Institutional Review Board

Checklist: Impaired Decision Making or Unable to Consent

NUMBER | HRP-417

IRB Number:	
Protocol Name:	
Investigator:	

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

1. Research 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) ☐ 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 or subjects who can give consent personally.
☐	The investigator is knowledgeable about the condition and any level of impairment that is likely to be present in the participant population.
☐	Risks to subjects are reasonable in relation to anticipated benefits to subjects.
☐	The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.
☐	The trial is not prohibited by law.
☐	Subjects will be particularly closely monitored.
☐	Subjects will be withdrawn if they appear to be unduly distressed.
☐	The proposed plan for the assessment of the capacity to consent is adequate.
☐	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 (LAR).
☐	If capable, the subject will sign and personally date the written informed consent or assent.

2. Research with NO anticipated direct benefit to the subject (Check if "yes". All must be checked)

☐	Subjects have a disease or condition for which the procedures involved in the research are intended.
☐	The investigator is knowledgeable about the condition and any level of impairment that is likely to be present in the participant population.
☐	The objectives of the trial cannot be met by means of study of subjects who can give consent personally.
☐	The foreseeable risks to the subjects are low.
☐	The negative impact on the subject's well-being is minimized and low.
☐	The trial is not prohibited by law.
☐	Subjects will be particularly closely monitored.
☐	Subjects will be withdrawn if they appear to be unduly distressed.
☐	The proposed plan for the assessment of the capacity to consent is adequate.
☐	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

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☐	The consent document includes a signature line for a Legally Authorized Representative (LAR)
☐	If capable, the subject will sign and personally date the written informed consent or assent. ☐ N/A

This population of research is: (Please check one, and sign/date)

- ☐ APPROVED
- ☐ Approved with Conditions, Minor Clarifications and/or Modifications back to the IRB Office
- ☐ Approved with Conditions, Major Clarifications and/or Modifications back to the Full (Convened) IRB Meeting
- ☐ Do Not Recommend approval at this time. List Reasons.
  (Convened board must agree by a vote if study is not approved.)

Comments Section:

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(Reviewer) (Date)