



CHECKLIST: Cognitively Impaired Adults

NUMBER	DATE	PAGE
HRP-417	5/1/2022	1 of 2

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer when research involves cognitively impaired adults as subjects. This checklist or its equivalent form or electronic equivalent must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)¹

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to the criteria for approval 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 or IRB staff attaches this checklist or equivalent to the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to the criteria for approval have changed, one of the following two options may be used:
 1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
 2. The convened IRB completes this checklist or equivalent form to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office (HRPP) uploads this checklist or equivalent to the protocol file or uses electronic equivalent.

IRB Number:	
Study Title:	
Short Title:	
Investigator:	

All other 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)

<input type="checkbox"/>	One of the following is true: (Check box that is true) <input type="checkbox"/> 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. <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>
<input type="checkbox"/>	Risks to subjects are reasonable in relation to anticipated benefits to subjects. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The trial is not prohibited by law. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	Subjects will be particularly closely monitored. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	Subjects will be withdrawn if they appear to be unduly distressed. <i>Provide protocol specific findings justifying this determination:</i>
<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>
<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>
<input type="checkbox"/>	Assent will be obtained from: (One of the following must be checked) <input type="checkbox"/> All subjects. <input type="checkbox"/> Some subjects, specify: <input type="checkbox"/> None of the subjects
<input type="checkbox"/>	The consent document includes a signature line for a <u>Legally Authorized Representative (LAR)</u> .
<input type="checkbox"/>	If capable, the subject will sign and personally date the written informed consent.

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

**CHECKLIST: Cognitively Impaired Adults**

NUMBER

DATE

PAGE

HRP-417

5/1/2022

2 of 2

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>
<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>
<input type="checkbox"/>	The foreseeable risks to the subjects are low. <i>Provide protocol specific findings justifying this determination:</i>
<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>
<input type="checkbox"/>	The trial is not prohibited by law. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	Subjects will be particularly closely monitored. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	Subjects will be withdrawn if they appear to be unduly distressed. <i>Provide protocol specific findings justifying this determination:</i>
<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>
<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: (One of the following must be checked) <input type="checkbox"/> All subjects. <input type="checkbox"/> Some subjects, specify: <input type="checkbox"/> None of the subjects
<input type="checkbox"/>	The consent document includes a signature line for a legally authorized representative.
<input type="checkbox"/>	If capable, the subject will sign and personally date the written informed consent.