RUTGERS UNIVERSITY
Office for Research

# CHECKLIST: Adults with Impaired Decision-Making Capacity

| NUMBER | DATE | PAGE |
|---|---|---|
| 7.101 (HRP-417) | 5/1/2024 | 1 of 2 |

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following 4.202 (HRP-314) - WORKSHEET - Criteria for Approval when research involves adults with impaired decision-making capacity as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)

- 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 Designated Review" activity. 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 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 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 and retains this checklist in the protocol file.

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| **IRB Number:** | |
| **Study Title:** | |
| **Short Title:** | |
| **Investigator:** | |

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

**1 Research Involving adults with impaired decision-making with anticipated direct benefit to the subject** (Check if **"Yes."** All must be checked)

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| ☐ | One of the following is true: **(Check box that is true)**<br>☐ 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.<br>☐ The objectives of the trial cannot be met by means of study of subjects who can give consent personally.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | Risks to subjects are reasonable in relation to anticipated benefits to subjects.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | The trial is not prohibited by law.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | Subjects will be particularly closely monitored.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | Subjects will be withdrawn if they appear to be unduly distressed.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | The proposed plan for the assessment of the capacity to consent is adequate.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | The subject will be informed about the research to the extent compatible with the subject's understanding.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | Assent will be obtained from: **(One of the following must be checked)**<br>☐ All subjects.<br>☐ Some subjects, specify:<br>☐ 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. |

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| **2** | **Research involving adults with impaired decision-making capacity 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.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | The objectives of the trial cannot be met by means of study of subjects who can give consent personally.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | The foreseeable risks to the subjects are low.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | The negative impact on the subject's well-being is minimized and low.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | The trial is not prohibited by law.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | Subjects will be particularly closely monitored.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | Subjects will be withdrawn if they appear to be unduly distressed.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | The proposed plan for the assessment of the capacity to consent is adequate.<br>*Provide protocol-specific findings justifying this determination:* |
| ☐ | 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)**<br>☐ All subjects.<br>☐ Some subjects, specify:<br>☐ 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. |