

Research Involving Cognitively Impaired Individuals**Principal Investigator:****Study Title:****PI Address:****PI Telephone / Email:****Date of Submission:**

1. Explain why it is necessary to involve cognitively impaired individuals as subjects for this research.

2. Appropriate provisions must be made for determining the participant's ability to provide consent or assent. Explain how the subject's mental status will be evaluated to determine whether they are capable of consenting or assenting. Tests or evaluation instruments used must be included with the application.

3. Is it reasonable to expect that during the course of the study, subjects may lose their capacity to consent or assent or their ability to withdraw (e.g., research involving administration of or withdrawal from psychotropic agents)?

No

Yes. Please explain what provisions have been made to protect the subjects' rights (e.g., power of attorney, consenting a caregiver as well as the subject, etc.).

4. Explain how persons authorized to give legally valid consent on behalf of any individual(s) judged incapable of consenting on their own behalf will be identified and how they will be adequately informed of their roles and obligations for protecting the subject.

5. Will the patient's physician or another health care provider be consulted before any individual is invited to participate in the research?

No

Yes. Please explain.

6. In your opinion, is the research likely to interfere with ongoing therapy or regimens?

No

Yes. Please explain.

7. Are institutionalized individuals going to be involved in the research?

No

Yes. Please provide justification for the use of that population and explain why non- institutionalized subjects are not appropriate for this research and why they may not be reasonably available.

8. Describe steps taken to minimize the possibility of coercion or undue influence. Check all that apply.

There will not be any threat of harm or adverse consequences if the subject does not agree to participate in the study.

The information provided during the consent/assent process will be presented in a balanced way with equal emphasis on all elements of consent/assent (e.g., there will not be over- emphasis of benefits and under-emphasis of risks).

Other (specify):

Please complete this section if the research is conducted at or funded by the VA

VA Studies Only: Research involving persons with impaired decision-making capability may only be approved when the following conditions are met. Please respond to each condition appropriately.

9. Explain how only incompetent persons or persons with impaired decision-making capacity are suitable as research subjects.

10. Explain how the research entails no significant risks, tangible or intangible, or if the research presents some probability of harm explain how there is a least a greater possibility of direct benefit to the participant.

11. Explain procedures that have been devised to ensure that subjects' representatives are well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision making capacity, including being given a description of both the research and their obligations.

Principal Investigator Acknowledgement

P.I.'s Name: _____ Date: _____

Electronic Signature:

Faculty Advisor Acknowledgement

Faculty Advisor's Name: _____ Date: _____

Electronic Signature:

Please save a copy of the form for your records and submit the final form electronically by clicking the "Submit Form" to the left or at top of page.