

**ELECTRONIC SUBMISSION REQUIRED**

**APPENDIX E**  
**Adults with Decisional Impairment**

Complete this form to request inclusion of adult participants who are decisionally impaired.

Adults with decisional impairment (i.e., with diminished decision-making capacity) may lack the ability to provide valid informed consent to participate in research, e.g., as a result of 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, etc.) should be performed, except in unusual circumstances.*

**Investigator Name**

1. Describe the expected range of participant impairment. Explain how, and by whom, the capacity to consent/assent will be determined.

2. Indicate whether assent will be obtained and if so, describe the process. If assent will not be obtained, explain.

3. If capacity is expected to fluctuate during research participation, describe the process for ensuring ongoing consent.

4. Select the one category that best describes the research and provide the corresponding information:

<input type="checkbox"/>	Minimal risk
<input type="checkbox"/>	Greater than minimal risk <i>with</i> the prospect of direct benefit for the individual
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>Explain how anticipated benefits, compared to risks, are as favorable as the alternatives (e.g., other treatments).</li> </ul>
<input type="checkbox"/>	Greater than minimal risk <i>without</i> the prospect of direct benefit for the individual
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>Explain how the risk presents only a minor increase over minimal risk.</li> </ul>