CHECKLIST: Research Involving Cognitively Impaired Adults

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The purpose of this checklist is to provide support for IRB members or the Designated Reviewer when reviewing research involving cognitively impaired adults as subjects. This checklist must be used.

- For review using the expedited procedure this checklist is to be completed by the Designated Reviewer to document determinations required by the regulations and protocol specific findings justifying those determinations.
- For review using the convened IRB this checklist is to be completed by the convened IRB to document determinations required by the regulations and protocol specific findings justifying those determinations and retained in the protocol file.

1 Research Involving Cognitively Impaired Adults in Which There is Anticipated Direct Benefit to the Subject (All items must be "Yes")	
☐ **Yes** ☐ **No**	One of the following is true**. (Check box that is true**) ☐ The risk to the subjects is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject. ☐ More than minimal risk to subjects is presented by a monitoring procedure that is likely to contribute to the subject's well-being.
☐ **Yes** ☐ **No**	The risk is justified by the anticipated benefit to the subjects.
☐ **Yes** ☐ **No**	The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.
☐ **Yes** ☐ **No**	The proposed plan for the assessment of the capacity to consent is adequate
☐ **Yes** ☐ **No**	Assent is required of: (One of the following must be "**Yes"**) One of the following is true: **(Check box that is true)** ☐ All subjects. ☐ All subjects capable of being consulted. ☐ None of the subjects
☐ **Yes** ☐ **No**	The consent document includes a signature line for a legally authorized representative.
2 Research Involving Cognitively Impaired Adults in Which There is NO Anticipated Direct Benefit to the Subject (All items must be "Yes")	
☐ **Yes** ☐ **No**	The proposed plan for the assessment of the capacity to consent is adequate
☐ **Yes** ☐ **No**	The objectives of the trial cannot be met by means of study of subjects who can give consent personally.
☐ **Yes** ☐ **No**	The foreseeable risks to the subjects are low.
☐ **Yes** ☐ **No**	The negative impact on the subject's well-being is minimized and low.
☐ **Yes** ☐ **No**	The trial is not prohibited by law.
☐ **Yes** ☐ **No**	Subjects have a disease or condition for which the procedures involved in the research are intended.
☐ **Yes** ☐ **No**	Subjects will be withdrawn if they appear to be unduly distressed.
☐ **Yes** ☐ **No**	The proposed plan for the assessment of the capacity to consent is adequate
☐ **Yes** ☐ **No**	Assent is required of: (One of the following must be "Yes") One of the following is true: (Check box that is true) ☐ All subjects. ☐ All subjects capable of being consulted. ☐ None of the subjects
☐ **Yes** ☐ **No**	The consent document includes a signature line for a legally authorized representative.