                   “(i) an assessment of the state of bio-  
5                   medical and behavioral research, including  
6                   areas of opportunity with respect to basic,  
7                   clinical, and translational research;

8                   “(ii) priorities and objectives to ad-  
9                   vance the treatment, cure, and prevention  
10                  of health conditions;

11                  “(iii) emerging scientific opportuni-  
12                  ties, rising public health challenges, and  
13                  scientific knowledge gaps; and

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

16           “(B) consider, in carrying out subpara-  
17           graph (A)—

18                   “(i) disease burden in the United  
19                   States;

20                   “(ii) rare diseases and conditions;

21                   “(iii) biological, social, and other de-  
22                   terminants of health that contribute to  
23                   health disparities; and

24                   “(iv) other factors the Director of  
25                   NIH determines appropriate;

1           “(C) include multi-institute priorities, in-  
2           cluding coordination of research among insti-  
3           tutes and centers;

4           “(D) include strategic priorities for fund-  
5           ing research through the Common Fund, in ac-  
6           cordance with section 402A(c)(1)(C);

7           “(E) address the agency’s proposed and  
8           ongoing activities related to training and the  
9           biomedical workforce; and

10          “(F) describe opportunities for collabora-  
11          tion with other agencies and departments, as  
12          appropriate.

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

20          (b)           CONFORMING            AMENDMENT.—Section  
21          402A(c)(1)(C) of the Public Health Service Act (42  
22          U.S.C. 282a(c)(1)(C)) is amended by striking “Not later  
23          than June 1, 2007, and every 2 years thereafter,” and  
24          inserting “As part of the NIH Strategic Plan required  
25          under section 402(m),”.

1 **SEC. 3. COLLABORATION TO ENHANCE DIVERSITY IN CLIN-**  
2 **ICAL RESEARCH.**

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

5 (1) by amending paragraph (4) to read as fol-  
6 lows:

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

9 “(A) information to better evaluate sci-  
10 entific opportunity, public health burdens, and  
11 progress in reducing health disparities; and

12 “(B) data on study populations of clinical  
13 research, funded by or conducted at each na-  
14 tional research institute and national center,  
15 which—

16 “(i) specifies the inclusion of—

17 “(I) women;

18 “(II) members of minority  
19 groups;

20 “(III) relevant age categories;

21 and

22 “(IV) other demographic vari-  
23 ables determined to be necessary by  
24 the Director of NIH;

25 “(ii) is disaggregated by research  
26 area, condition, and disease categories; and

1 “(iii) is to be made publicly available  
2 on the Internet website of the National In-  
3 stitutes of Health;” and

4 (2) in paragraph (8)—

5 (A) in subparagraph (A), by striking  
6 “and” at the end; and

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

8 “(C) foster collaboration between clinical  
9 research projects funded by the respective na-  
10 tional research institutes and national centers  
11 that—

12 “(i) conduct research involving human  
13 subjects; and

14 “(ii) collect similar data; and

15 “(D) encourage the collaboration described  
16 in subparagraph (C) to—

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

19 “(ii) utilize diverse study populations,  
20 with special consideration to biological, so-  
21 cial, and other determinants of health that  
22 contribute to health disparities;”.

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

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

5 “(3) STRATEGIC PLANNING.—

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

17 “(B) STRATEGIC PLANS.—Any strategic  
18 plan issued by a national institute or national  
19 center shall include details on the objectives de-  
20 scribed in subparagraph (A).”.

21 (b) CLARIFICATION OF REQUIREMENTS.—Section  
22 492B(c) of the Public Health Service Act (42 U.S.C.  
23 289a–2(c)) is amended—

24 (1) by striking “In the case” and inserting the  
25 following:

26 “(1) IN GENERAL.—In the case”; and

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

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

10 “(A) and which is an applicable clinical  
11 trial as defined in section 402(j), the entity con-  
12 ducting such clinical research shall submit the  
13 results of such valid analysis to the clinical trial  
14 registry data bank expanded under section  
15 402(j)(3), and the Director of NIH shall, as ap-  
16 propriate, consider whether such entity has  
17 complied with the reporting requirement de-  
18 scribed in this subparagraph in awarding any  
19 future grant to such entity, including pursuant  
20 to section 402(j)(5)(A)(ii) when applicable; and

21 “(B) the Director of NIH shall encourage  
22 the reporting of the results of such valid anal-  
23 ysis described in paragraph (1) through any ad-  
24 ditional means determined appropriate by the  
25 Director.”.



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

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

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

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

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

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

13 “(A) The number of women included as  
14 subjects, and the proportion of subjects that are  
15 women, in any project of clinical research con-  
16 ducted during the applicable reporting period,  
17 disaggregated by categories of research area,  
18 condition, or disease, and accounting for single-  
19 sex studies.

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

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

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

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

9 “(ii) are being carried out during such  
10 reporting period and have not been com-  
11 pleted.

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

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

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

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

1 **“SEC. 404M. RESEARCH RELATED TO SEXUAL AND GENDER**  
2 **MINORITY POPULATIONS.**

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

6 “(1) facilitating increased participation of sex-  
7 ual and gender minority populations in clinical re-  
8 search supported by the National Institutes of  
9 Health, and reporting on such participation, as ap-  
10 plicable;

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

14 “(3) addressing methodological challenges.”.

15 (b) REPORTING.—

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

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

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



1           nerships between the national research insti-  
2           tutes and national centers and may encourage  
3           the funding of collaborative research projects to  
4           achieve the goals of the National Institutes of  
5           Health that are related to minority health and  
6           health disparities.”.

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

9           (a) ESTABLISHMENT.—Not later than 1 year after  
10          the date of enactment of this Act, the Secretary of Health  
11          and Human Services, acting through the Director of the  
12          National Institutes of Health, shall convene a working  
13          group under the Advisory Committee to the Director of  
14          the National Institutes of Health, appointed under section  
15          222 of the Public Health Service Act (42 U.S.C. 217a),  
16          to develop and issue recommendations for a formal policy,  
17          which may incorporate or be informed by relevant existing  
18          and ongoing activities, to enhance rigor and reproduc-  
19          ibility of scientific research funded by the National Insti-  
20          tutes of Health.

21          (b) CONSIDERATIONS.—In developing and issuing the  
22          recommendations under subsection (a), the working group  
23          established under such subsection shall consider, as appro-  
24          priate—

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

3           (2) clinical experiment design, including—

4                 (A) the diversity of populations studied for  
5 clinical research, with respect to biological, so-  
6 cial, and other determinants of health that con-  
7 tribute to health disparities;

8                 (B) the circumstances under which sum-  
9 mary information regarding biological, social,  
10 and other factors that contribute to health dis-  
11 parities should be reported; and

12                 (C) the circumstances under which clinical  
13 studies, including clinical trials, should conduct  
14 an analysis of the data collected during the  
15 study on the basis of biological, social, and  
16 other factors that contribute to health dispari-  
17 ties;

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

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

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

24           (c) POLICIES.—Not later than 18 months after the  
25 date of enactment of this Act, the Director of the National

1 Institutes of Health shall consider the recommendations  
2 developed by the working group under subsection (a) and  
3 develop or update policies as appropriate.

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

16 (e) CONFIDENTIALITY.—Nothing in this section shall  
17 authorize the Secretary of Health and Human Services to  
18 disclose any information that is a trade secret, or other  
19 privileged or confidential information, described in section  
20 552(b)(4) of title 5, United States Code, or section 1905  
21 of title 18, United States Code.

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

24 (a) TASK FORCE ON RESEARCH SPECIFIC TO PREG-  
25 NANT WOMEN AND LACTATING WOMEN.—

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

10           (2) DUTIES.—The Task Force shall provide ad-  
11 vice and guidance to the Secretary regarding Fed-  
12 eral activities related to identifying and addressing  
13 gaps in knowledge and research regarding safe and  
14 effective therapies for pregnant women and lactating  
15 women, including the development of such therapies  
16 and the collaboration on and coordination of such  
17 activities.

18           (3) MEMBERSHIP.—

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

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

24                   (ii) The Director of the National In-  
25 stitutes of Health, the Director of the Eu-



1 nice Kennedy Shriver National Institute of  
2 Child Health and Human Development,  
3 and the directors of such other appropriate  
4 national research institutes.

5 (iii) The Commissioner of Food and  
6 Drugs.

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

9 (v) The Director of the National Vac-  
10 cine Program Office.

11 (vi) The head of any other research-  
12 related agency or department not described  
13 in clauses (i) through (v) that the Sec-  
14 retary determines appropriate, which may  
15 include the Department of Veterans Af-  
16 fairs and the Department of Defense.

17 (B) NON-FEDERAL MEMBERS.—The Task  
18 Force shall be composed of each of the fol-  
19 lowing non-Federal members, including—

20 (i) representatives from relevant med-  
21 ical societies with subject matter expertise  
22 on pregnant women, lactating women, or  
23 children;

1 (ii) nonprofit organizations with ex-  
2 pertise related to the health of women and  
3 children;

4 (iii) relevant industry representatives;  
5 and

6 (iv) other representatives, as appro-  
7 priate.

8 (C) LIMITATIONS.—The non-Federal mem-  
9 bers described in subparagraph (B) shall—

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

13 (ii) be appointed by the Secretary.

14 (4) TERMINATION.—

15 (A) IN GENERAL.—Subject to subpara-  
16 graph (B), the Task Force shall terminate on  
17 the date that is 2 years after the date on which  
18 the Task Force is established under paragraph  
19 (1).

20 (B) EXTENSION.—The Secretary may ex-  
21 tend the operation of the Task Force for one  
22 additional 2-year period following the 2-year pe-  
23 riod described in subparagraph (A), if the Sec-  
24 retary determines that the extension is appro-

1           appropriate for carrying out the purpose of this sec-  
2           tion.

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

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

15                 (A) A plan to identify and address gaps in  
16                 knowledge and research regarding safe and ef-  
17                 fective therapies for pregnant women and lac-  
18                 tating women, including the development of  
19                 such therapies.

20                 (B) Ethical issues surrounding the inclu-  
21                 sion of pregnant women and lactating women in  
22                 clinical research.

23                 (C) Effective communication strategies  
24                 with health care providers and the public on in-

1           formation relevant to pregnant women and lac-  
2           tating women.

3           (D) Identification of Federal activities, in-  
4           cluding—

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

7                 (ii) recommendations for the coordina-  
8                 tion of, and collaboration on research re-  
9                 lated to pregnant women and lactating  
10                women;

11                (iii) dissemination of research findings  
12                and information relevant to pregnant  
13                women and lactating women to providers  
14                and the public; and

15                (iv) existing Federal efforts and pro-  
16                grams to improve the scientific under-  
17                standing of the health impacts on pregnant  
18                women, lactating women and, related birth  
19                and pediatric outcomes, including with re-  
20                spect to pharmacokinetics, pharmacody-  
21                namics, and toxicities.

22           (E) Recommendations to improve the de-  
23           velopment of safe and effective therapies for  
24           pregnant women and lactating women.

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

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

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

18 (2) CRITERIA FOR EXCLUDING PREGNANT OR  
19 LACTATING WOMEN.—In updating any regulations or  
20 guidance described in paragraph (1), the Secretary  
21 shall consider any appropriate criteria to be used by  
22 institutional review boards and individuals reviewing  
23 grant proposals for excluding pregnant women or  
24 lactating women as a study population requiring ad-

1       ditional protections from participating in human  
2       subject research.

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

4       (a) BASIC RESEARCH.—

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

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

15           (B) how differences between male and fe-  
16      male cells, tissues, or animals may be examined  
17      and analyzed.

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

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

24           (A) shall consult with—

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

3 (ii) the Office of Laboratory Animal  
4 Welfare; and

5 (iii) appropriate members of the sci-  
6 entific and academic communities; and

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

15 (4) ADDITIONAL REQUIREMENTS.—The Direc-  
16 tor of NIH shall—

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

22 (B) encourage that the results of such re-  
23 search, when published or reported, be  
24 disaggregated as appropriate with respect to  
25 the analysis of any sex differences.

1 (b) CLINICAL RESEARCH.—

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

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

13 (A) reflect the science regarding sex dif-  
14 ferences;

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

20 (C) clarify the circumstances under which  
21 studies should be designed to support the con-  
22 duct of analyses to detect significant differences  
23 in the intervention effect due to demographic  
24 factors related to section 492B of the Public  
25 Health Service Act, including in the absence of



1           prior studies that demonstrate a difference in  
2           study outcomes on the basis of such factors and  
3           considering the effects of the absence of such  
4           analyses on the availability of data related to  
5           demographic differences.

○