Syracuse University Institutional Review Board

Vulnerable Populations:

COGNITIVELY IMPAIRED

**Principal Investigator:**

**Study Title:**

*Attach this completed form to the IRB Application when “Cognitively Impaired” is checked in Section 7 – Characteristics of Participants.*

1. Provide adequate justification as to why it is necessary to include this population.

1. Describe the potential benefits of the research to this population.

1. If the research proposes to involve institutionalized individuals, provide sufficient justification for the use of that population.

1. Explain why non-institutionalized subjects are not appropriate for this research and why they may not be reasonably available.

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1. Does the research pertain to aspects of the institutionalization?

[ ]  N/A [ ]  No [ ]  Yes

If yes, provide a description of the research as it pertains to institutionalization*.*

1. If applicable, provide justification of any plan to hospitalize participants or extend their hospitalization for research purposes.

1. Explain how competency to provide consent will be determined and the plan for obtaining surrogate consent.

1. Describe how individuals who may lose their capacity to consent or their ability to withdraw during the course of the study will be protected.

1. Describe the methods for assuring adequate protections for the privacy of the participants.

1. Describe the methods for assuring adequate protections for the confidentiality of information gathered.

1. Describe how the Principal Investigator will identify persons authorized to give legally valid consent on behalf of any individual(s) judged incapable of consenting on their own behalf.

1. Describe how permission will be obtained and documented from these legally authorized individuals.

1. If applicable, describe how assent and dissent will be obtained and documented or explain the reason for a waiver of assent or dissent is requested.

1. If applicable, describe the process for consulting with the patient's physician or another health care provider before any individual is invited to participate in the research .

1. If applicable, describe any research procedures that may likely interfere in the participant’s ongoing therapy or regimes.