




MENTALLY DISABLED PERSONS OR PERSONS WITH COGNITIVE OR DECISIONAL IMPAIRMENT

If all of the following are answered "yes", the study has made adequate provisions to protect the rights and welfare of the participants:

Yes No Clear	Does the investigator demonstrate that there is a compelling reason to include individuals who are mentally disabled and/or persons with impaired decision-making capacity? <ul style="list-style-type: none"> <i>Individuals who are mentally disabled and/or persons with impaired decision-making capacity must not be subjects in research simply because they are readily available.</i>
Yes No 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? <ul style="list-style-type: none"> <i>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.</i> <p><i>Who can act as legally authorized representative</i> </p>

The following must be answered "yes" for VA research in order for the research to be conducted:

N/A Research will not be conducted at the VA

Yes No Clear	Does the proposed research entail no significant risks, tangible or intangible? Or if the research presents some probability of harm, is there at least a greater probability of direct benefit to the participant? <ul style="list-style-type: none"> <i>Cognitively impaired persons or persons with impaired decision making capacity must not be subjects in VA research that imposes a risk of injury, unless that research is intended to benefit that subject and the probability of benefit is greater than the probability of harm.</i>
--------------------	--

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? <i>If yes, you will be required to complete the assent checklist.</i> If Yes:	
Yes No	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	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
Clear

- *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