

CHECKLIST – REQUIREMENTS FOR RESEARCH INVOLVING COGNITIVELY IMPAIRED ADULTS

SC 501-C

01/01/07

Investigator: _____

IRB #: _____

Study Title: _____

	Yes	No	NA
Does the IRB need to include a member knowledgeable about and experienced with the mentally disabled or cognitively impaired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the research pertain to mental disabilities so that it is necessary to involve persons who are mentally disabled as subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If the investigator proposes to involve institutionalized individuals, has he or she provided sufficient justification for using that population? Are noninstitutionalized subjects appropriate for the research and reasonably available? Does the research pertain to aspects of institutionalization?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are adequate procedures proposed for evaluating the mental status of prospective subjects to determine whether they are capable of consenting? Are these procedures appropriate both to the subject population and the nature of the proposed research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is more than minimal risk involved? If so, is the risk justified by anticipated benefits to the participating subjects and the importance of the knowledge that may reasonably be expected to result?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is it possible to identify persons authorized to give legally valid consent on behalf of any individuals judged incapable of consenting on their own behalf? Should assent of the prospective subjects also be required? If incapable of giving valid consent, can subjects' objection to participation be overridden? Under what circumstances?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Should an advocate or consent auditor be appointed to ensure that the preferences of potential subjects are elicited and respected? Should someone ensure the continuing agreement of subjects to participate, as the research progresses?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Comments: _____

Primary Reviewer_____
Date