

**DISCLAIMER: This document has not been updated to reflect regulatory changes effective January 21, 2019.**

## Research involving Cognitively Impaired Adults

[Federal regulations](#) specify that individuals with impaired decision-making capacity deserve special care and protection as human participants in research. This category of includes, but is not limited to, people experiencing mental retardation, neurological diseases and disabilities affecting judgment, mental disorders producing delusion or confusion, and/or dementia. All research projects focused on these populations require full committee review.

Investigators must take special care when assessing informed consent and voluntary participation with participants who may experience impaired decision-making capacity. In general, the informed consent process must address the need to preserve participant decision-making autonomy. Researchers must show that they have made every possible attempt to seek the informed consent of the participant as well as the informed consent of the participant's proxy. The IRB will ask researchers to assure that potential participants are fully informed about the voluntary nature of their participation, and that they remain free to withdraw at any time, even when proxy consent has been obtained. It is also essential that both participants and their proxies are fully informed about the risks, costs, and risk/benefit ratio of the study.

Studies involving cognitively impaired adults can pose somewhat unique problems. In general, resolution of issues will require full IRB discussion. Unfortunately, no one federal document exists that discusses these issues in depth. The American Geriatrics Society has produced an [informative paper](#) on conducting research with older adults with dementia. Although this paper is specifically focused on research participants with dementia, the principles are similar for those applied to participants with other types of cognitive impairments. We urge all researchers to read this document.