

## **Equity in Neuroscience and Alzheimer's Clinical Trials (ENACT) Act of 2021**

**PROBLEM:** Alzheimer's and other dementia disproportionately affect older Black and Hispanic Americans compared to older Whites. Black Americans are twice as likely to develop Alzheimer's and Hispanic Americans are one and a half times more likely to develop the disease. However, most of the Alzheimer's research to date has not included sufficient numbers of Blacks, Hispanics, Asian Americans/Pacific Islanders and Native Americans to be representative of the U.S. population. The underrepresentation of these populations not only hinders the ability of researchers to understand these health disparities, it also restricts their knowledge of how an approved drug or diagnostic may affect the population most likely to need the treatment. There is therefore an urgent need for current and future research to include increased numbers of Blacks, Hispanics, Asian Americans/Pacific Islanders, and Native Americans in clinical trials to ensure everyone benefits from advances in Alzheimer's science.

**BACKGROUND:** The National Institute on Aging (NIA) has established a good foundation of centers across the country that offer local resources, support, and opportunities to participate in Alzheimer's and other dementia research. NIA currently funds 31 [Alzheimer's Disease Research Centers](#) (ADRCs) at major medical institutions across the United States and four Exploratory ADRCs that are designed to expand and diversify research and education opportunities to new areas of the country, new populations, and new areas of science and approaches to research. There are also eight Alzheimer's disease-focused [Resource Centers for Minority Aging Research](#) (RCMARs) which focus on enhancing the diversity of the aging research workforce by mentoring promising scientists from underrepresented groups for sustained careers in aging research. These ADRCs and RCMARs are well-positioned to increase education and outreach activities to underrepresented populations within their communities. Strong community relationships can serve to address misconceptions and mistrust about research because the community has a sense of ownership in the research initiative. Community-based participatory research and engagement with community-based organizations are two strategies that can accomplish this goal.

**SOLUTION:** The ENACT Act would increase the participation of underrepresented populations in Alzheimer's and other dementia clinical trials by expanding education and outreach to these populations, encouraging the diversity of clinical trial staff, and reducing participation burden, among other priorities. Specifically, the ENACT Act would:

1. **Expand access and increase outreach and education to underrepresented populations**
  - a. Expand the number of ADRCs in areas with higher concentrations of underrepresented populations, such as through entities like Historically Black Colleges and Universities (HBCU), Hispanic-Serving Institutions, Tribal Colleges and Universities (TCU) or centers of excellence for other underrepresented populations.
  - b. Increase education and outreach activities from ADRCs and RCMARs to underrepresented communities and primary care physicians to increase awareness of current trial opportunities, the importance of participation and the disparate impact of the disease on their populations.
  - c. ADRCs/RCMARs would use community-based participatory research methodologies to engage with underrepresented populations.
2. **Enhance the diversity of principal investigators and study staff**
  - a. Encourage greater diversity among principal investigators and clinical trial study staff, so the researchers running the trials are more representative of the populations they're targeting for enrollment.
  - b. Provide training to principal investigators from underrepresented populations on topics like clinical protocols and grant writing to ensure they have the necessary expertise.

3. **Reduce participation burden**
  - a. Increase the number of Alzheimer's clinical trial sites in areas with high concentrations of underrepresented populations (identified by data from the U.S. Census and Medicare claims), to make it easier for these populations to enroll and participate.
  - b. Ensure grantees use community-based participatory research methodologies and engage with community-based organizations in order to build trust and awareness within underrepresented populations.
  - c. Encourage the use of remote health technologies like remote patient monitoring to reduce participation burden.
4. **Increase flexibility of clinical trial design**
  - a. Ensure inclusion and exclusion criteria are not unnecessarily restrictive so that older adults, individuals with a mild form of comorbid conditions and individuals at the extreme ends of the weight range are included, unless there is a strong clinical or scientific justification to exclude them.
  - b. Encourage the use of adaptive clinical trial design which could expand to include broader populations as the trial progresses through Phases I, II and III.
  - c. This is important because Black and Hispanic Americans with Alzheimer's have higher rates of comorbid conditions, such as cardiovascular disease and diabetes, and these conditions should not unnecessarily disqualify these populations from participating in clinical trials.
  - d. This is consistent with FDA's November 2020 guidance, "[Enhancing the Diversity of Clinical Trial Populations - Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry.](#)"
5. **Maintain NIA Resource Center**
  - a. Ensure NIA provides resource information and technical assistance to grantees to assist with their efforts to increase the participation of underrepresented populations and maintain a central resource library, such as through [ADORE](#), in order to collect and disseminate information on grantees' strategies and best practices.
6. **Annual Progress Reports**
  - a. Direct NIA to submit annual progress reports to Congress and HHS' Advisory Council on Alzheimer's Research, Care, and Services, including information on the types of incentives offered and how successful those incentives were in increasing participation of underrepresented populations in clinical trials.
7. **Authorization of Appropriations**
  - a. Authorizes \$60 million each year for fiscal years 2022-2026.

For additional information or to cosponsor the bill, please contact Betsey Coulbourn with Rep. Blunt Rochester at [Betsey.Coulbourn@mail.house.gov](mailto:Betsey.Coulbourn@mail.house.gov) or Adrianna Lagorio with Rep. Herrera Beutler at [Adrianna.Lagori@mail.house.gov](mailto:Adrianna.Lagori@mail.house.gov).