SPECTRUM HEALTH	CHECKLIST: Research Involving Adults with Impaired Decision Making Capacity			IRB #
	NUMBER	DATE	PAGE	Review Type:
	HRP-422	12/31/2018	1 of 3	Status:

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval and Additional Considerations when research involves cognitively impaired adults as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.) The research must meet one of the sets of criteria in sections 1-3.

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to CHECKLIST: Non-Committee Review and the IRB office retain this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the TEMPLATE MINUTES to document determinations required by the regulations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations and the IRB office retains this checklist in the protocol file.

1 Minimal Risk[1] Research (All must be "Yes" or "N/A")

☐Yes ☐No	The research involves no more than minimal risk to adults with impaired decision making capacity.
☐Yes ☐No ☐ N/A	For research sponsored/funded by the Dept. of Defense, the research does not involve human beings as *experimental subjects*.[2] (N/A if not DoD sponsored/funded.)
☐Yes ☐No ☐ N/A	Assent will be required of the following: (N/A if a waiver of consent has been granted. If Yes, one of the following must be checked.) ☐ All subjects ☐ All subjects who have the cognitive ability to be assented consistent with the protocol (or application) specifications ☐ None of the subjects ☐ Other Specify:
☐Yes ☐No ☐ N/A	The consent document includes a signature line for a legally authorized representative and consent is required in accordance with Spectrum Health policy. (N/A if a waiver of consent has been granted.)

2 Research Involving Adults with Impaired Decision Making Capacity 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) ☐ 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:*
☐Yes ☐No	Risks to subjects are reasonable in relation to anticipated benefits to subjects. *Provide protocol specific findings justifying this determination:*
☐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. *Provide protocol specific findings justifying this determination:*
☐Yes ☐No	The trial is not prohibited by law. *Provide protocol specific findings justifying this determination:*
☐Yes ☐No	Subjects will be particularly closely monitored. *Provide protocol specific findings justifying this determination:*

[1]*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal persons or during the performance of routine or psychological examinations or tests in normal persons.

[2]Department of Defense defines "research involving a human being as an experimental subject" as "an activity for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction."

☐Yes ☐No	Subjects will be withdrawn if they appear to be unduly distressed. *Provide protocol specific findings justifying this determination:*
☐Yes ☐No	The proposed plan for the assessment of the capacity to consent is adequate. *Provide protocol specific findings justifying this determination:*
☐Yes ☐No	The subject will be informed about the research to the extent compatible with the subject's understanding. *Provide protocol specific findings justifying this determination:*
☐Yes ☐No	Assent will be required of the following: (One of the following must be checked) ☐ All subjects ☐ All subjects who have the cognitive ability to be assented consistent with the protocol (or application) specifications ☐ None of the subjects ☐ Other Specify:
☐Yes ☐No	The consent document includes a signature line for a legally authorized representative and consent is required in accordance with Spectrum Health policy.
☐Yes ☐No	If capable, the subject will sign and personally date the written informed consent.
3 Research Involving Adults with Impaired Decision Making Capacity in Which There is NO Anticipated Direct Benefit to the Subject (All items must be "Yes")	
☐Yes ☐No	Subjects have a disease or condition for which the procedures involved in the research are intended. *Provide protocol specific findings justifying this determination:*
☐Yes ☐No	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:*
☐Yes ☐No	The foreseeable risks to the subjects are low. *Provide protocol specific findings justifying this determination:*
☐Yes ☐No	The negative impact on the subject's well-being is minimized and low. *Provide protocol specific findings justifying this determination:*
☐Yes ☐No	The trial is not prohibited by law. *Provide protocol specific findings justifying this determination:*
☐Yes ☐No	Subjects will be particularly closely monitored. *Provide protocol specific findings justifying this determination:*

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[2]Department of Defense defines "research involving a human being as an experimental subject" as "an activity for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction."

☐Yes ☐No	Subjects will be withdrawn if they appear to be unduly distressed. *Provide protocol specific findings justifying this determination:*
☐Yes ☐No	The proposed plan for the assessment of the capacity to consent is adequate. *Provide protocol specific findings justifying this determination:*
☐Yes ☐No	The subject will be informed about the research to the extent compatible with the subject's understanding. *Provide protocol specific findings justifying this determination:*
☐Yes ☐No	Assent is required of the following: (One of the following must be checked) ☐ All subjects ☐ All subjects who have the cognitive ability to be assented consistent with the protocol (or application) specifications ☐ None of the subjects ☐ Other Specify:
☐Yes ☐No	The consent document includes a signature line for a legally authorized representative and consent is required in accordance with Spectrum Health policy.
☐Yes ☐No	If capable, the subject will sign and personally date the written informed consent.

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