

117TH CONGRESS
1ST SESSION

S. _____

To amend the Public Health Service Act to improve the diversity of participants in research on Alzheimer’s disease, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. LUJÁN (for himself and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Public Health Service Act to improve the diversity of participants in research on Alzheimer’s disease, 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 “Equity in Neuroscience
5 and Alzheimer’s Clinical Trials Act of 2021” or the
6 “ENACT Act of 2021”.

1 **SEC. 2. INCENTIVES, IMPROVEMENTS, AND OUTREACH TO**
2 **INCREASE DIVERSITY IN ALZHEIMER'S DIS-**
3 **EASE RESEARCH.**

4 (a) IMPROVING ACCESS FOR AND OUTREACH TO
5 UNDERREPRESENTED POPULATIONS.—

6 (1) EXPANDING ACCESS TO ALZHEIMER'S RE-
7 SEARCH CENTERS.—

8 (A) IN GENERAL.—Section 445(a)(1) of
9 the Public Health Service Act (42 U.S.C. 285e-
10 2(a)(1)) is amended—

11 (i) by striking “(a)(1) The Director of
12 the Institute may” and inserting the fol-
13 lowing:

14 “(a)(1) The Director of the Institute—

15 “(A) may”;

16 (ii) by striking “disease.” and insert-
17 ing “disease; and”; and

18 (iii) by adding at the end the fol-
19 lowing:

20 “(B) beginning January 1, 2022, shall enter
21 into cooperative agreements and make grants to
22 public or private nonprofit entities under this sub-
23 section for the planning, establishment, and oper-
24 ation of new such centers that are located in areas
25 with a higher concentration of minority groups (as
26 determined under section 444(d)(3)(D)), such as en-

1 tities that are historically Black colleges and univer-
2 sities, Hispanic-serving institutions, Tribal colleges
3 and universities, or centers of excellence for other
4 minority populations.”.

5 (B) USE OF FUNDING FOR CLINICS TO OP-
6 ERATE CLINICAL TRIALS.—Section 445(b) of
7 the Public Health Service Act (42 U.S.C. 285e–
8 2(b)) is amended by adding at the end the fol-
9 lowing:

10 “(3) Federal payments made under a cooperative
11 agreement or grant under subsection (a) from funds made
12 available under section 2(g) of the ENACT Act of 2021
13 shall, with respect to Alzheimer’s disease, be used in part
14 to establish and operate diagnostic and treatment clinics
15 designed—

16 “(A) to meet the special needs of minority and
17 rural populations and other underserved populations;
18 and

19 “(B) to operate clinical trials”.

20 (2) OUTREACH.—

21 (A) ALZHEIMER’S DISEASE CENTERS.—
22 Section 445(b) of the Public Health Service Act
23 (42 U.S.C. 285e–2(b)), as amended by para-
24 graph (1)(B), is further amended by adding at
25 the end the following new paragraph:

1 “(4) Federal payments made under a cooperative
2 agreement or grant under subsection (a) shall be used to
3 establish engagement centers to carry out public outreach,
4 education efforts, and dissemination of information for
5 members of minority groups about clinical trial participa-
6 tion. Activities funded pursuant to the preceding sentence
7 shall include—

8 “(A) using established mechanisms to encour-
9 age members of minority groups to participate in
10 clinical trials on Alzheimer’s disease;

11 “(B) expanding education efforts to make mem-
12 bers of minority groups aware of ongoing clinical
13 trials;

14 “(C) working with trial sponsors to increase the
15 number of recruitment events for members of minor-
16 ity groups;

17 “(D) conducting outreach to national, State,
18 and local physician professional organizations, espe-
19 cially for members of such organizations who are
20 primary care physicians or physicians who specialize
21 in dementia, to increase awareness of clinical re-
22 search opportunities for members of minority
23 groups; and

1 “(E) using community-based participatory re-
2 search methodologies to engage with minority popu-
3 lations.”.

4 (B) RESOURCE CENTERS FOR MINORITY
5 AGING RESEARCH.—Section 444(c) of the Pub-
6 lic Health Service Act (42 U.S.C. 285e–1(c)) is
7 amended—

8 (i) by striking “(c)” and inserting
9 “(c)(1)” ; and

10 (ii) by adding at the end the following
11 new paragraph:

12 “(2) The Director, acting through the Resource Cen-
13 ters for Minority Aging Research of the Institute, shall
14 carry out public outreach, education efforts, and dissemi-
15 nation of information for members of minority groups
16 about participation in clinical research on Alzheimer’s dis-
17 ease carried out or supported under this subpart.”.

18 (b) INCENTIVES TO INCREASE DIVERSITY IN ALZ-
19 HEIMER’S DISEASE RESEARCH THROUGH PRINCIPAL IN-
20 VESTIGATORS AND RESEARCHERS FROM UNDERREP-
21 RESENTED POPULATIONS.—

22 (1) ALZHEIMER’S CLINICAL RESEARCH AND
23 TRAINING AWARDS.—Section 445I of the Public
24 Health Service Act (42 U.S.C. 285e–10a) is amend-

1 ed by adding at the end the following new sub-
2 section:

3 “(d) ENHANCING THE PARTICIPATION OF PRINCIPAL
4 INVESTIGATORS AND RESEARCHERS WHO ARE MEMBERS
5 OF UNDERREPRESENTED POPULATIONS.—

6 “(1) IN GENERAL.—The Director shall enhance
7 diversity in the conduct or support of clinical re-
8 search on Alzheimer’s disease under this subpart by
9 encouraging the participation of individuals from
10 groups that are underrepresented in the biomedical,
11 clinical, behavioral, and social sciences as principal
12 investigators of such clinical research, as researchers
13 for such clinical research, or both.

14 “(2) TRAINING FOR PRINCIPAL INVESTIGA-
15 TORS.—The Director of the Institute shall provide
16 training for principal investigators who are members
17 of a minority group with respect to skills for—

18 “(A) the design and conduct of clinical re-
19 search and clinical protocols;

20 “(B) applying for grants for clinical re-
21 search; and

22 “(C) such other areas as the Director de-
23 termines to be appropriate.”.

24 (2) SENIOR RESEARCHER AWARDS.—Section
25 445B(a) of the Public Health Service Act (42

1 U.S.C. 285e–4(a)) is amended by inserting “, in-
2 cluding senior researchers who are members of a mi-
3 nority group” before the period at the end of the
4 first sentence.

5 (c) INCENTIVES TO INCREASE DIVERSITY IN ALZ-
6 HEIMER’S DISEASE RESEARCH THROUGH TRIAL SITES.—
7 Section 444(d) of the Public Health Service Act (42
8 U.S.C. 285e–1(d)) is amended—

9 (1) by striking “(d)” and inserting “(d)(1)” ;
10 and

11 (2) by adding at the end the following new
12 paragraphs:

13 “(2) In conducting or supporting clinical research on
14 Alzheimer’s disease for purposes of this subpart, in addi-
15 tion to requirements otherwise imposed under this title,
16 including under section 492B, the Director of the Institute
17 shall increase the participation of members of minority
18 groups in such clinical research through one or more of
19 the activities described in paragraph (3).

20 “(3)(A) The Director of the Institute shall provide
21 incentives for the support of clinical research on Alz-
22 heimer’s disease with clinical trial sites established in
23 areas with a higher concentration of minority groups, in-
24 cluding rural areas if practicable.

1 “(B) In determining whether to conduct or support
2 clinical research on Alzheimer’s disease, the Director of
3 the Institute shall encourage the conduct of clinical re-
4 search with clinical trial sites in areas described in sub-
5 paragraph (A) as a higher-level priority criterion among
6 the criteria established to evaluate whether to conduct or
7 support clinical research.

8 “(C) In determining the amount of funding to be pro-
9 vided for the conduct or support of such clinical research,
10 the Director of the Institute shall provide additional fund-
11 ing for the conduct of such clinical research with clinical
12 trial sites in areas described in subparagraph (A).

13 “(D) In determining whether an area is an area with
14 a higher concentration of minority groups, the Director
15 of the Institute—

16 “(i) shall consider the most recent data col-
17 lected by the Bureau of the Census; and

18 “(ii) may also consider—

19 “(I) data from the Centers for Medicare &
20 Medicaid Services on the incidence of Alz-
21 heimer’s disease in the United States by region;
22 and

23 “(II) such other data as the Director de-
24 termines appropriate.

1 “(4) In order to facilitate the participation of mem-
2 bers of minority groups in clinical research supported
3 under this subpart, in addition to activities described in
4 paragraph (3), the Director of the Institute shall—

5 “(A) ensure that such clinical research uses
6 community-based participatory research methodolo-
7 gies; and

8 “(B) encourage the use of remote health tech-
9 nologies, including telehealth, remote patient moni-
10 toring, and mobile technologies, that reduce or elimi-
11 nate barriers to participation of members of minor-
12 ity groups in such clinical research.

13 “(5)(A) Clinical research on Alzheimer’s disease con-
14 ducted or supported under this subpart shall ensure that
15 such research includes outreach activities designed to in-
16 crease the participation of members of minority groups in
17 such research.

18 “(B)(i) Each applicant for a grant under this subpart
19 for clinical research on Alzheimer’s disease shall submit
20 to the Director of the Institute in the application for such
21 grant—

22 “(I) a budget for outreach activities to members
23 of minority populations with respect to participation
24 in such clinical research; and

1 “(II) a description of the plan to conduct such
2 outreach.

3 “(ii) The Director of the Institute shall encourage ap-
4 plicants for, and recipients of, grants under this subpart
5 to conduct clinical research on Alzheimer’s disease to en-
6 gage with community-based organizations to increase par-
7 ticipation of minority populations in such research.

8 “(6) For purposes of this subpart:

9 “(A) The term ‘clinical research’ includes a
10 clinical trial.

11 “(B) The term ‘minority group’ has the mean-
12 ing given such term by reason of section 492B(g).”.

13 (d) PARTICIPANT ELIGIBILITY CRITERIA.—Section
14 445I of the Public Health Service Act (42 U.S.C. 285e–
15 10a), as amended by subsection (b)(1), is further amended
16 by adding at the end the following new subsection:

17 “(e) PARTICIPANT ELIGIBILITY CRITERIA.—The Di-
18 rector of the Institute shall take such actions as are nec-
19 essary to ensure that clinical research on Alzheimer’s dis-
20 ease conducted or supported under this subpart is de-
21 signed with eligibility criteria that ensure the clinical trial
22 population reflects the diversity of the prospective patient
23 population. Such actions may include the following:

24 “(1) EXAMINATION OF CRITERIA.—

1 “(A) IN GENERAL.—An examination of
2 each exclusion criterion to determine if the cri-
3 terion is necessary to ensure the safety of trial
4 participants or to achieve the study objectives.

5 “(B) MODIFICATION OF CRITERIA.—In the
6 case of an exclusion criterion that is not nec-
7 essary to ensure the safety of trial participants
8 or to achieve the study objectives—

9 “(i) encouraging the modification or
10 elimination of the criterion; or

11 “(ii) encouraging tailoring the cri-
12 terion as narrowly as possible to avoid un-
13 necessary limits to the population of the
14 clinical study.

15 “(2) REQUIREMENT FOR STRONG JUSTIFICA-
16 TION FOR EXCLUSION.—A review of each exclusion
17 criterion to ensure that populations are included in
18 clinical trials, such as older adults, individuals with
19 a mild form of disease, individuals at the extremes
20 of the weight range, or children, unless there is a
21 strong clinical or scientific justification to exclude
22 them.

23 “(3) USE OF ADAPTIVE DESIGN.—Encouraging
24 the use of an adaptive clinical trial design that—

1 “(A) starts with a defined population
2 where there are concerns about safety; and

3 “(B) may expand to a broader population
4 based on initial data from the trial and external
5 data.”.

6 (e) RESOURCE CENTER FOR SUCCESSFUL STRATE-
7 GIES TO INCREASE PARTICIPATION OF UNDERREP-
8 RESENTED POPULATIONS IN ALZHEIMER’S DISEASE
9 CLINICAL RESEARCH.—Section 444 of the Public Health
10 Service Act (42 U.S.C. 285e–1) is amended by adding at
11 the end the following new subsection:

12 “(e)(1) Acting through the Office of Special Popu-
13 lations of the Institute and in consultation with the Divi-
14 sion of Extramural Activities, the Director of the Institute
15 shall support resource information and technical assist-
16 ance to grantees under section 445 (relating to Alz-
17 heimer’s disease centers), other grantees, and prospective
18 grantees, designed to increase the participation of minor-
19 ity populations in clinical research on Alzheimer’s disease
20 conducted or supported under this subpart.

21 “(2) The resource information and technical assist-
22 ance provided under paragraph (1) shall include the main-
23 tenance of a central resource library in order to collect,
24 prepare, analyze, and disseminate information relating to
25 strategies and best practices used by recipients of grants

1 under this subpart and other researchers in the develop-
2 ment of the clinical research designed to increase the par-
3 ticipation of minority populations in such clinical re-
4 search.”.

5 (f) ANNUAL REPORTS.—Section 444 of the Public
6 Health Service Act (42 U.S.C. 285e–1), as amended by
7 subsection (e), is further amended by adding at the end
8 the following new subsection:

9 “(f)(1)(A) The Director of the Institute shall submit
10 annual reports to Congress on the impact of the amend-
11 ments made to this subpart by the ENACT Act of 2021.

12 “(B) The Secretary shall transmit a copy of each
13 such report to the Advisory Council on Alzheimer’s Re-
14 search, Care, and Services established under section 2(e)
15 of the National Alzheimer’s Project Act (Public Law 111–
16 375).

17 “(2) In each report under paragraph (1), the Director
18 of the Institute shall include information and data on the
19 following matters with respect to clinical trials on Alz-
20 heimer’s disease conducted during the preceding year:

21 “(A) The number of participants who are mem-
22 bers of a minority group in such clinical trials.

23 “(B) The number of such clinical trials for
24 which incentives under subsection (d)(3) were made
25 available, the nature of such incentives, the amount

1 of increased funding (if any) made available for re-
2 search on Alzheimer’s disease, and the training pro-
3 vided to principal investigators who are members of
4 a minority group and the amount of funding (if any)
5 for such training.

6 “(C) The number of such clinical trials for
7 which the principal investigator is a member of a mi-
8 nority group.

9 “(D) The number of such clinical trials for
10 which a significant percentage of researchers are
11 members of a minority group.

12 “(E) Modifications to patient eligibility criteria
13 in clinical trial designs under section 445I(e).

14 “(F) Outreach and education efforts conducted
15 under section 445(b)(3).

16 “(3) The Director of the Institute shall make each
17 report under paragraph (1) available to the public, includ-
18 ing through posting on the appropriate website of the De-
19 partment of Health and Human Services.”.

20 (g) AUTHORIZATION OF APPROPRIATIONS.—For each
21 of fiscal years 2022 through 2026, there is authorized to
22 be appropriated to the Secretary of Health and Human
23 Services \$60,000,000 to carry out the amendments made
24 by this section, to remain available until expended.