Persons with Cognitive or Decisional Impairment

Risk and Intent Approval Categories

The research must have an acceptable level of risk and appropriate intent in order for the IRB to approve the study involving individuals with impaired decision making capacity.

Please select the appropriate risk category for this study (at least one must apply)
The research presents:

- [ ] No greater than minimal risk to the subject as determined by the IRB.
- [ ] Greater than minimal risk, but offers the prospect of direct benefit(s) or may contribute to the well-being of the individual.
- [ ] A minor increase over minimal risk and no prospect of direct benefit to the participants, but is likely to yield generalizable knowledge about the individual's disorder or condition that is of vital importance for the understanding or amelioration of the individual's disorder or condition.

Please select the appropriate intent category (one must apply):
The intent of the research is to study:

- ( ) The disorder leading to the individual's decision making capacity, if the study cannot be performed with only persons who retain decision-making capability.
- ( ) A disorder not directly related to the individual's lack of decision-making capacity, but the investigator can make a compelling argument for including individuals who lack decision-making capacity in the study.

Clear

Consent and Assent Considerations

If you select any of the following conditions, please specify any requirements below:

( ) Yes
( ) No
Clear

For persons with impaired decision-making capacity or mentally disabled adults, would an assent process be more appropriate along with informed consent from a legal representative?
If yes, you will be required to complete the assent checklist.
If Yes:

( ) Yes
( ) No
Clear

Should a re-assenting or re-consenting process take place throughout the study to ensure voluntary participation?
If yes, indicate time interval(s) below.

( ) Yes
( ) No
( ) N/A
Clear

Have procedures been devised to ensure that the participant's representatives are well informed regarding their roles and obligations to protect cognitively impaired persons or persons with impaired decision making capacity?

- *Representatives must be informed in writing that their obligation is to try to determine what the participant would do if competent, or if the subject's wishes cannot be determined, what is in the participant's best interest. Roles and obligations must be outlined in the informed consent document.*

( ) Yes
( ) No
( ) N/A
Clear

For those participants who may recover an adequate amount of decision-making capacity, are there plans to obtain full informed consent from the participant?

- *N/A for mentally disabled persons.*

Consent and Assent Requirements:

Specific Concerns:

If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolutions to Concerns:
Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

REMINDER: *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

DETERMINATION: Have additional safeguards been included in the study to protect the rights and welfare of mentally disabled persons or persons with impaired decision making capacity?

- ○ Yes
- ○ No

Clear