

DECISION-MAKING CAPACITY ASSESSMENT TOOL

INSTRUCTIONS: This form may be used to assess the decision-making capacity of potential subjects who may have or may be experiencing cognitive impairments.

Who should assess capacity? In general, the consent assessor should be a member of the research team or consultant familiar with dementias and/or cognitive impairment, and qualified to assess and monitor capacity to consent on an ongoing basis.

Potential Subject Name: _____ **IRB Protocol #:** _____

Study Title: _____

ASSESSMENT QUESTIONS:

1. Does the individual understand he/she would be participating in research and that research is voluntary?
 Yes No
2. Does the individual understand what will happen to him/her if he/she decides to participate?
 Yes No
3. Does the individual know how long he/she will be in the research study?
 Yes No
4. Can the individual explain one or two risks associated with the research study?
 Yes No
5. Can the individual explain what he/she should do to stop being in this research study?
 Yes No
6. Does the individual know who to contact if he/she experiences problems or has questions about the study?
 Yes No
7. **Interventional studies:** Can the individual explain what alternatives there are if he/she chooses not to participate?
 Yes No

INVESTIGATOR EVALUATION:

8. Does the individual express a choice about whether or not to participate?
 Yes No*
9. Does the individual have the decision-making capacity to give informed consent for this study?
 Yes No*

Printed Name of Investigator

Signature of Investigator

Date

* **NOTE:** Potential subjects who are found to have diminished capacity must be excluded **unless** the UCLA IRB has approved the use of surrogate consent from legally authorized representatives for the study in question.