

CHECKLIST FOR PRINCIPAL INVESTIGATORS TO COMPLETE REGARDING RESEARCH
INVOLVING **PARTICIPANTS WHO ARE COGNITIVELY IMPAIRED**

1. Will the research study enroll participants who have impaired decision-making capabilities? Y __ N__
2. Will the research study enroll participants who are legally competent? Y__ N__
3. Will **all** or **only some** participants be cognitively impaired? All ___Some ___
4. What following methods will be used to assess decision-making?
- Standardized Tests? Y __N__
 - List if any: _____
 - Comprehension Tool? Y __N__
 - List if any: _____
 - Other? Y __N__
 - List if any: _____
5. Who will sign the informed consent document:
- Participant (signing an assent form)? Y __N__
 - Next of kin? Y __N__
 - Legally authorized representative? Y __N__
6. Will a family member or caregiver be involved in the consenting process? Y __N__
7. Will the primary health care provider be involved in the consenting process? Y __N__
8. Is the researcher also the primary health care provider? Y __N__
9. Have risks been minimized? Y __N__
10. Will there be potential benefit to participants? Y __N__
11. Please provide justification for enrolling cognitively impaired participants:
