**Decision Making Capacity Assessment Tool**

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 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 they decides to participate? |  | YES | NO |  |
| 3. Does the individual know how long they 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 they should do to stop being in this research study? |  | YES | NO |  |
| 6. Does the individual know who to contact if they experience problems or have questions about the study? |  | YES | NO |  |
| 7. **Interventional studies:** Can the individual explain what alternatives there are if they choose 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.