HRP-417 | 9/25/2023

CHECKLIST: CONGITIVELY IMPAIRED ADULTS

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when both of the following are true:

1. The research involves cognitively impaired adults as subjects, AND
2. The research involves a consent process or other intervention or interaction with cognitively impaired subject(s).

This checklist must be used for all reviews where a consent process is required per the protocol, or where interventions or interactions will be required with the subjects (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure).[i] This checklist does not need to be used for reviews where the research qualifies for waiver or alteration of consent processes per **HRP-410 – CHECKLIST – Waiver or Alteration of Consent Process**, and where there will be no interventions or interactions with the subjects.

- 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 HRP-402 - CHECKLIST - Non-Committee Review. The IRB Office retains 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 HRP-501 - 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.

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.

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: **(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: Click or tap here to enter text.

☐ Risks to subjects are reasonable in relation to the 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.

☐ The trial is not prohibited by law.

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.

☐ The subject will be informed about the research to the extent compatible with the subject's understanding.

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

☐ Assent will be obtained from: **(One of the following must be checked)**

- ☐ All subjects.
- ☐ Some subjects, specify: Click or tap here to enter text.
- ☐ 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.

2. Research involving cognitively impaired adults 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.

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

☐ 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: Click or tap here to enter text.

☐ The foreseeable risks to the subjects are low.

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

☐ The negative impact on the subject's well-being is minimized and low.

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

☐ The trial is not prohibited by law.

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.

☐ The subjects 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: Click or tap here to enter text.
- ☐ None of the subjects.

☐ The consent document includes a signature line for a (LAR).

☐ If capable, the subject will sign and personally date the written informed consent.

[i] This document satisfies AAHRPP elements I-9, II.1.A, II.4.A, II.4.B, II.5.B