PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

August 12, 2026

U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Submitted electronically via Regulations.gov

Re: Comment on the "HHS Request for Comment on the Update to the National Plan To Address Alzheimer's Disease" (July 24, 2026) (Docket No. HHS-ASPE-2026-0298)

To Department of Health and Human Services

Public Responsibility in Medicine and Research (PRIM&R), which has more than 3,300 active members throughout the research enterprise, appreciates the opportunity to respond to the Notice of Request for Information (RFI) to inform a comprehensive update to the National Plan to Address Alzheimer's Disease.

PRIM&R is a nonprofit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community. PRIM&R seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science. Our perspective is informed by the experiences of professionals responsible for implementing federal research regulations across academic, healthcare, government, and independent research institutions.

As noted in the RFI, "HHS released the first National Plan to Address Alzheimer's Disease in 2012, establishing a comprehensive framework to accelerate scientific progress and improve support for individuals living with Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD) and their families. Since then, the National Plan has been updated annually and has guided federal efforts across research, care delivery, public health, and data infrastructure. HHS is now updating the overall National Plan to lead federal efforts through 2035."

HHS states it would like input to inform the future direction of these federal efforts, specifically on approaches to advancing AD/ADRD research and development of new interventions to prevent and treat dementia, risk reduction strategies, early detection and diagnostic tools, and/or enhanced care, services, and supports for people living with dementia and their families, caregivers, and care partners.

PRIM&R represents institutional review board (IRB) professionals, researchers, research administrators, institutional officials, and others responsible for the ethical oversight of research.

Our members interpret federal research protections every day across research institutions nationwide. Their work depends on a regulatory system that is clear, consistent, and predictable. Given this perspective, we are focusing our comments on HHS's question regarding opportunities and challenges in advancing research and development of interventions to prevent or treat AD/ADRD, including translating scientific progress into effective, scalable treatments and care.

On behalf of our community, we would like to offer the following comment with respect to this question included in the RFI: *What opportunities or challenges exist in advancing research and development of interventions to prevent or treat AD/ADRD, including translating scientific progress into effective and scalable treatments and care?*

Expanding the Scope of Alzheimer's and Alzheimer's Disease-Related Dementias Clinical Trials

Advancing Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD) research requires that clinical trials reflect the full scope of those affected by the disease. PRIM&R strongly supports efforts to ensure that AD/ADRD clinical trials reflect the vast array of populations affected by these conditions. Broad participation is essential to the ethical conduct of research and to generating evidence that is applicable across the populations who will ultimately receive these interventions.[1]

Recent research from the Yale School of Public Health found that AD/ADRD clinical trials have consistently failed to reflect the nation's racial and ethnic depth, despite the disproportionate burden of disease borne by many underrepresented populations. Limited representation raises important questions about the generalizability of trial findings and the evaluation of treatment safety and efficacy.

Likewise, the Alzheimer's Association, which is the largest nonprofit funder of Alzheimer's research, comments on the need for clinical trials to continue progress. The Association states, "Recruiting and retaining diverse trial participants is now the greatest obstacle, other than funding, to developing the next generation of Alzheimer's treatments. Individuals with dementia, caregivers and healthy volunteers are all needed to participate in clinical studies focused on Alzheimer's and other dementias."[2]

HHS should prioritize strategies that expand access to AD/ADRD trials for communities across the country, including reducing barriers to participation such as transportation, language, and geography. HHS must also prioritize increasing trial sites in communities with historically lower clinical trial participation rates. Ensuring representative participation is critical to advancing scientifically rigorous, ethically conducted research.

[1] https://ysph.yale.edu/news-article/study-finds-persistent-lack-of-diversity-in-us-alzheimers-clinical-trials/

[2] https://www.alz.org/alzheimers-dementia/research-and-progress/clinical-trials

Informed Consent and Decision-Making Capacity
Informed consent is foundational to ethical research, and it is particularly complex in the context of AD/ADRD, where cognitive decline may significantly affect a participant's capacity to make autonomous decisions.

The Belmont Report, which underlies the federal framework for human subjects research, holds three essential principles: Respect for Persons; Beneficence; and Justice. "Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them."[3]

PRIM&R calls on HHS to ensure the updated National Plan explicitly addresses the ethical complexities and obligations of researchers and IRBs in evaluating and protecting the decision-making capacity of AD/ADRD research participants throughout the course of a study, to include ongoing assessment of capacity to consent, re-consenting when appropriate, use of Legally Authorized Representatives (LARs), and training for researchers regarding consent in AD/ADRD research.

The Importance of Robust Research Oversight
The United States has long been the global leader in biomedical research, in significant part because of its rigorous and trusted system of human subjects protections.
IRBs and the human subjects research oversight infrastructure are what makes the research enterprise trustworthy. PRIM&R urges HHS to affirm and strengthen this oversight system in the updated National Plan, recognizing that robust protections and scientific progress are complementary, not competing, goals.

As HHS updates the National Plan, PRIM&R encourages prioritization of:

- Representative participation pools in AD/ADRD research
- Ethical practices of informed consent and decision-making capacity assessment
- Continued investment in human subjects research oversight
- Investment and support of the research enterprise infrastructure that advances scientific innovation while maintaining public trust

We welcome the opportunity to provide additional information or work collaboratively with HHS to develop approaches that advance accountability while continuing to foster rigorous research that benefits the American public. Thank you for your consideration of these comments.

Sincerely,

Ivy R. Tillman

Ivy R. Tillman, EdD, CIP
Executive Director
Public Responsibility in Medicine and Research (PRIM&R)

[3] https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html#xinform