UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	**OIA-417 CHECKLIST:** Cognitively Impaired Adults		
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The purpose of this checklist is to provide support for IRB members or the designated reviewer following the *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent, when a clinical trial involves cognitively impaired adults as subjects. This checklist, or equivalent, may be used for all reviews (initial, continuing, amendment, review by the convened IRB, and review using the expedited procedure). It does not need to be completed or retained.

IRB Number:	
Investigator:	

All research must meet the criteria in Sections 1 or 2.

	1 Research Involving cognitively impaired adults with anticipated direct benefit to the subject (Check if **"Yes."** All must be checked)
☐	One of the following is true: **(Check box that is true)** ☐ The research involves only minimal risk ☐ Subjects have a disease or condition for which the procedures involved in the research hold out a prospect of direct benefit to the individual subject that is unavailable outside the research context. ☐ The objectives of the trial cannot be met by means of study of subjects who can give consent personally. *Provide protocol specific findings justifying this determination:*
☐	Risks to subjects are reasonable in relation to anticipated benefits to subjects. *Provide protocol specific findings justifying this determination:*
☐	The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches. *Provide protocol specific findings justifying this determination:*
☐	The trial is not prohibited by law. *Provide protocol specific findings justifying this determination:*
☐	Subjects will be particularly closely monitored. *Provide protocol specific findings justifying this determination:*
☐	Subjects will be withdrawn if they appear to be unduly distressed. *Provide protocol specific findings justifying this determination:*
☐	The proposed plan for the assessment of the capacity to consent is adequate. *Provide protocol specific findings justifying this determination:*
☐	The subject will be informed about the research to the extent compatible with the subject's understanding. *Provide protocol specific findings justifying this determination:*
☐	Assent will be obtained from: **(One of the following must be checked)** ☐ All subjects. ☐ Some subjects, specify: ☐ None of the subjects
☐	The consent document includes a signature line for a legally authorized representative.
☐	If capable, the subject will sign and personally date the written informed consent.

	2 Research involving cognitively impaired adults with NO anticipated direct benefit to the subject[1] (Check if **"Yes."** All must be checked)
☐	Subjects have a disease or condition for which the procedures involved in the research are intended. *Provide protocol specific findings justifying this determination:*
☐	The objectives of the trial cannot be met by means of study of subjects who can give consent personally. *Provide protocol specific findings justifying this determination:*
☐	The foreseeable risks to the subjects are low. *Provide protocol specific findings justifying this determination:*
☐	The negative impact on the subject's well-being is minimized and low. *Provide protocol specific findings justifying this determination:*
☐	The trial is not prohibited by law. *Provide protocol specific findings justifying this determination:*
☐	Subjects will be particularly closely monitored. *Provide protocol specific findings justifying this determination:*
☐	Subjects will be withdrawn if they appear to be unduly distressed.

[1] If consent is to be obtained from the legal representative of the experimental subjects as defined in Department of Defense Instruction (DODI) 3216.02, the research must intend to benefit each participant enrolled in the study.

	Provide protocol specific findings justifying this determination:
☐	The proposed plan for the assessment of the capacity to consent is adequate. *Provide protocol specific findings justifying this determination:*
☐	The subject will be informed about the research to the extent compatible with the subject's understanding.
☐	Assent will be obtained from: **(One of the following must be checked)** ☐ All subjects. ☐ Some subjects, specify: ☐ None of the subjects
☐	The consent document includes a signature line for a legally authorized representative.
☐	If capable, the subject will sign and personally date the written informed consent.