NOTE: Investigators, please include this form with IRB application if your research involves cognitively impaired (decisionally impaired or decisionally challenged) persons. If your research involves people with more than one vulnerability, please complete the supplementary form for that population as well.

The IRB may ask you to designate an impartial observer to monitor the consent process or it may send its own representative to do so.

Section 1.
Check the box next to the category that in your best judgment applies to your research, and provide the information requested in the space provided.

Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests. (i.e., daily life of health persons)

☐ Category 1
My research does not involve greater than minimal risk.

Explain. If appropriate, describe what provisions are in place for allowing a Legally Authorized Representative (LAR) or other person with the subject’s best interests at heart to assist the subject in navigating the research process:

☐ Category 2
My research presents greater than minimal risk and prospect of direct benefit to the subjects.

Explain. If appropriate, describe what provisions are in place for allowing a Legally Authorized Representative (LAR) or other person with the subject’s best interests at heart to assist the subject in navigating the research process:

☐ Category 3
My research presents greater than minimal risk and no prospect of direct benefit to the subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition, because:
Explain. If appropriate, describe what provisions are in place for allowing a Legally Authorized Representative (LAR) or other person with the subject’s best interests at heart to assist the subject in navigating the research process.

☐ Category 4
My research does not fall under Category 1, 2, or 3, listed above.

If you check this category, the IRB determines additional safeguards on a case-by-case basis.

Section 2.

1. Explain why individuals with impaired decision-making capacity are suitable for this research. If the objective(s) of the study allow for inclusion of competent subjects, provide compelling justification for inclusion of incompetent subjects.

2. Describe who will determine individuals’ competency to consent and the criteria to be used in determining competency (e.g., use of standardized measurements, consults with another qualified professional, etc...).

3. It should be recognized that decision-making capacity may fluctuate, requiring ongoing assessment during the course of the research. Is it reasonable to expect that during the course of the research, subjects may lose their capacity to consent or their ability to withdraw?

☐ Yes If yes, answer 3 a, b, and c. ☐ No If no, skip to Q. #4.

(a) Describe what provisions are in place for periodic reconsent. Include the rationale and procedure, the proposed interval, any changes in behavior that might signal the need to reconsent whether or not the proposed interval has elapsed, and any consultative resources that are available for these decisions. Describe the process for reconsent or reassent, or reassessment of willingness to continue participation.

(b) Describe what provisions are in place to protect the subjects’ rights in the event they lose their capacity to consent or their capacity to withdraw during the course of the research. (e.g., power of attorney, consent a caregiver as well as the patient, etc.).

(c) Describe what provisions are in place for use of additional waiting periods to allow potential participants time to consult with family members about whether or not to participate.

4. Explain how you will identify who is authorized to give legally valid consent on behalf of any individual(s) determined to be incapable of consenting on their own behalf.

5. Explain the criteria you will use for determining when assent is required for subjects who are not competent.
6. Explain what methods will be used for **evaluating dissent** (e.g., description of behaviors that would indicate individual does not want to participate (such as moving away, certain facial expressions, head movements, etc.).

7. The research protocol should include someone who can be reasonably assumed to have the subject’s best interest in mind and can assist the subject in navigating the consent and research process. A person holding durable power of attorney or other legal designee, spouse, close relative who is involved in ongoing care of subject, other person with a personal or blood relationship who is involved in ongoing care of subject, or other close relatives or friends may assume this role. Describe how individuals will be identified to serve in this capacity. If this request is not appropriate for this study, justify why it should be waived.

8. If applicable, describe when and how the individual’s health care provider will be consulted prior to participation in the research. **NOTE:** If the Principal Investigator (PI) is also the individual’s health care provider, address how the PI will separate the roles of clinician and researcher.

9. Will the research interfere with current therapy or medications?
   - [ ] No
   - [ ] Yes
   If yes, describe what the changes may entail (i.e., if the subject will be removed from routine drugs/treatments, wash out periods, etc.) and the potential risks.

10. Does your research involve institutionalized individuals?
    - [ ] Yes If yes, answer 9(a).
    - [ ] No If no, skip to the next section.
    (a) Justify the use of institutionalized individuals and explain why non-institutionalized individuals can not be substituted.

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**Section 3.**
Complete this section if your research involves **individuals from the Department of Veterans Affairs (VA).**

1. Address procedures you will use to ensure the subject’s representative is informed regarding his/her role and obligation to protect the incompetent subject or person with impaired decision-making capacity.

2. Address procedures you will use to ensure the subject’s representative has been told of his/her obligation to try to determine what the prospective subject would do if competent, or if the prospective subject’s wishes cannot be determined, what the subject’s representative thinks is in the incompetent person’s best interests:

3. The VA has specific requirements and procedures for determining and documenting in the person’s medical record that an individual is incompetent or decisionally-impaired. There are
additional requirements if the lack of decision-making capacity is based on diagnoses of mental illness. These requirements are outlined in the Veterans Health Administration (VHA) Handbook 1200.5, Section II. Have you reviewed these requirements and included them in your procedures?

☐ Yes  ☐ No

4. Justify that the research involves no significant risks, or if the research presents probability of harm, justify that there is at least a greater probability of direct benefit to the subject:

[Veterans Health Administration Handbook 1200.5, July 15, 2003, Section 11 - Research Involving Human Subjects with Surrogate Consent, and Appendix D Vulnerable Populations, Section 6(c)]

Section 4.
For research involving cognitively impaired persons outside the state of Alabama, also complete this section.

a) Provide information regarding the state definition of legally authorized representative, child, decisionally-impaired, or guardian, as applicable to the research and to the federal definitions. [If the research is to be conducted in more than one state outside of Alabama, provide this information for each state.]

Definitions:

Assent - is defined as a child’s or decisionally challenged individual’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Competence – “Technically, a legal term, used to denote capacity to act on one’s own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.” [OHRP Institutional Review Board Guidebook, Chapter VI, Section D]

Permission is defined as the agreement of parent(s) or guardian to the participation of their child or ward in research or clinical investigation. Permission includes the element of consent set forth in federal regulations and outlined in the informed consent template included in the IRB expedited and full review applications.

In Alabama child/children refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Guidance: Alabama Law on Children, Minors, Consent, and Other Research-Related Topics. Individuals less than 18 years of age who are not emancipated meet the federal definition for “child” (e.g., Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), and U.S. Department of Education).

Legally authorized representative (LAR) is an individual who has the authority to make research participation decisions on behalf of another. Alabama law does not specify who may make such decisions. UA legal counsel recommends the following in this order of preference: A legally appointed guardian, a health care proxy or person authorized to make medical decisions in conjunction with a durable power of attorney, a spouse, an adult child, next of kin, or a person or agency acting in loco parentis.

NOTE: Consent from a legally authorized representative involves all the ethical and regulatory concerns that apply to consent from the prospective participant.