

119TH CONGRESS
1ST SESSION

S. 3564

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.

IN THE SENATE OF THE UNITED STATES

DECEMBER 18, 2025

Mr. KIM (for himself and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 FUNDED**
2 **BY THE NATIONAL INSTITUTES OF HEALTH.**

3 (a) APPLICATIONS.—Beginning on the date of enact-
4 ment of this Act, the Secretary of Health and Human
5 Services, acting through the Director of the National In-
6 stitutes of Health (referred to in this section as the “Sec-
7 retary”), shall require that a research organization or enti-
8 ty funded by the National Institutes of Health (referred
9 to in this section as an “NIH-funded research organiza-
10 tion or entity”) seeking to conduct a clinical trial inves-
11 tigating a drug or device (as those terms are defined in
12 section 201 of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 321)) or a biological product (as defined in
14 section 351(i) of the Public Health Service Act (42 U.S.C.
15 262(i))) that is funded by the National Institutes of
16 Health or a behavioral intervention, the protocol for which
17 is approved by the National Institutes of Health, submit
18 an application (or renewal thereof) for such funding or
19 approval that includes—

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

22 (A) the race, ethnicity, age, and sex of pa-
23 tients with the disease or condition being inves-
24 tigated; or

25 (B) as scientifically or ethically justified
26 and appropriate, the race, ethnicity, age, and

1 sex of the general population of the United
2 States if the prevalence of the disease or condi-
3 tion is not known;

4 (2) a rationale for the goals specified under
5 paragraph (1) that specifies—

6 (A) how investigators will determine the
7 number of participants for each population cat-
8 egory that reflect the population groups speci-
9 fied in paragraph (1); or

10 (B) strategies that will be used to enroll
11 and retain participants across the different
12 race, ethnicity, age, and sex categories;

13 (3) a detailed plan for how the clinical trial will
14 achieve the goals specified under paragraph (1) that
15 specifies—

16 (A) the requirements for researchers, in
17 conducting the trial, to analyze the population
18 groups specified in paragraph (1) separately;
19 and

20 (B) how the trial will recruit a study popu-
21 lation that is—

22 (i) scientifically and ethically appro-
23 priate in terms of the scientific objectives
24 and proposed study design; and

1 (ii) in sufficient numbers to obtain
2 clinically and statistically meaningful de-
3 terminations of the safety and effectiveness
4 of the drug, device, or behavioral interven-
5 tion being studied in the respective race,
6 ethnicity, age, and sex groups; and

7 (4) the NIH-funded research organization or
8 entity's plan for implementing, or an explanation of
9 why the NIH-funded research organization or entity
10 cannot implement, alternative clinical trial follow-up
11 requirements that are less burdensome for trial par-
12 ticipants, such as—

13 (A) requiring fewer follow-up visits;

14 (B) allowing phone follow-up or home vis-
15 its by appropriately qualified staff (in lieu of in-
16 person visits by patients);

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

18 (D) permitting the patient's primary care
19 provider to perform some of the follow-up visit
20 requirements;

21 (E) allowing for evening and weekend
22 hours for required follow-up visits;

23 (F) allowing virtual or telemedicine visits;

24 (G) use of wearable technology to record
25 key health parameters; and

1 (H) use of alternate labs or imaging cen-
2 ters, which may be closer to the residence of the
3 patients participating in the trial.

4 (b) TERMS.—

5 (1) IN GENERAL.—As a condition on the receipt
6 of funding through the National Institutes of
7 Health, as described in subsection (a), with respect
8 to a clinical trial, the NIH-funded research organiza-
9 tion or entity of the clinical trial shall agree to terms
10 requiring that—

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

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

20 (ii) such populations that reflect the
21 prevalence of the disease or condition that
22 is the subject of the clinical trial involved
23 (as available and as appropriate to the sci-
24 entific objective for the study, as deter-

1 mined by the Director of the National In-
2 stitutes of Health);

3 (B) the NIH-funded research organization
4 or entity submits to the program officer and
5 grants management specialist of the specific in-
6 stitute, center, or office of the National Insti-
7 tutes of Health, annually or as frequently as
8 such officer or specialist determines necessary,
9 the retention rate of participants in the clinical
10 trial, disaggregated by race, ethnicity, age, and
11 sex;

12 (C) the clinical trial researchers complete
13 education and training programs on diversity in
14 clinical trials; and

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

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

1 (c) EXCEPTION.—In lieu of submitting an application
 2 under subsection (a) and documentation of goals as re-
 3 quired by paragraph (1) of such subsection, an applicant
 4 may provide reasoning for why the recruitment of each
 5 of the population groups specified in paragraph (1) of sub-
 6 section (a) is not necessary and why such recruitment is
 7 not scientifically justified or possible.

8 **SEC. 3. ELIMINATING COST BARRIERS.**

9 Not later than 2 years after the date of enactment
 10 of this Act, the Secretary of Health and Human Services,
 11 acting through the Director of the National Institutes of
 12 Health, shall conduct and complete a study on—

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

17 (2) the modernization of such regulations and
 18 guidance to establish updated guidelines for reim-
 19 bursement of out-of-pocket expenses of human sub-
 20 jects, compensation of human subjects for time
 21 spent participating in the clinical trial, and incen-
 22 tives for recruitment of human subjects; and

23 (3) the need for updated safe harbor rules
 24 under section 1001.952 of title 42, Code of Federal
 25 Regulations (or successor regulations), and section

1 1128B of the Social Security Act (commonly re-
2 ferred to as the “Federal Anti-Kickback Statute”
3 (42 U.S.C. 1320a–7b)) with respect to the assist-
4 ance provided under this section.

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

6 (a) NATIONAL CAMPAIGN.—The Secretary of Health
7 and Human Services (referred to in this section as the
8 “Secretary”), in consultation with the stakeholders speci-
9 fied in subsection (e), shall carry out a national campaign
10 to increase the awareness and knowledge of individuals in
11 the United States, including health care professionals, pa-
12 tients, and others, with respect to the need for diverse clin-
13 ical trials among the demographic groups identified pursu-
14 ant to section 2(a)(1).

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

17 (1)(A) the development and distribution of writ-
18 ten educational materials;

19 (B) the development and placing of public serv-
20 ice announcements that are intended to encourage
21 individuals who are members of the demographic
22 groups identified pursuant to section 2(b)(1)(A)(i)
23 to seek to participate in clinical trials; and

24 (C) the development of curricula for health care
25 professionals on—

1 (i) how to participate in clinical trials as
2 an investigator; and

3 (ii) how such professionals can enroll pa-
4 tients in trials;

5 (2) such efforts as are reasonable and necessary
6 to ensure meaningful access by consumers with lim-
7 ited English proficiency; and

8 (3) the development and distribution of best
9 practices and training for recruiting underrep-
10 resented study populations, including a method for
11 sharing such best practices among clinical trial spon-
12 sors, providers, community-based organizations who
13 assist with recruitment, and with the public.

14 (c) HEALTH DISPARITIES.—In developing the na-
15 tional campaign under subsection (a), the Secretary shall
16 recognize and address—

17 (1) health disparities among individuals who
18 are members of the population groups specified in
19 section 2(b)(1)(A) with respect to access to care and
20 participation in clinical trials; and

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

24 (d) GRANTS.—The Secretary shall establish a pro-
25 gram to award grants to nonprofit private entities (includ-

1 ing community-based organizations and faith commu-
2 nities, institutions of higher education eligible to receive
3 funds under section 371 of the Higher Education Act of
4 1965 (20 U.S.C. 1067q), national organizations that serve
5 underrepresented populations, and community phar-
6 macies) to enable such entities—

7 (1) to test alternative outreach and education
8 strategies to increase the awareness and knowledge
9 of individuals in the United States, with respect to
10 the need for diverse clinical trials that reflect the
11 race, ethnicity, age, and sex of patients with the dis-
12 ease or condition being investigated; and

13 (2) to cover administrative costs of such entities
14 in assisting in diversifying clinical trials subject to
15 section 2.

16 (e) **STAKEHOLDERS SPECIFIED.**—The stakeholders
17 specified in this subsection are the following:

18 (1) Representatives of the Food and Drug Ad-
19 ministration, the Health Resources and Services Ad-
20 ministration, the Office on Minority Health of the
21 Department of Health and Human Services, the
22 Centers for Disease Control and Prevention, and the
23 National Institutes of Health.

24 (2) Community-based resources and advocates.

1 (f) AUTHORIZATION OF APPROPRIATIONS.—There is
2 authorized to be appropriated to carry out this section
3 \$10,000,000 for each of fiscal years 2026 through 2029.

4 **SEC. 5. DEFINITION.**

5 In this Act, the term “clinical trial” means a research
6 study in which one or more human subjects are prospec-
7 tively assigned to one or more interventions (which may
8 include placebo or other control) to evaluate the effects
9 of those interventions on health-related biomedical or be-
10 havioral outcomes.

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