

**Principal Investigator:**

**Study Title:**

Please complete if your research involves individuals who are cognitively impaired or have other reductions in mental functions.

**1. Cognitively Impaired Subjects**

a. Describe the cognitively impaired subjects to be included in this research:

Click here to enter text.

b. Explain why these subjects need to be included in this research:

Click here to enter text.

c. Are any of these subjects institutionalized? ☐ Yes ☐ No

If yes, describe the setting and provide documentation of permission from the institution:

Click here to enter text.

## 2. Risk/Benefit

- a. Are the risks to subjects in this research no more than minimal? ☐ Yes ☐ No
- b. If the research involves greater than minimal risk to subjects, are there direct benefits to the individual subjects? ☐ Yes ☐ No

If yes, describe:

Click here to enter text.

## 3. Consent and Assent

- a. Describe the procedures to be used to determine the individual subject's capacity to provide consent:

Click here to enter text.

**Note:** The decision-making capacity of individual subjects should not be assumed because of a condition or diagnosis. The decision-making capacity of individual subjects should be determined through the use of a standardized measure or by consultation with a qualified professional.

- b. For subjects where it has been determined that they lack the capacity to give consent, describe the provisions for obtaining consent from the subjects' legally authorized representative:

Click here to enter text.

- c. Describe how the assent of the subjects will be obtained and documented. Attach copies of all assent forms, if any:

Click here to enter text.