

## Appendix E: COGNITIVELY IMPAIRED INDIVIDUALS

Federal regulations require additional safeguards to protect the rights and welfare of all subjects who are “likely to be vulnerable to coercion or undue influence.” 45 CFR 46.111(b) includes “mentally disabled persons” in this category. This can include persons with impaired decision-making capacity as a result of trauma, mental retardation, some forms of mental illness, or dementia, whether temporary, progressive, or permanent. While the regulations do not specify what additional consent requirements must be observed, the IRB must be assured that the rights of the subject and in a manner consistent with the laws of the jurisdiction in which the research is conducted. Generally, if an adult subject lacks capacity to consent, consent may only be given by that individual's legally authorized representative. If you will be seeking a waiver or alteration of the consent process, please so indicate in the appropriate section below, including a justification for the waiver or alteration.

1. Describe the level of the subjects' incapacity.
2. If the subject is not legally capable of providing consent, describe how consent will be obtained from the subject's legally authorized representative.
3. Should the subject regain or develop the capacity to consent, then his or her consent must be obtained for any further research, as the consent of the legally authorized representative is no longer valid. Describe how the consent will then be obtained, if applicable.
4. Should the subject experience effects of progressive or intermittent disorders that lead to decisional impairment during the course of the study, investigators should consider the need to discuss with the prospective subjects whether they should designate someone to serve as a **legally authorized representative** at the outset of the study, consistent with all applicable laws. Even if a subject has consented on his or her own accord, a designated representative would be ready to step in as the legally authorized representative if the subject's ability to assess his or her own needs and interests becomes compromised during the study. If this pertains to your study, please describe how it will be addressed.
5. It is also usually desirable to obtain the assent of the subject. Describe how you will explain the study in a way that will be understandable to the subjects.