



Federal Wide Assurance #: FWA00011521

IRB Registration #: IRB00004891

### IRB REVIEWER CHECKLIST: Cognitively Impaired Adults

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: This checklist must be used for all reviews as applicable. Initial review requires the use of this checklist. Continuing review and modifications where the determinations relevant to this checklist have changed require an updated checklist.

For review by the expedited procedure, the completed checklist is provided to the Designated Reviewer as an attachment in the assign review function. . The Designated Reviewer may accept or require changes to this checklist via the “Submit Non-Committee Review” activity, either by uploading a revised checklist or including the changes that are requested in the review comment. The IRB Office retains this checklist in the protocol file.

For review by the convened IRB, the board completes this checklist and the IRB Office uploads this checklist in the “Submit Committee Review” activity and retains this checklist in the protocol file.

#### 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: **(Checkbox 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 the study of subjects who can give consent personally.

*Provide protocol specific findings justifying this determination:* Click or tap here to enter text.

- Risks to subjects are reasonable in relation to anticipated benefits to subjects.

*Provide protocol specific findings justifying this determination:* Click or tap here to enter text.

- 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:* Click or tap here to enter text.

- Subjects will be particularly closely monitored.

*Provide protocol specific findings justifying this determination:* Click or tap here to enter text.

- Subjects will be withdrawn if they appear to be unduly distressed.

*Provide protocol specific findings justifying this determination:* Click or tap here to enter text.

- The proposed plan for the assessment of the capacity to consent is adequate.

*Provide protocol specific findings justifying this determination:* Click or tap here to enter text.

<input type="checkbox"/>	The subject will be informed about the research to the extent compatible with the subject's understanding. <i>Provide protocol specific findings justifying this determination:</i> Click or tap here to enter text.
<input type="checkbox"/>	Assent will be obtained from: <b>(One of the following must be checked)</b> <input type="checkbox"/> All subjects. <input type="checkbox"/> Some subjects, please <i>specify</i> : Click or tap here to enter text. <input type="checkbox"/> None of the subjects
<input type="checkbox"/>	The trial is not prohibited by law.
<input type="checkbox"/>	The consent document includes a signature line for a Legally Authorized Representative (LAR).
<input type="checkbox"/>	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** (Check if "Yes". All must be checked)

<input type="checkbox"/>	Subjects have a disease or condition for which the procedures involved in the research are intended. <i>Provide protocol specific findings justifying this determination:</i> Click or tap here to enter text.
<input type="checkbox"/>	The objectives of the trial cannot be met by means of study of subjects who can give consent personally. <i>Provide protocol specific findings justifying this determination:</i> Click or tap here to enter text.
<input type="checkbox"/>	The foreseeable risks to the subjects are low. <i>Provide protocol specific findings justifying this determination:</i> Click or tap here to enter text.
<input type="checkbox"/>	The negative impact on the subject's well-being is minimized and low. <i>Provide protocol specific findings justifying this determination:</i> Click or tap here to enter text.
<input type="checkbox"/>	Subjects will be particularly closely monitored. <i>Provide protocol specific findings justifying this determination:</i> Click or tap here to enter text.
<input type="checkbox"/>	Subjects will be withdrawn if they appear to be unduly distressed. <i>Provide protocol specific findings justifying this determination:</i> Click or tap here to enter text.
<input type="checkbox"/>	The proposed plan for the assessment of the capacity to consent is adequate. <i>Provide protocol specific findings justifying this determination:</i> Click or tap here to enter text.
<input type="checkbox"/>	The subject will be informed about the research to the extent compatible with the subject's understanding.
<input type="checkbox"/>	Assent will be obtained from: <b>(One of the following must be checked)</b> <input type="checkbox"/> All subjects. <input type="checkbox"/> Some subjects, <i>specify</i> : Click or tap here to enter text. <input type="checkbox"/> None of the subjects
<input type="checkbox"/>	The trial is not prohibited by law.
<input type="checkbox"/>	The consent document includes a signature line for a LAR.
<input type="checkbox"/>	If capable, the subject will sign and personally date the written informed consent.