

[~118H3503]

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(Original Signature of Member)

119TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To direct the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, to take certain steps to increase clinical trial diversity, and for other purposes.

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**IN THE HOUSE OF REPRESENTATIVES**

Ms. KELLY of Illinois introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To direct the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, to take certain steps to increase clinical trial diversity, 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 “NIH Clinical Trial In-  
5       tegrity Act”.

1 **SEC. 2. DIVERSITY GOALS FOR CLINICAL TRIALS.**

2 (a) APPLICATIONS.—Beginning on the date of the en-  
3 actment of this Act, the Secretary of Health and Human  
4 Services, acting through the Director of the National In-  
5 stitutes of Health (in this section referred to as the “Sec-  
6 retary”), shall require that a sponsor seeking to conduct  
7 a clinical trial investigating a drug, device (as those terms  
8 are defined in section 201 of the Federal Food, Drug, and  
9 Cosmetic Act (21 U.S.C. 321 et seq.)), biological product  
10 (as defined in section 351(i) of the Public Health Service  
11 Act (42 U.S.C. 262(i))), or behavioral intervention, the  
12 protocol for which is approved by the National Institutes  
13 of Health, to submit an application (or renewal thereof)  
14 for such approval that includes—

15 (1) clear and measurable goals for the recruit-  
16 ment and retention of participants that reflect—

17 (A) the race, ethnicity, age, and sex of pa-  
18 tients with the disease or condition being inves-  
19 tigated; or

20 (B) the race, ethnicity, age, and sex of the  
21 general population of the United States if the  
22 prevalence of the disease or condition is not  
23 known;

24 (2) a rationale for the goals specified under  
25 paragraph (1) that specifies—

1 (A) how investigators will calculate the  
2 number of participants for each population cat-  
3 egory that reflect the population groups speci-  
4 fied in paragraph (1); or

5 (B) strategies that will be used to enroll  
6 and retain participants across the different  
7 race, ethnicity, age, and sex categories;

8 (3) a detailed plan for how the clinical trial will  
9 achieve the goals specified under paragraph (1) that  
10 specifies—

11 (A) the requirements for researchers, in  
12 conducting the trial, to analyze the population  
13 groups specified in paragraph (1) separately;

14 (B) the role of community partners or  
15 community institutional review boards in re-  
16 viewing the plans; and

17 (C) how the trial will recruit a study popu-  
18 lation that is—

19 (i) in proportion to the prevalence of  
20 the disease or condition in such groups rel-  
21 ative to the prevalence of the disease or  
22 condition in the overall population of the  
23 United States;

24 (ii) in sufficient numbers to obtain  
25 clinically and statistically meaningful de-

1 terminations of the safety and effectiveness  
2 of the drug, device, biological product, or  
3 behavioral intervention being studied in the  
4 respective race, ethnicity, age, and sex  
5 groups; and

6 (iii) consistent with the guidance  
7 under section 505(b)(1) of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C.  
9 355(b)(1)) and guidance issued by the Na-  
10 tional Institutes of Health on the inclusion  
11 of women and minorities in clinical trials;

12 (4) the sponsor's plan for implementing, or an  
13 explanation of why the sponsor cannot implement,  
14 alternative clinical trial follow-up requirements that  
15 are less burdensome for trial participants, such as—

16 (A) requiring fewer follow-up visits;

17 (B) allowing phone follow-up or home vis-  
18 its by nurse trial coordinators (in lieu of in-per-  
19 son visits by patients);

20 (C) allowing for online follow-up options;

21 (D) permitting the patient's primary care  
22 provider to perform some of the follow-up visit  
23 requirements;

24 (E) allowing for evening and weekend  
25 hours for required follow-up visits;

1 (F) allowing virtual or telemedicine visits;

2 (G) use of wearable technology to record  
3 key health parameters; and

4 (H) use of alternate labs or imaging cen-  
5 ters, which may be closer to the residence of the  
6 patients participating in the trial; and

7 (5) the sponsor's education and training re-  
8 quirements for researchers and other individuals  
9 conducting or supporting the clinical trial with re-  
10 spect to diversity and health inequities in, and the  
11 development of, curricula for healthcare profes-  
12 sionals on how to participate in clinical trials as an  
13 investigator and how they can enroll patients in  
14 trials, which may include consultation with, and the  
15 review of materials made available by, such commit-  
16 tees, task forces, working groups, and other entities  
17 the Director determines are appropriate, including  
18 the following:

19 (A) The Equity Committee of the National  
20 Institutes of Health.

21 (B) The National Advisory Council on Mi-  
22 nority Health and Health Disparities.

23 (C) The Advisory Committee on Research  
24 on Women's Health.

1 (D) The Tribal Health Research Coordi-  
2 nating Committee of the National Institutes of  
3 Health.

4 (b) TERMS.—

5 (1) IN GENERAL.—As a condition on the ap-  
6 proval of a protocol to conduct a clinical trial by the  
7 National Institutes of Health, as described in sub-  
8 section (a), the sponsor of the clinical trial shall  
9 agree to terms requiring that—

10 (A) the aggregate demographic information  
11 of trial participants be shared on an annual  
12 basis with the Secretary while participant re-  
13 cruitment and data collection in such trial is  
14 ongoing, and that such information is provided  
15 with respect to—

16 (i) underrepresented populations, in-  
17 cluding populations grouped by race, eth-  
18 nicity, age, and sex; and

19 (ii) such populations that reflect the  
20 prevalence of the disease or condition that  
21 is the subject of the clinical trial involved  
22 (as available and as appropriate to the sci-  
23 entific objective for the study, as deter-  
24 mined by the Director of the National In-  
25 stitutes of Health);

1 (B) the sponsor submits to the program of-  
2 ficer and grants management specialist of the  
3 specific National Institutes of Health national  
4 research institute or national center, annually  
5 or as frequently as such officer or specialist de-  
6 termines necessary, the retention rate of par-  
7 ticipants in the clinical trial, disaggregated by  
8 race, ethnicity, age, and sex;

9 (C) both the clinical trial researchers and  
10 the applicant reviewers complete education and  
11 training programs on diversity in clinical trials;  
12 and

13 (D) at the conclusion of the trial, the spon-  
14 sor submits to the Secretary the number of par-  
15 ticipants in the trial, disaggregated by race,  
16 ethnicity, age, and sex.

17 (2) PRIVACY PROTECTIONS.—Any data shared  
18 under paragraph (1) may not include any individ-  
19 ually identifiable information or protected health in-  
20 formation with respect to clinical trial participants  
21 and shall only be disclosed to the extent allowed  
22 under Federal privacy laws.

23 (c) EXCEPTION.—In lieu of submitting an application  
24 under subsection (a) and documentation of goals as re-  
25 quired by paragraph (1) of such subsection, an applicant

1 may provide reasoning for why the recruitment of each  
2 of the population groups specified in paragraph (1) of sub-  
3 section (a) is not necessary and why such recruitment is  
4 not scientifically justified or possible.

5 (d) PUBLICATION.—The Secretary shall—

6 (1) publish on a public website of the National  
7 Institutes of Health, upon receipt of an application  
8 to which subsection (a) applies—

9 (A) a summary of the disease being tar-  
10 geted in the clinical trial that is the subject of  
11 the application and the prevalence of such dis-  
12 ease across race, ethnicity, age, sex, and the  
13 clinical trial representation in each such cat-  
14 egory;

15 (B) the goals specified in such application,  
16 as required by subsection (a)(1); or

17 (C) the reasoning described in subsection  
18 (c); and

19 (2) ensure that, in publishing information relat-  
20 ing to an application under paragraph (1), the de-  
21 sign of the study involved is not disclosed.

22 (e) REMEDIATION.—

23 (1) IN GENERAL.—In the case of a clinical trial  
24 subject to subsection (a) that fails to meet the condi-  
25 tion specified pursuant to subsection (a) by such



1 date as may be agreed upon by the sponsor of the  
2 trial and the program officer and grants manage-  
3 ment specialist of the specific National Institutes of  
4 Health national research institute or national center,  
5 the Secretary shall require the sponsor of that clin-  
6 ical trial, not later than 90 days after such date oc-  
7 curs—

8 (A) to develop, in consultation with the  
9 Secretary and advocacy and community-based  
10 organizations representing individuals who are  
11 members of relevant demographic groups speci-  
12 fied in subsection (a)(1), a strategic plan to in-  
13 crease participation in such clinical trial of such  
14 individuals; and

15 (B) to submit to the Secretary such stra-  
16 tegic plan.

17 (2) PUBLICATION.—The Secretary shall make  
18 publicly available on the website of the National In-  
19 stitutes of Health, the strategic plan received under  
20 paragraph (1) as soon as possible after receipt. The  
21 Secretary shall ensure that, in publishing such plan  
22 under the preceding sentence, the design of the  
23 study involved is not disclosed.

24 (3) IMPLEMENTATION.—The sponsor of the  
25 clinical trial that is the subject of the strategic plan

1 published under paragraph (2), shall, not later than  
2 90 days after such date as may be agreed upon by  
3 the sponsor of the trial and the appropriate program  
4 officer and grants management specialist of the Na-  
5 tional Institutes of Health, implement the strategic  
6 plan.

7 (4) TECHNICAL ASSISTANCE.—The Secretary  
8 may provide technical assistance to a sponsor of a  
9 clinical trial, as necessary for the sponsor to meet  
10 the requirements of paragraph (3).

11 (f) WAIVER FOR CERTAIN CLINICAL TRIALS.—

12 (1) IN GENERAL.—In the case of a clinical trial  
13 that received funding through the National Insti-  
14 tutes of Health and is ongoing as of the date of the  
15 enactment of this Act, the sponsor of such clinical  
16 trial is exempt from the requirements of (and associ-  
17 ated penalties imposed by) this Act.

18 (2) REPORT.—The Secretary shall include in  
19 the triennial report required to be submitted under  
20 section 403 of the Public Health Service Act (42  
21 U.S.C. 283), a list of all clinical trials receiving  
22 funding through the National Institutes of Health  
23 that requested and received waivers under this sec-  
24 tion.

25 (g) STUDY.—

1           (1) IN GENERAL.—The Comptroller General of  
2           the United States shall conduct a study that—

3                   (A) examines which actions Federal agen-  
4                   cies have taken to address barriers to participa-  
5                   tion in federally funded clinical trials by the de-  
6                   mographic groups specified in subsection (a)(1);  
7                   and

8                   (B) identifies challenges, if any, in imple-  
9                   menting such actions.

10          (2) REPORT.—Not later than 1 year after the  
11          date of the enactment of this Act, the Comptroller  
12          General of the United States shall submit to Con-  
13          gress a report on the findings of the study con-  
14          ducted under paragraph (1).

15          (h) NONDISCRIMINATION.—Section 1557 of the Pa-  
16          tient Protection and Affordable Care Act (42 U.S.C.  
17          18116) shall apply with respect to a clinical trial subject  
18          to subsection (a).

19       **SEC. 3. ELIMINATING COST BARRIERS.**

20          Not later than 2 years after the date of the enact-  
21          ment of this Act, the Secretary of Health and Human  
22          Services, acting through the Director of the National In-  
23          stitutes of Health (referred to in this section as the “Sec-  
24          retary”), shall conduct and complete a study on—

1 (1) the need for review of human subject regu-  
2 lations specified in part 46 of title 45, Code of Fed-  
3 eral Regulations (or successor regulations), and re-  
4 lated guidance;

5 (2) the modernization of such regulations and  
6 guidance to establish updated guidelines for reim-  
7 bursement of out-of-pocket expenses of human sub-  
8 jects, compensation of human subjects for time  
9 spent participating in the clinical trial, and incen-  
10 tives for recruitment of human subjects; and

11 (3) the need for updated safe harbor rules  
12 under section 1001.952 of title 42, Code of Federal  
13 Regulations (or successor regulations) and section  
14 1128B of the Social Security Act (commonly re-  
15 ferred to as the Federal Anti-Kickback Statute (42  
16 U.S.C. 1320a–7b)) with respect to the assistance  
17 provided under this section.

18 **SEC. 4. PUBLIC AWARENESS AND EDUCATION CAMPAIGN.**

19 (a) NATIONAL CAMPAIGN.—The Secretary of Health  
20 and Human Services, acting through the Director of the  
21 National Institutes of Health and the Commissioner of  
22 Food and Drugs (referred to in this section as the “Sec-  
23 retary”) and in consultation with the stakeholders speci-  
24 fied in subsection (e), shall carry out a national campaign  
25 to increase the awareness and knowledge of individuals in

1 the United States, including healthcare professionals, pa-  
2 tients, and others, with respect to the need for diverse clin-  
3 ical trials among the demographic groups identified pursu-  
4 ant to section 2(a)(1).

5 (b) REQUIREMENTS.—The national campaign con-  
6 ducted under this section shall include—

7 (1)(A) the development and distribution of writ-  
8 ten educational materials;

9 (B) the development and placing of public serv-  
10 ice announcements that are intended to encourage  
11 individuals who are members of the demographic  
12 groups identified pursuant to section 2(b)(1)(A)(I)  
13 to seek to participate in clinical trials; and

14 (C) the development of curricula for health care  
15 professionals on—

16 (i) how to participate in clinical trials as  
17 an investigator; and

18 (ii) how such professionals can enroll pa-  
19 tients in trials;

20 (2) such efforts as are reasonable and necessary  
21 to ensure meaningful access by consumers with lim-  
22 ited English proficiency;

23 (3) the development and distribution of best  
24 practices and training for recruiting underrep-  
25 resented study populations, including a method for

1 sharing such best practices among clinical trial spon-  
2 sors, providers, community-based organizations who  
3 assist with recruitment, and with the public; and

4 (4) the conduct of focus groups to better under-  
5 stand the concerns and fears of certain underrep-  
6 resented groups who may be reluctant to participate  
7 in clinical trials.

8 (c) HEALTH INEQUITIES.—In developing the national  
9 campaign under subsection (a), the Secretary shall recog-  
10 nize and address—

11 (1) health inequities among individuals who are  
12 members of the population groups specified in sec-  
13 tion 2(b)(1)(A) with respect to access to care and  
14 participation in clinical trials; and

15 (2) any barriers in access to care and participa-  
16 tion in clinical trials that are specific to individuals  
17 who are members of such groups.

18 (d) GRANTS.—The Secretary shall establish a pro-  
19 gram to award grants to nonprofit private entities (includ-  
20 ing community based organizations and faith commu-  
21 nities, institutions of higher education eligible to receive  
22 funds under section 371 of the Higher Education Act of  
23 1965 (20 U.S.C. 1067q), national organizations that serve  
24 underrepresented populations, and community phar-  
25 macies) to enable such entities—

1 (1) to test alternative outreach and education  
2 strategies to increase the awareness and knowledge  
3 of individuals in the United States, with respect to  
4 the need for diverse clinical trials that reflect the  
5 race, ethnicity, age, and sex of patients with the dis-  
6 ease or condition being investigated; and

7 (2) to cover administrative costs of such entities  
8 in assisting in diversifying clinical trials subject to  
9 section 2.

10 (e) STAKEHOLDERS SPECIFIED.—The stakeholders  
11 specified in this subsection are the following:

12 (1) Representatives of the Health Resources  
13 Services Administration, the Office on Minority  
14 Health of the Department of Health and Human  
15 Services, the Centers for Disease Control and Pre-  
16 vention, and the National Institutes of Health.

17 (2) Community-based resources and advocates.

18 (f) AUTHORIZATION OF APPROPRIATIONS.—There is  
19 authorized to be appropriated to carry out this section  
20 \$10,000,000 for each of fiscal years 2027 through 2030.

21 **SEC. 5. DEFINITIONS.**

22 In this Act:

23 (1) CLINICAL TRIAL.—The term “clinical trial”  
24 means a research study in which one or more human  
25 subjects are prospectively assigned to one or more

1        interventions (which may include placebo or other  
2        control) to evaluate the effects of those interventions  
3        on health-related biomedical or behavioral outcomes.

4            (2) SPONSOR.—The term “sponsor” has the  
5        meaning given such term in section 50.3 of title 21,  
6        Code of Federal Regulations (or successor regula-  
7        tions).