Title: SPECIAL CATEGORIES OF RESEARCH: COGNITIVELY IMPAIRED

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to provide guidance on the special ethical and regulatory considerations of cognitively impaired individuals involved in human subjects research under the jurisdiction of the Syracuse University (SU) Institutional Review Board (IRB).

2.0 Policy:

It is the policy of the SU IRB to review, approve, and provide guidance on the special ethical and regulatory considerations when cognitively impaired participants are involved in human subjects research.

The ethical principle of respect for persons requires respect for the autonomy of individuals and special protections for those with diminished autonomy. Some persons may be limited in their competence to make informed decisions about their lives by virtue of mental, intellectual, or cognitive disabilities (e.g., "mental illness," "dementia," "Alzheimer's," "mental retardation"). Although investigators should be sensitive to the possibility that persons with disabilities may have limited capacity to consent to participating in research, they must not presume incompetence simply because a person has a disability diagnosis or label. Most adults with mental, intellectual, or cognitive disabilities are capable of making decisions for themselves and should be presumed to be competent. Investigators must respect the autonomy of all persons unless there is clear evidence that they are incapable of decision-making.

2.1 IRB Review and Approval of Research Involving Cognitively Impaired Participants.

2.1.1 Because cognitively impaired individuals may have diminished autonomy that may limit their capacity to provide consent or their ability to withdraw, research involving cognitively impaired participants should be reviewed and approved through consideration of the SU IRB policies and the special considerations as determined by the *Belmont Report*, Federal and State regulations, and guidance documents.

2.1.2 The SU IRB must review all research in which cognitively impaired individuals will be considered as participants to assure that the Investigator has provided additional safeguards to protect the rights and welfare of this vulnerable population.

2.1.3 The IRB must consider the degree of cognitive impairment of the participant, the level of risk, and the prospect of benefit to the individual participant.

2.2 Requirements for Evaluating Decision-Making Capacity for Cognitively Impaired Participants.

2.2.1 The IRB must find that appropriate provisions are made for determining the participant's ability to provide consent or their ability to withdraw, through evidence of one or more of the following pertaining to the individual:

2.2.1.1 The ability to make a choice;

2.2.1.2 The ability to understand relevant information;

2.2.1.3 The ability to appreciate the situation and its likely consequences; and

2.2.1.4 The ability to manipulate information rationally.

2.2.2 The determination of capacity to consent or ability to withdraw may be made through a standardized measure or consultation with another qualified professional. The IRB must approve the process for making such a determination.

2.2.3 Because the capacity to consent or the ability to withdraw may fluctuate, the IRB must evaluate the process for continued verification of understanding and willingness to participate.

2.2.3.1 The consent procedures should describe a plan for protecting individuals who may lose their capacity to provide consent or their ability to withdraw while participating in research activities (e.g., use of an ombudsman).

2.2.3.2 The IRB may require that an outside witness observe and confirm the consenting process.

2.2.4 For participants who lack decision-making capacity, the permission of the individual's legally authorized representative is required and assent should be obtained from the participant (See *SOP 016)*.

2.2.4.1 In research situations where there is the potential for direct benefit to the participant, the IRB may waive the requirement to obtain assent. However, permission from the legally authorized representative must be obtained.

2.2.4.2 Even where the IRB determines that the individuals are capable of consenting or withdrawing, the IRB may still waive the consent requirements under the circumstances described in the SU IRB informed consent policy (See *SOP 018)*.

2.2.5 The IRB must also review and approve the appropriate consent documents with the required elements of consent written in a language understandable to the participant.

2.3 Appropriate Provisions for Legally Authorized Representative Consent.

2.3.1 When it is determined by the Investigator that the participant lacks decision-making capacity, the IRB must find that appropriate provisions are made for soliciting the permission of each individual's legally authorized representative unless the criteria are met to approve a waiver of informed consent (See *SOP 018)*.

2.4 Institutionalized Participants.

2.4.1 The IRB must consider the rationale and justification for involvement of institutionalized participants, including an explanation as to why non-institutionalized individuals could not be used.

2.4.2 Regardless of financial support or funding, the SU IRB must assure that all performance sites "engaged" in research have approval from the IRB of Record for the proposed research to be conducted at the site.

2.4.3 When performance sites are "not engaged" in research and have an established IRB, the Investigator must obtain approval to conduct the research at the "not engaged" site from the site's IRB or provide documentation that the site's IRB has determined that approval is not necessary for SU to conduct the proposed research at the site.

2.4.4 When performance sites are "not engaged" in research and the "not engaged" site does not have an established IRB, a letter of cooperation must be obtained demonstrating that the appropriate institutional officials are permitting the research to be conducted at the performance site.

2.5 Composition of IRB when Cognitively Impaired Participants are Involved in Research.

2.5.1 When reviewing research involving cognitively impaired participants, the IRB Committee will include into its composition one or more individuals who are knowledgeable about and experienced in working with the cognitively impaired.

2.5.2 When the study requires review by the full IRB Committee, it must meet the special composition requirements when conducting reviews for initial review, continuing review, protocol amendments, and reports of unanticipated problems when the research involves cognitively impaired individuals.

3.0 References and Reference Documents:

The Belmont Report
SU IRB Handbook, Chapter 6 "Persons who are Impaired in their Decision-Making"
SOP 016 on Legally Effective and Prospectively Obtained Informed Consent
SOP 018 on Waiver of Informed Consent.

4.0 Procedure:

4.1 Investigator Responsibilities.

4.1.1 The Investigator will submit the supplemental form for "Vulnerable Populations: Cognitively Impaired" for cognitively impaired individuals with any new study submission in which cognitively impaired participants will be a target population for research activities.

4.1.2 The research plan should address the following considerations:

4.1.2.1 A rationale as to why it is necessary to include this population;

4.1.2.2 A description of potential benefits to this population;

4.1.2.3 A justification for the use of institutionalized individuals, if applicable;

4.1.2.4 A description as to why non-institutionalized individuals could not be used;

4.1.2.5 A description of the research as it pertains to the institutionalization, if applicable;

4.1.2.6 A justification of any plan to hospitalize participants or extend their hospitalization for research purposes;

4.1.2.7 A description of the procedure for determining capacity for decision-making of the individuals;

4.1.2.8 A description as to how individuals will be protected in the event they lose their capacity to consent and their capacity to withdraw;

4.1.2.9 A description of the methods for assuring adequate protections for the privacy of the participants and the confidentiality of the information gathered;

4.1.2.10 A description as to how permission will be obtained and documented from the legally authorized representative, if applicable;

4.1.2.11 A detailed description on how assent and dissent will be obtained and documented, or request consideration of a waiver of assent and dissent.

4.1.2.12 A process for consulting with the participant's health care provider, when applicable; and

4.1.2.13 A description of any research procedures that may likely interfere in the participant's ongoing therapy or regimes.

4.1.3 An Investigator should not solicit consent of a participant who lacks decision-making capacity without intending to take his/her wishes seriously. In situations where the potential benefits of the study are such that the physicians and legally authorized representative would enroll the participant regardless, and the participant's capacity is so diminished that he/she could not understand the ramifications of not participating, the participant should simply be told what is planned and should not be deceived.

4.1.3.1 A request of wavier for consent should be submitted to the IRB for determination (See *SOP 018).*

4.1.3.2 Should a situation exist in which the target population lacks decision-making capacity either through trauma, life-threatening condition, or coma, the Investigator may submit a request for surrogate consent (See *SOP 016).*

4.1.4 The Investigator must present an informed consent document to the IRB for review containing the appropriate amount of information for the participant to make an informed decision. If, in the opinion of the Investigator, a complete informed consent document is not appropriate, a waiver or alteration of informed consent should be requested including a rationale for the alteration.

4.1.5 Once approved, the Investigator may proceed with consent of the participant and/or legally authorized representative as outlined in the SU IRB Policy regarding Legally

Effective and Prospectively Obtained Informed Consent, unless a waiver has been granted (see *SOP 016*).

4.1.6 If the research will involve institutionalized participants and depending on whether the performance site is "engaged in research," a letter of IRB approval or a letter of cooperation from the institutional official from that site must be submitted to the IRB for review and approval.

4.2 IRB Responsibilities.

4.2.1 The IRB Committee must review the proposed research taking into consideration all applicable SU policies, as well as the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the participant. In addition, the IRB must be sure that additional safeguards are in place to protect the rights and welfare of these participants.

4.2.2 The effects of separation from supportive family or friends, of disruption in schooling or employment, and the question of responsibility for bearing any additional costs should be carefully considered by the IRB.

4.2.3 When determining whether the participants are capable of providing consent or assent, the IRB shall take into account the decision-making capacity of the study population. This determination may apply to all participants to be involved in the study, or on a case-by-case basis, as deemed necessary by the IRB.

4.2.4 The methods in which the full IRB Committee approves a new study submission will be followed. The Committee will determine whether the study meets criteria 45 CFR 46.111 for approval, the Primary Reviewer must also complete the "Review of Research Checklist" to assure that adequate provisions and documentation of such provisions have been made for this population.

4.2.5 The Committee may not review or make a determination regarding studies involving the cognitively impaired, as a target population, unless it has sufficient expertise in the ethical, clinical, and psychosocial issues impacting this population. Therefore, a Committee member who is knowledgeable about and experienced in working with these subjects must be in attendance at the convened meeting or an expert consultant who has this knowledge must be consulted by the IRB. When the IRB Committee renders its determination it will include:

4.2.5.1 Requirements for determining the decision-making capacity of the target population or on a case-by-case bases, or a rationale why this requirement will be waived; and

4.2.5.2 Appropriate methods for assuring the amount of information contained in the consent documents is appropriate for the target population and the legally authorized representative, when necessary.

4.2.6 When institutionalized individuals are involved in research, the IRB must verify that the institution has granted approval for the research to take place at that site. Depending on whether the performance site is "engaged in research," a letter of IRB approval or a letter of cooperation signed by the Institutional Official is required.

4.3 ORIP/IRB Administrator Responsibilities.

4.3.1 The ORIP/IRB Administrator will verify that the supplemental form for "Vulnerable Populations: Cognitively Impaired" is completed as part of the initial study documents.

4.3.2 The ORIP/IRB Administrator will place the new study on the next available Committee agenda.

4.3.3 The ORIP Director and IRB Chair will assign the study to Reviewers who have the expertise in the area of the proposed research and the population targeted. If a member with those qualifications is not a regular Committee member, an expert consultant will be sought.

4.3.4 The ORIP/IRB Administrator prepare the Reviewer and Committee packets.

SOP 023: SPECIAL CATEGORIES OF RESEARCH: COGNITIVELY IMPAIRED

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