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Jerry Menikoff, MD, JD  
Office for Human Research Protections  
Department of Health and Human Services  
1101 Wootton Parkway, Suite 200  
Rockville, Maryland 20852

December 29, 2015

Re: Federal Policy for the Protection of Human Subjects

Dear Dr. Menikoff,

The Alzheimer's Association appreciates the opportunity to comment on the Federal Policy for the Protection of Human Subjects, or the "Common Rule." 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. Clinical trials are indispensable to these ends. Increased participation in clinical trials is a priority for the Association, engaging persons with dementia, caregivers, and healthy volunteers through its TrialMatch® program, a matching service that includes more than 225 promising clinical studies being conducted at more than 700 trials sites across the country. We appreciate federal departments' and agencies' efforts to advance research while adhering to the highest scientific and ethical standards.

### **Specific Comments**

The Alzheimer's Association supports the proposed expansion of the definition of "human subject" to include biospecimens. We appreciate the balance that affected departments and agencies must strike between advancing clinical research, respecting personal privacy, and encouraging public trust. As you weigh these concerns, the Association believes that including biospecimens in the definition of "human subject" will bring clarity to consent issues for institutional review boards (IRBs), as is noted in the rule discussion. Because Alzheimer's and other dementias require lengthy trials, the efficiency of IRB processes is particularly important to our constituents.

We also support broad consent for use of biospecimens and identifiable private information. We believe this form of consent balances the facilitation of research while sufficiently informing participants of the possible use of their biospecimens and providing an opportunity to refuse consent. However, the Association strongly opposes a 10-year time limit (or any time limit) on broad consent. While we understand the intention behind it, this time limit is arbitrary and unlikely to provide participants with a meaningful understanding of the consequences. We believe time limits will impede critical research, especially research into chronic conditions such as Alzheimer's and other dementias.

The Alzheimer's Association opposes the proposed broad consent element requiring consent for the public posting of non-identifiable data. Not only does this not provide meaningful protection to research participants--their data is not identifiable--but it may cause confusion and hinder access to information, slowing research progress. Finally, we also note requiring that consent forms "prominently note" a

researcher's option to publically post potentially sensitive information is also likely to confuse participants, as most participants have little or no experience with public research databases of this kind.

Thank you for the opportunity to comment. 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, Government Affairs