Title: ASSENT/DISSENT BY CHILDREN OR COGNITIVELY IMPAIRED ADULTS WHO LACK DECISION-MAKING CAPACITY

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the process for obtaining assent and dissent in children and cognitively impaired adults who lack the capacity for decision-making for participation in research activities.

2.0 Policy:

It is the policy of the Syracuse University (SU) Institutional Review Board (IRB) to assure that adequate provisions are made for soliciting the assent and dissent of children and cognitively impaired adults who lack decision-making capacity.

In instances where the participant is not legally capable of giving informed consent (e.g., minors) or where the participant is cognitively impaired, the IRB must find that adequate provisions are made for soliciting the assent of the participant when in the judgment of the IRB, the participant is capable of providing assent. (See *SOP 016)*.

In determining whether participants are capable of assenting, the IRB shall take into account the age, maturity, and psychological state of the participant involved. This judgment may be made for all participants to be involved in research under a particular protocol, or for each participant, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the participants is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the participant and is available only in the context of the research, the assent of the participant is not a necessary condition for proceeding with the research. Even where the IRB determines that the participants are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with SU IRB Policy on Waiver of Informed Consent (See *SOP 018*).

For children under 18 years of age, one or more parents or a legal guardian must provide informed consent for them to participate in research, with exceptions as noted below. Informed consent must contain the elements and be documented as described above. For research that has more than minimal risk and offers no direct benefit to children, consent must be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available or when one parent has legal responsibility for the care and custody of the child.

In addition to requiring parental consent, the IRB requires investigators to obtain oral assent from children themselves to participate in research unless it determines that they are incapable of understanding the research and agreeing to participate. Children functioning at a normal developmental age of seven should ordinarily provide oral assent to participate in research. Investigators should submit to the IRB a script to be read to children. The script should briefly explain the research activities in language appropriate to the children's ages and indicate that the children do not have to participate if they do not want to and can change their minds about participating at any time. The script should conclude with a question asking children if they are willing to participate. The date at which oral assent is obtained must be documented in a log or other written form (e.g., field notes or interview transcripts). The documentation must be made available to the IRB upon request. Since obtaining informed

consent is a process and not a one-time event, investigators also must be attuned to nonverbal behavior or other indications that children do not wish to participate in the research. For example, if a child actively resists participating in an experiment, the research should be terminated with that child, even if parental consent and oral assent have been obtained.

The requirement for children's oral assent may be waived by the IRB in accord with criteria for the waiver of informed consent described above or if the IRB determines that the research holds out a prospect of direct benefit to the children and is available only in the context of the research.

The IRB may waive the requirement for parental consent for research involving children if it determines that the research offers the potential of direct benefit or contributing to knowledge surrounding the situation of children, has no greater than minimum risks, and parental or guardian consent is not a reasonable requirement to protect the children. Examples include abused or neglected children, children in foster care whose parental ties have been severed, and runaway children if the purpose of the research is designed to examine the experiences of children in these situations. A waiver generally will not be granted for research that can be conducted among children for whom parent or guardian permission can be obtained. If the IRB waives the requirement for parental or guardian consent, it will require the appointment of an advocate who has the background and experience to act in the best interests of the child for the duration of the research and who is independent of the research, the investigator, and a public or private agency acting as guardian for the child. The advocate will be asked to make an independent determination about the risks and benefits of the child's participation in the research and ensure that the child's participation is voluntary. The IRB must approve advocates appointed for this purpose.

"Passive" parental consent for children to participate in research (sending a letter home with a child and asking parents to contact the investigator if they do not want the child to participate) is not an acceptable substitute for active parent consent.

When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

3.0 References and Reference Documents:

The Belmont Report
45 CFR 46 Subpart D
SOP 016, Legally Effective and Prospectively Obtained Informed Consent
SOP 018, Waiver of Informed Consent
SOP 021, Special Categories of Research: Children
SOP 023, Special Categories of Research: Persons with Cognitive Disabilities

4.0 Procedure:

4.1 Investigator Responsibilities.

4.1.1 The Investigator will provide a description of the targeted study population as instructed in the "IRB Application for Expedited and Full Board Review." When the targeted population includes children or cognitively impaired adults who lack decision-making capacity, the Investigator will also provide 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 The Investigator will submit the "Vulnerable Population: Children" Form or "Vulnerable Population: Cognitively Impaired" Form with any new study submission in which cognitively impaired participants or children will be the target population for research activities.

4.1.3 The Investigator will draft the assent documents and may utilize the assent template located on the IRB website.

4.1.4 The Investigator will provide plans for assessment and documentation of examples of behaviors demonstrating assent and dissent in the targeted populations.

4.1.5 The Investigator will obtain permission from the child's parents or legal guardians in conjunction with assent requirements. Documentation of permission from the child's parents or legal guardians is provided by their signature and date on the informed consent document.

4.1.6 Permission must also be obtained for research participants who are cognitively impaired and/or lack decision-making capacity from the individual's legally authorized representative, unless a waiver of informed consent has been granted by the IRB.

4.1.7 Permission will be documented by the legally authorized representative's signature and date on the informed consent document.

4.1.8 The investigator will complete the "Vulnerable Populations: Children" form when it is indicated on the application that children will be involved in the study.

4.2 IRB Committee Responsibilities.

4.2.1 The IRB Committee will review research involving children and cognitively impaired adults who lack decision-making capacity to determine whether assent and dissent is:

4.2.1.1 Required of all participants in the proposed research; or

4.2.1.2 Required on a case-by-case basis, when in the Investigator's opinion, the individual is able to comprehend the proposed research purpose and associated activities and procedures.

4.2.2 The IRB Committee will also consider granting a waiver of assent in circumstances in which the targeted population does not have the ability to comprehend the proposed research purpose and/or associated procedures.

4.2.3 The IRB Committee will consider granting a waiver of assent in circumstances in which the research holds out the prospect of direct benefit that is important to the health or well-being of the participant and is available only in the context of the research.

4.2.4 The IRB shall take into account the age, maturity, and psychological state of the participants involved to determine if and when assent is required and the method of documenting assent.

4.2.5 The IRB will review the Investigator's plan for assessment of the research participant's ability to provide assent and dissent and determine if the plan is appropriate. The IRB will make recommendations for additional requirements, when necessary.

4.2.6 When the Investigator completes the "Vulnerable Populations: Children" form the Reviewers will complete the "Checklist for Research Involving Children".

4.3 ORIP Responsibilities.

4.3.1 The ORIP/IRB Administrator will verify that the supplemental form for "Vulnerable Populations: Cognitively Impaired" or "Vulnerable Populations: Children" 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 Reviewers with the appropriate expertise.

4.3.4 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.

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

SOP 019: ASSENT/DISSENT BY CHILDREN

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