**Complete this form to request inclusion of adult participants with decisional impairments (i.e., with diminished decision-making capacity) or those that 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.**

|  |  |
| --- | --- |
| **Basic Information** | |
| **Title of Study:** |  |
| **Short Title:** |  |
| **Principal Investigator Name:** |  |
| **Section 1: Cognitively Impaired Individuals** | |
| Describe the expected range of participant impairment. | |
| Explain how, and by whom, the capacity to consent/assent will be determined. Specify the qualifications of person(s) making the capacity determination. | |
| If capacity is expected to fluctuate during research participation, describe the process for ensuring ongoing capacity assessment and consent. | |
| Describe how assent/consent will be obtained. **(If a Waiver of Consent is being requested, please indicate that here and complete the *Appendix for Waiver or Alteration of Consent or PHI.*)** | |
| Describe the steps that will be taken to identify, locate, and obtain informed consent from the legally authorized representative (LAR). **(Reference HSPP guidance on *Cognitively Impaired Adults*)** | |