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Francis S. Collins, MD, PhD
Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892

January 23, 2015

Re: Draft Policy, Single Institutional Review Board for Multi-Site Research

Dear Dr. Collins,

The Alzheimer's Association appreciates the opportunity to comment on the National Institutes of Health's (NIH) proposed policy on a single Institutional Review Board (IRB). As the largest non-profit funder of Alzheimer's research, the Association is committed to accelerating the progress of new treatments, preventions, and ultimately, a cure. We applaud NIH's efforts to improve safety for research volunteers, reduce approval times for clinical protocols, and safely expedite research progress.

As NIH notes, there is evidence that a single IRB for multi-site studies can lead to enhanced protections for patients through increased accountability, a decrease in conflicts of interest, and improved efficiency through a refocusing of resources. These benefits plus the acceleration of the pace of research is particularly important to individuals affected by Alzheimer's disease and other dementias. Alzheimer's remains the sixth leading cause of death in the United States, and the only cause of death among the top 10 without a way to prevent, cure, or even slow its progression.¹ The problems associated with multi-site IRB reviews are particularly relevant for neurodegenerative diseases such as Alzheimer's and other dementing illnesses: these diseases require already-lengthy trials and the need for sites to apply through each of their IRBs can delay progress for an additional year or more. The Alzheimer's research community overwhelmingly supports the concept of a centralized IRB, as have participants in several expert think tank and strategy meetings, including the 2012 Alzheimer's Disease Research Summit and meetings of the Advisory Council on Alzheimer's Research, Care, and Services.

Thank you for your leadership in these efforts. The Alzheimer's Association looks forward to our continued partnership with NIH. Please contact Laura Thornhill, Manager of Regulatory Affairs, at 202-638-7042 or lthornhill@alz.org if you have questions or if we can be of assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Egge", with a long horizontal flourish extending to the right.

Robert Egge
Executive Vice President

¹ Alzheimer's Association. (2014). *2014 Alzheimer's Disease Facts and Figures*.