**Clinical Research Involving Cognitively Impaired Adults**

**Supplemental Submission Form**

***Utilize this submission form when conducting clinical research involving participants who are cognitively impaired.*** *Cognitively impaired adults are individuals who have a diminished capacity for judgment and reasoning due to a psychiatric, organic, developmental, or other disorder that affects cognitive or emotional functions. Other individuals may be considered decisionally impaired or have limited decision-making ability because they are under the influence of or dependent on drugs or alcohol, suffering from degenerative diseases affecting the brain, are terminally ill, or have severely disabling physical handicaps.*

**Inclusion of Cognitively Impaired Individuals**

1. Does the research include participants who have the conditions above that may impair their judgement or prevent them from providing consent?

[ ]  **Yes 🡪** continue below[ ]  **No 🡪** Submission of this form is not required.

*A subject is unable to consent if he/she/they are unable to voluntarily reason, understand, and appreciate the nature and consequences of proposed health research interventions, including the subject’s diagnosis and prognosis, the burdens, benefits, and risks of, and alternatives to, any such research, and to reach an informed decision.*

1. Can the objectives of the research be met by conducting the research in a population that does not have the disorder that may affect decision making capacity?

[ ]  **Yes 🡪** Please explain why this study is still ethical to conduct in this population:*Click or tap here to enter text.*

[ ]  **No 🡪** Please explain:*Click or tap here to enter text.*

1. Is the research designed for a disease or condition relevant to the vulnerable population under study?

[ ]  **Yes, continue below**

[ ]  **No 🡪** Please explain why this study is still ethical to conduct in this population:*Click or tap here to enter text.*

1. Does the research involve in-patients being treated for mental illness or mental health concerns?

[ ]  **Yes 🡪 Please note the following for research conducted in NJ:**

* *NJ state law precludes a waiver of informed consent for this patient population when “experimental research” is being conducted.*
* *“Experimental research” must be “directly related to the goals of the patient’s treatment program.”*

*Consultation with**the Office of General Counsel may be required.*

[ ]  **No, continue below**

**Capacity to Provide Consent**

*The protocol or application should describe the following in relation to the plan to determine capacity:*

* ***When*** *and* ***how*** *participants will be assessed for capacity, on an individual basis, and whether there may be a secondary confirmation;*
* *Criteria for determining competence,* ***based on the degree of risk or discomfort presented by the research procedures and the extent to which therapeutic gain can be anticipated;***
* *Plans for surrogate consent from an authorized representative. Please see IRB SOP IC 705 for a list of appropriate LARs based on state law.*
* *Plans for assent of the cognitively impaired participant and consent if capacity may be regained during the course of the study. Please see IRB SOP IC 704 for policy on assent.*
1. Is the research being conducted in New Jersey?

[ ]  **No**

[ ]  **Yes 🡪** Answer the following questions

1. Please confirm that capacity will be determined by an attending physician with no connection to the research:

[ ]  **Yes 🡪** Continue[ ]  **No 🡪** *The research may not be approvable under NJ law.*

**NOTE:** NJ state law requires that *“a determination that a subject is unable to consent, as well as the extent of his incapacity and the likelihood that he will regain decision-making capacity,* ***shall be made by an attending physician with no connection to the proposed research*** *and shall be made to a reasonable degree of medical certainty…. a subject’s objection to a determination of incapacity or objection to the proposed research intervention shall be binding, unless a court of competent jurisdiction determines that the subject lacks decision-making capacity.”*

1. Confirm that a witness will be present during the consent discussion.

[ ]  **Yes 🡪** Ensure your consent form includes a witness signature line

[ ]  **No 🡪** *The research may not be approvable under NJ law.*

1. If there is any planned compensation, please confirm that planned compensation will not be provided to the individual who provides surrogate consent.

[ ]  **N/A, no compensation**

[ ]  **No 🡪** *The research may not be approvable under NJ law.*

[ ]  **Yes**

**Risk/ Benefit Determinations**

1. Please identify the risk/benefit ratio for this population (choose 1):
2. [ ]  **Minimal risk**
3. [ ]  **More than minimal risk with a prospect of direct benefit**

*If the research may be conducted in New Jersey, please answer the following questions:*

1. Explain why the risk is justified by the anticipated benefit to the subject: *Click or tap here to enter text.*
2. Explain why the relation of anticipated benefit to risk is at least as favorable, to the subject, as that presented by available alternative approaches: *Click or tap here to enter text.*
3. If a currently recognized treatment exists, please confirm that the subject or his guardian or authorized representative, as applicable, shall be presented with the choice of the recognized treatment and the research protocol: *Click or tap here to enter text.*
4. [ ]  **More than minimal risk without a prospect of direct benefit, but of vital importance to the vulnerable population.**

*If this is a non-therapeutic clinical trial with no direct clinical benefit, please answer the following two questions:*

1. Explain how the research will ensure negative impact on participant’s wellbeing will be minimized and low: *Click or tap here to enter text.*
2. Explainplans for withdrawal of participants if they become unduly distressed: *Click or tap here to enter text.*

*If the research may be conducted in New Jersey, please also answer the following three questions:*

1. Explain how the study is likely to yield generalizable knowledge about the subject's disorder or condition: *Click or tap here to enter text.*
2. Explain why, by its very nature, the research cannot be conducted without the participation of decisionally incapacitated persons as subjects: *Click or tap here to enter text.*
3. Explain how the research involves no more than a minor increase over minimal risk: *Click or tap here to enter text.*