Title: LEGALLY EFFECTIVE AND PROSPECTIVELY OBTAINED INFORMED CONSENT

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the responsibilities of the Syracuse University (SU) Institutional Review Board (IRB) and the Investigator in obtaining legally effective and prospective informed consent from research participants.

2.0 Policy:

It is the policy of the SU IRB to assure that provisions are made to obtain legally authorized informed consent prospectively from each research participant or permission from his or her legally authorized representative. However, there are circumstances in which the IRB may grant a waiver of informed consent in accordance with Federal regulations (See *SOP 018*).

Documentation of informed consent is obtained unless alternate procedures are approved by the IRB. The IRB reviews all informed consent documents to assure the adequacy of the information contained in the consent document, and adherence to Federal regulations regarding the required elements of informed consent.

Informed consent is obtained from the participant or permission from a legally authorized representative prior to initiating research activities. This includes recruitment and screening procedures.

The IRB provides extra scrutiny of research involving vulnerable populations who, by virtue of their situations, are susceptible to exploitation or may have difficulties exercising informed consent. The IRB pays special attention to the risks and benefits of research, incentives for participation, and the informed consent process on research involving vulnerable populations.

2.1 Legally Authorized Representative. Under federal law a "Legally Authorized Representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to that subject's participation in the procedures involved in the research, [45 CFR 46.402(c)]. In New York State "Authorized Representative" means an individual or judicial or other body authorized under New York State Law (Public Health Law, Article 24) to give permission on behalf of a perspective adult subject for the subject's participation in the procedure(s) involved in the research. The role of the authorized representative is to assist the subject as necessary in understanding the research procedures and to ensure that the subject's rights and welfare are protected. The following persons may act as authorized representatives for adults who have been determined to lack capacity (listed in descending order of priority):

- **2.1.1** A health care agent properly designated on a health care proxy form;
- **2.1.2** A court appointed guardian or committee under the New York Surrogates Court Procedure Act Article 17-A;
- **2.1.3** The spouse;
- **2.1.4** An adult son or daughter;
- **2.1.5** A parent; or
- **2.1.6** An adult brother or sister.

2.2 Children. Under federal law "children" are persons who have not attained the legal age for consent to treatments or procedures involved in research or clinical investigations, under the applicable law of the jurisdiction in which the research or clinical investigation will occur. In New York State individuals under the age of 18 are children unless emancipated (see 2.3 below) Only the parents or guardians may grant permission for their child's participation in research. Assent is to be sought from the child, only after permission has been obtained from the parents. Grandparents and other relatives or caregivers may not grant permission unless they have been granted formal custody of the child by a court. In such cases, the Principal Investigator (PI) must obtain evidence of that person's authority to grant permission for participation in research on the child's behalf. The IRB may approve research involving children by following the Checklist for Research Involving Children. The IRB requires consultation with legal counsel when research is conducted outside of New York, involves children, and it is uncertain who under the local jurisdiction meets the Subpart D definition of "child."

For research in New York State, individuals are authorized to consent to the general medical care of a child and therefore meet the DHHS definition of "guardian". For research outside of New York State, investigators must provide on the IRB application the definition of a guardian in the jurisdiction in which enrollment will take place. Only those individuals will be able to provide consent for children.

2.3 Emancipated Minors.

2.3.1 In New York State, emancipated minors have attained the legal age for consent to treatments or procedures involved in the research. Therefore, the provisions of Subpart D do not apply and these individuals may consent to research as adults. Although there is no court proceeding in New York State to have a young person declared an emancipated minor, New York State Law recognizes the status of emancipation and the rights of emancipated minors. The term emancipated applies to youth over the age of 16 and under 18 who fall into one of the following categories:

2.3.1.1 The parents expressly consent to the child's emancipation;

2.3.1.2 The child becomes economically independent of their parents through employment (this must be determined on a case by case basis to ascertain whether the child is in fact still economically dependent on the parents);

2.3.1.3 The child enters into military service (if service ends prior to the child reaching 21 years of age, the child may choose to revert to unemancipated status or remain self-supporting);

2.3.1.4 The child is married; and

2.3.1.5 The child voluntarily and without sufficient cause leaves the parent's home and withdraws from parental control and supervision.

2.4 Persons with Cognitive Disabilities Who are Impaired in their Decision-Making. 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.

2.4.1 For research conducted in New York State, the IRB may not allow or require informed consent to be provided by any individual (including guardians, parents, spouses, and next of kin) unless that individual is authorized under New York State law to consent on behalf of a prospective subject to the individual's participation in procedures involved in

that research. The IRB will determine whether investigators must obtain the assent of such individuals to participate in research. The IRB requires consultation with legal counsel when research is conducted outside of New York State and may involve adults unable to consent to determine who under the local jurisdiction meets the Subpart A definition of "legally authorized representative."

2.4.2 In making determinations regarding safeguards for persons with mental, intellectual, or cognitive disabilities, the IRB takes into account the risks and potential benefits to participants. The greater the risks and lesser the benefits, the more stringent the requirements the IRB will place on research to ensure voluntary participation by people with mental, intellectual, or cognitive disabilities. An individual may be capable of consenting to participate in research that has minimal risks (e.g., oral histories, evaluations of public programs and services), but incapable of providing consent to participate in research in which the risks are complex (e.g., certain forms of psychological or medical research).

2.4.3 When informed consent is provided by guardians or surrogates, the research must carry no more than a slight increase over minimal risk and have a reasonable expectation of providing a direct benefit to participants or contributing to knowledge that would improve the situation or condition of persons with that disability.

2.5 Research over Extended Periods. Studies involving participants who have cognitive disabilities may take place over extended periods of time. The IRB considers whether and when periodic reconsenting of individuals is required to assure that a participant's continued involvement is voluntary. The IRB may require that the Investigator reconsent participants after taking into account the study's anticipated length and the condition of the individuals to be included. Additionally, the IRB considers whether and when to require a reassessment of decision-making capacity.

2.6 Observation of the Consent Process.

The IRB has the authority to observe, or have a third party observe, the informed consent process of research it has approved, and to verify that the study is being conducted as required by the IRB and within the Institutional policies and procedures and site-specific procedures, as appropriate. Before the IRB or third party observes the consent process, verbal consent of the participant may be sought. Mechanisms by which observation of the consent process might be implemented include, but are not limited to, the following situations:

2.6.1 The IRB may determine it is necessary to observe the informed consent process in order to provide additional protections and may conduct informed consent observations in the following situations:

- **2.6.1.1** Non-compliance per SOP 028;
- **2.6.1.2** Unanticipated problems involving risks to participants or others per SOP 027;
- **2.6.1.3** Protocol deviations as per SOP 026;
- **2.6.1.4** Participant complaints; or
- **2.6.1.5** Any other situation the IRB deems appropriate where additional protections are necessary.

2.6.2 Additionally, Investigators may be asked to submit copies of signed informed consent forms or other documents to ensure their compliance with IRB requirements. The IRB may conduct interviews with screened and/or enrolled subjects as deemed necessary.

2.6.3 All findings are confidential and are not disclosed to entities outside of the Institution, unless otherwise required by state or federal law. Findings/results from the observations are reviewed at the next scheduled IRB meeting.

3.0 References and Reference Documents:

45 CFR 46.111
45 CFR 46.116
45 CFR 46.117

SOP 018, Waiver of Informed Consent
SOP 026, Protocol Deviation/Violation Reporting
SOP 027, Reporting of Unanticipated Problems Involving Risks to Participants or Others
SOP 028, Investigating and Managing Potential Issues of Non-Compliance

4.0 Procedure:

4.1 Investigator Responsibilities.

4.1.1 Except as otherwise provided in this policy, Investigators must not involve a human being as a research participant unless the Investigator has obtained the informed consent of the participant or the participant's authorized representative. An Investigator shall seek such consent only under circumstances that provide the individual or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

4.1.2 The Investigator provides a detailed description of the intended method for obtaining informed consent.

4.1.3 Written consent forms should be typed on Syracuse University departmental letterhead. The name of the principal Investigator, or faculty advisor in the case of student research, must be provided on the consent form. The IRB, with its phone number, should be listed on the consent form in the event that people have questions.

4.1.4 All informed consent documents (full written documents, oral scripts, assent and dissent forms) are submitted for review and approval by the SU IRB prior to use.

4.1.5 Any changes in the informed consent documents are submitted as an amendment to the IRB for review and approval prior to use.

4.1.6 Informed consent must:

4.1.6.1 Be solicited in circumstances that minimize the possibility of coercion and undue influence;

4.1.6.2 Utilize language understandable to the participant. Investigators should avoid the use of jargon or specialized language in the consent process. Investigators should seek to provide participants with necessary information about the research without going into excessive details that will make forms difficult to read and understand. Typically, a written consent form should be no more than two pages;

4.1.6.3 Not waive or appear to waive participants' rights; and

4.1.6.4 Include each of the required elements and applicable additional elements of informed consent describing the research and the nature of research participation as required by Federal regulations.

4.1.7 Unless specifically waived by the IRB, informed consent is documented in writing through the use of a current IRB-approved informed consent document signed and dated by the participant or by the participant's legally authorized representative prior to enrollment or participation in any phase of the research study.

4.1.8 The Investigator assures that the informed consent process in research is an ongoing exchange of information between the research team and the study participants throughout the course of a research study. Informed consent is a continuous process of communication and acknowledgement over time, not just a signed document, or a one-time event. Investigators should be attuned to participants' preferences or second-thoughts about participating in research and periodically remind them of the voluntary nature of their participation.

4.1.9 Persons should be able to withdraw consent either orally or in writing.

4.2 IRB Responsibilities.

4.2.1 The IRB Committee, the IRB Chair or his/her designee reviews the planned research activities to assure that the informed consent document is congruent with the IRB application, Sponsor's or Investigator's protocol, grant and/or contract, and contains the necessary elements of informed consent as required by the Federal regulations.

4.2.2 When reviewing the informed consent document, the Reviewers may request necessary revisions to the content, language, punctuation, and/or grammar in order for the intended target population to clearly understand the proposed research activities and make an informed decision on whether to participate in the research.

4.2.3 The IRB Committee, the IRB Chair or his/her designee reviews and approves the informed consent process and method of documentation, indicating whether the proposed consent process is appropriate for the proposed research activities and the target population as a part of the overall IRB approval of the study.

4.2.4 The IRB or designee shall observe the informed consent process to verify compliance (see 2.5 above).

4.2.4.1 During an evaluation:

4.2.4.1.1 The consent process shall be reviewed to determine outcome and areas of improvement;

4.2.4.1.2 The consent process shall be reviewed to confirm it is being conducted in accordance with applicable federal regulations, state law, and institutional policies;

4.2.4.1.3 Informed Consent Form (ICF) shall be reviewed to ensure the most current IRB approved version is being used; and

4.2.4.1.4 Any other materials shall be reviewed as necessary.

4.2.4.2 A third party might be used to conduct the observation, if appropriate.

4.2.5 Elements of Informed Consent.

Unless a waiver is granted by the IRB, the following information must be provided to participants in obtaining their informed consent to participate in the research (see the IRB's web site for a sample consent form).

4.2.5.1 A statement that the study involves research, an explanation of the purposes and expected duration of the research, a description of the procedures to be followed, and identification of any procedures that are experimental.

4.2.5.2 A description of any reasonably foreseeable risks or discomforts to participants.

4.2.5.3 A description of benefits to participants or others (including contributions to knowledge) that may reasonably be expected from the research.

4.2.5.4 For interventions, a disclosure of appropriate alternative procedures or treatments, if any, that might be advantageous to participants.

4.2.5.5 A statement describing the extent, if any, to which confidentiality will be maintained. Investigators should describe the steps they will take to protect confidentiality, but refrain from making absolute guarantees that confidentiality can be protected under any and all circumstances.

4.2.5.6 For research that involves more than minimal risk, an explanation as to whether medical treatments and compensation are available if injury occurs and where further information may be obtained.

4.2.5.7 An explanation of whom to contact for answers to questions about the research, research participants' rights, and, if appropriate, research-related injury. Typically, the principal Investigator and, in the case of students, the faculty advisor should be listed, along with the phone number of the SU IRB.

4.2.5.8 An explanation of how to contact the research team for concerns or complaints about the research. An explanation of how to contact the Syracuse University Institutional Review Board and a contact name in case the participant has any questions about his or her rights as a research participant, the participant has questions, concerns, or complaints that they wish to address to someone other than the investigator, or if the participant cannot reach the investigator.

4.2.5.9 A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the participant may withdraw from the study at any time without penalty.

4.2.6 When appropriate, the IRB requires one or more of the following elements of information to be provided to participants as part of the informed consent process:

4.2.6.1 For certain medical treatments or interventions, a statement that a procedure may involve risks that are currently unforeseeable.

4.2.6.2 Anticipated circumstances under which a participant's participation may be terminated by the Investigator without regard to the person's consent (e.g., if a participant in an intervention study undertakes treatment on his or her own that might interfere with the research).

4.2.6.3 Any additional costs that may result from participation in the research.

4.2.6.4 The consequences (e.g., medical, psychological) of a person's decision to withdraw from the research and procedures for orderly termination by the participant.

4.2.6.5 A statement that significant new findings developed during the course of the research that may relate to the person's willingness to continue participation will be provided to the person.

4.2.6.6 The approximate number of participants in a study.

4.2.6.7 For research that involves observations or interview or survey questions about possible illegal behavior, an explanation of the certificate of confidentiality, if applicable, or a statement that the Investigator is not immune from legal subpoena.

4.2.6.8 For research that involves a realistic possibility that child abuse or neglect might be discovered, an explanation of the Investigator's professional obligations and intentions with regard to reporting abuse or neglect.

4.2.6.9 If payments or incentives are used to recruit participants, an explanation of how they will be paid or awarded and the procedure for prorating payments or awards for partial participation in the research.

4.2.6.10 In research in which Investigators wish to record data using audio- or videotapes or take photographs of participants, an explanation that tapes will be recorded or photographs taken and a description of how they will be used. The Investigator may request separate permission to use tapes or take photographs.

4.2.7 The IRB <u>may waive</u> the requirements to obtain informed consent or alter some or all of the elements of informed consent specified above if it finds and documents protocol-specific findings justifying the following:

4.2.7.1 The research involves no more than minimal risk to participants;

4.2.7.2 The waiver or alteration will not adversely affect the rights and welfare of participants;

4.2.7.3 The research could not practically be carried out without the waiver or alteration;

4.2.8 When the IRB approves a waiver or alteration, it will require that participants be provided with additional information about the research after participation, whenever appropriate.

Approved by: BR Ware 7-20-08

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Diane Young, Ph.D. — Date
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