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:
    ___________________________________________________________________________
    ___________________________________________________________________________
    ___________________________________________________________________________