UCI Office of Research

Decision Making Capacity Assessment Tool

Version 07-27-22

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/they 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 UCI IRB (or relying IRB) has approved the use of surrogate consent from legally authorized representatives for the study in question.