# **APPENDIX A: Adults with Impaired Decision-making Capacity**

|  |  |
| --- | --- |
|  **IRB Study Number:** | Click or tap here to enter text. |

|  |
| --- |
| Complete the questions below to request the inclusion of adult participants with impaired decision-making capacity. Adults with decisional impairment (i.e., with diminished decision-making capacity) may lack the ability to provide valid informed consent to participate in research because of conditions such as trauma, intellectual disability, certain mental illnesses, cognitive impairment, or dementia. **NOTE**: Decisional impairment/diminished decision-making capacity may be temporary, permanent, progressive, or fluctuating during research participation. For research involving GREATER than minimal risk, an independent assessment of the potential participant’s capacity to consent (e.g., subjective assessment by a qualified professional independent of the research team, use of a valid objective instrument designed to evaluate capacity) should be performed, except in unusual circumstances. **Review HRP-417 - CHECKLIST - Adults with Impaired Decision-making Capacity to ensure that you have provided sufficient information.** |
|  |
| 1. Describe the expected range of participant impairment.

Click or tap here to enter text. |
| 1. Explain how, and by whom, the capacity to consent/assent will be determined.

Click or tap here to enter text. |
| 1. Indicate if assent will be obtained from all or only some participants and describe the process. If assent will not be obtained, explain.
 | [ ]  All participantsDescribe the process:Click or tap here to enter text.[ ]  Some participants Describe the process: Click or tap here to enter text.[ ]  None of the participants Explain: Click or tap here to enter text. |
| 1. If capacity is expected to fluctuate during research participation, describe the process for ensuring ongoing consent.

Click or tap here to enter text. |
| 1. Describe how the research is not prohibited by law.

Click or tap here to enter text. |
| 1. Describe how participants will be particularly closely monitored.

Click or tap here to enter text. |
| 1. Describe how participants will be withdrawn if they appear to be unduly distressed.

Click or tap here to enter text. |
| 1. Describe how the participant will be informed about the research to the extent compatible with the participant’s understanding.

Click or tap here to enter text. |
| 1. Confirm that if capable, the participant will sign and personally date the written informed consent.

Click or tap here to enter text. |
| 1. Select which category below best describes the research, and provide the corresponding information:
 |
|[ ]  Research involving adults with impaired decision-making capacity with anticipated direct benefit to the participant. *Select one of the following and explain:* [ ]  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.Explain: Click or tap here to enter text.[ ]  The research objectives cannot be met by the study of participants who can provide consent personally.Explain: Click or tap here to enter text.*Explain the following statements in the context of this study:** Risks to participants are reasonable in relation to the anticipated benefits.

Explain: Click or tap here to enter text.* The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.

Explain: Click or tap here to enter text. |
|[ ]  Research involving adults with impaired decision-making capacity with NO anticipated direct benefit to the participant*Explain the following statements in the context of this study:** Participants have a disease or condition for which the procedures involved in the research are intended.

Explain: Click or tap here to enter text.* Research objectives cannot be met by the study of participants who can provide consent personally.

Explain: Click or tap here to enter text.* The foreseeable risks to the participants are low.

Explain: Click or tap here to enter text.* The negative impact on the participant’s well-being is minimized and low.

Explain: Click or tap here to enter text. |