UNIVERSITY OF MINNESOTA

HRP-417 | 3/29/2024

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 will likely encounter cognitively impaired adults as participants, will exclude or include those individuals in the study, AND
2. The research involves a consent process or other intervention or interaction where there is a likelihood of encountering cognitively impaired individual(s).

This checklist must be used for all reviews where a consent process is required per the protocol, or where the interventions or interactions will be required with the participants.[i] This checklist does not need to be completed for studies that will include the general populous (incidental encounters). 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 participants.

- 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 "Submit Non-Committee Review" activity.
- 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, the convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity.

Submission Information

Basic Information	Submission Details
IRB Number:	
Study Title:	
Short Title:	
Investigator:	
Panel or Designated Reviewer Completing Checklist:	
Date Checklist Completed:	

1. EXCLUSION: For studies planning to exclude adults with impaired decision making capacity, the protocol includes one of the following based on the level of risk.[ii] (Check all that apply or "**N/A**".) ☐ **N/A**

☐ The proposed plan for assessing capacity to consent includes the use of:

☐ MacCAT-CR for Greater than Minimal Risk Research

☐ UBACC for Minimal Risk Research

☐ An alternate validated tool appropriate for the population of the study is included for assessing capacity to consent and was reviewed by the Vulnerable Populations Advisor.

☐ If there is a likelihood that capacity to consent will fluctuate during the study, the protocol includes a plan for ongoing assessment of capacity and safe withdrawal procedures if applicable (Complete Section 4).

Provide protocol specific findings justifying this determination:

All human research that will include adults with impaired decision making capacity, must meet the criteria in Sections 2 or 3. If there is a likelihood that capacity may fluctuate, Section 4 must be completed.

2. INCLUSION and GREATER THAN MINIMAL RISK RESEARCH including cognitively impaired adults (Check "**Yes**" or "**N/A**". All must be checked as prompted.)

☐ Both are true: **(Both a. and b. must be checked)**:

☐ a. Participants have a disease or condition for which the procedures involved in the research hold out a prospect of direct benefit to the individual participant that is unavailable outside the research context.[iii]

☐ b. The objectives of the trial cannot be met by means of study of participants who can give consent personally.

Provide protocol specific findings justifying this determination:

☐ Risks to participants are reasonable in relation to the anticipated benefits to participants.

Provide protocol specific findings justifying this determination:

☐ The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.

Provide protocol specific findings justifying this determination:

☐ The trial is not prohibited by law (see HRP-111 and HRP-112).

Provide protocol specific findings justifying this determination:

☐ Participants will be particularly closely monitored.

Provide protocol specific findings justifying this determination:

☐ Participants will be withdrawn if they appear to be unduly distressed.

Provide protocol specific findings justifying this determination:

☐ The proposed plan for the assessment of the capacity to consent includes the use of the MacCAT-CR. [iv]

☐ An alternate validated tool appropriate for the population of the study is included for assessing capacity to consent and the tool has been reviewed by the Vulnerable Populations Advisor. ☐ N/A

Provide protocol specific findings justifying this determination:

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

Provide protocol specific findings justifying this determination:

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

☐ All participants.
☐ Some participants, specify:
☐ None of the participants.

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

☐ In the study consent form.
☐ Through another mechanism or method, specify:
☐ Participants will be unable to assent to participation.

☐ The protocol includes a plan for honoring dissent.[v]

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

☐ If appropriate, additional safeguards are included:

☐ Inclusion of a participant advocate
☐ Inclusion of a health care professional to serve as a consultant to participants and their LARs
☐ Require a consent audit/observation by the Quality Assurance Program during the course of the study
☐ Require the involvement of a witness to the consent process
☐ Require the use of participant-facing brochures
☐ Other, specify: Click or tap here to enter text.
☐ No additional safeguards are needed for this study

☐ There is a likelihood that individuals whose capacity to consent will fluctuate during the study (Complete Section 4) ☐ **N/A**

3. INCLUSION and MINIMAL RISK RESEARCH including cognitively impaired adults (Check "**Yes**" or "**N/A**". All must be checked as prompted.)

☐ Participants have a disease or condition for which the procedures involved in the research are intended.

Provide protocol specific findings justifying this determination:

☐ The objectives of the trial cannot be met by means of study of participants who can give consent personally.

Provide protocol specific findings justifying this determination:

☐ The foreseeable risks to the participants are low.

Provide protocol specific findings justifying this determination:

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

Provide protocol specific findings justifying this determination:

☐ The trial is not prohibited by law (see HRP-111 and HRP-112).

Provide protocol specific findings justifying this determination:

☐ Participants will be particularly closely monitored.

Provide protocol specific findings justifying this determination:

☐ Participants will be withdrawn if they appear to be unduly distressed.

Provide protocol specific findings justifying this determination:

☐ The proposed plan for the assessment of the capacity to consent includes the use of the UBACC.

☐ An alternate validated tool appropriate for the population of the study is included for assessing capacity to consent and the tool has been reviewed by the Vulnerable Populations Advisor. ☐ N/A

Provide protocol specific findings justifying this determination:

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

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

☐ All participants.
☐ Some participants, specify:
☐ None of the participants.

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

☐ In the study consent form.
☐ Through another mechanism or method, specify:
☐ Participants will be unable to assent to participation.

☐ The protocol includes a plan for honoring dissent.[vi]

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

☐ If appropriate, other enhancements to the consent process, specify:

☐ There is a likelihood that individuals whose capacity to consent will fluctuate during the study (Complete Section 4)

4. Fluctuating Capacity to Consent (All must be checked.)

☐ The protocol includes a plan for re-assessing capacity after initiation of the study for participants whose cognition may decline or change during study participation.[vii]

☐ The protocol includes a proactive plan for participants to identify an LAR and include the LAR in study related visits, activities, and/or conversations.

☐ The protocol include a plan for participants, if able, to define the limits of their own research participation or remain actively involved in the decision to enroll and remain enrolled in the research, if appropriate. [viii]

☐ The study team will involve an LAR in the consent process either initially or later in the study if consent capacity diminishes or is reevaluated. [ix]

5. **Continued participation in a Greater than minimal risk study without prospect of direct benefit to research participants if capacity is lost and participant: 1) becomes an adult during participation or 2) is included in an FDA mandated long term follow-up/extension study.** The IRB must consider the following to determine if continued participation should be allowed in some or all study activities. ☐ **N/A**

This request falls under one of the following **(One of the following must be checked)**:

☐ An adult participant had previously provided consent when deemed capable to do so.

☐ The participant was enrolled as a minor and the only condition that has changed is the participant become an adult.

☐ This is a long term follow-up or extension study mandated by the FDA.[x]

The following must be true for studies that have been previously approved by the IRB **(All must be checked)**:

☐ The participant has not expressed a desire to withdraw.

☐ Consent from the LAR and assent from the participant, when appropriate, will be obtained prior to continued participation.

☐ The protocol includes a plan for honoring dissent.

☐ The remaining study activities are minimal risk or represent only a minor increase over minimal risk.

The following conditions may also be considered by the committee to allow continued participation:

☐ Remaining study activities that represent greater than minimal risk can be eliminated or modified for the participant without jeopardizing scientific merit. Identify which activities will be eliminated or modified:

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

[ii] A plan is required if there is a likelihood of encountering individuals who are, may be, or may become cognitively impaired. General assessment plans are acceptable (teach-back method) for studies that will include the general populous (incidental encounters) and do not require completion of this checklist.

[iii] For GTMR research that with no prospect of direct benefit, the IRB cannot allow inclusion. If consent was obtained initially (with capacity) and capacity has changed, the IRB may consider allowing the participant to continue if requirements in Section 5 are met.

[iv] Submission of the MacCAT-CR or UBACC assessment form does not be uploaded in the IRB submission. Translation of the assessment tool is not required unless the assessor will conduct the assessment in the participant's language. See Investigator Manual (HRP-103) for further details.

[v] The study team should continuously monitor for indications of dissent which may be verbal or non-verbal.
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[vii] https://www.fda.gov/media/88915/download
[viii] https://www.fda.gov/media/88915/download
[ix] https://www.fda.gov/media/88915/download
[x] https://www.fda.gov/media/113768/download