

114TH CONGRESS
2D SESSION

H. R. 6224

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2016

Mrs. BEATTY (for herself, Ms. SEWELL of Alabama, and Mr. YOUNG of Iowa) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to promote the inclusion of minorities and women 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 “Enhancing Minority
5 and Women Representation in NIH Medical Research Act
6 of 2016”.

1 **SEC. 2. 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. 3. 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 Enhancing Minority and Women Rep-
7 resentation in NIH Medical Research Act of 2016,
8 or any date thereafter, for which a valid analysis is
9 provided 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 402(j)(3),
15 and the Director of NIH shall, as appropriate,
16 consider whether such entity has complied with
17 the reporting requirement described in this sub-
18 paragraph in awarding any future grant to such
19 entity, including pursuant to section
20 402(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. 4. IMPROVING COORDINATION RELATED TO MINOR-**
21 **ITY HEALTH AND HEALTH DISPARITIES.**

22 Section 464z–3 of the Public Health Service Act (42
23 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
8 officials” 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 insti-
18 tutes and national centers and may encourage
19 the 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.”.

23 **SEC. 5. WOMEN AND MINORITIES IN RESEARCH.**

24 (a) BASIC RESEARCH.—

1 (1) DEVELOPING POLICIES.—Not later than 2
2 years after the date of enactment of this Act, the
3 Director of the National Institutes of Health (re-
4 ferred to in this section as the “Director of NIH”)
5 shall develop policies for projects of basic research
6 funded by National Institutes of Health to assess—

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

9 (B) how differences between male and fe-
10 male cells, tissues, or animals may be examined
11 and analyzed.

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

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

18 (A) shall consult with—

19 (i) the Office of Research on Women’s
20 Health;

21 (ii) the Office of Laboratory Animal
22 Welfare; and

23 (iii) appropriate members of the sci-
24 entific and academic communities; and

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

9 (4) ADDITIONAL REQUIREMENTS.—The Direc-
10 tor of NIH shall—

11 (A) ensure that projects of basic research
12 funded by the National Institutes of Health are
13 conducted in accordance with the policies devel-
14 oped, updated, or revised under this section, as
15 applicable; and

16 (B) encourage that the results of such re-
17 search, when published or reported, be
18 disaggregated as appropriate with respect to
19 the analysis of any sex differences.

20 (b) CLINICAL RESEARCH.—

21 (1) IN GENERAL.—Not later than 1 year after
22 the date of enactment of this Act, the Director of
23 NIH, in consultation with the Director of the Office
24 of Research on Women’s Health and the Director of
25 the National Institute on Minority Health and

1 Health Disparities, shall update the guidelines estab-
2 lished under section 492B(d) of the Public Health
3 Service Act (42 U.S.C. 289a–2(d)) in accordance
4 with paragraph (2).

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

7 (A) reflect the science regarding sex dif-
8 ferences;

9 (B) improve adherence to the requirements
10 under section 492B of the Public Health Serv-
11 ice Act (42 U.S.C. 289a–2), including the re-
12 porting requirements under subsection (f) of
13 such section; and

14 (C) clarify the circumstances under which
15 studies should be designed to support the con-
16 duct of analyses to detect significant differences
17 in the intervention effect due to demographic
18 factors related to section 492B of the Public
19 Health Service Act, including in the absence of
20 prior studies that demonstrate a difference in
21 study outcomes on the basis of such factors and
22 considering the effects of the absence of such
23 analyses on the availability of data related to
24 demographic differences.

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