**OBTAINING INFORMED CONSENT**

**PURPOSE AND SCOPE**

This SOP describes the procedures study personnel are required to complete in order to fulfill the regulatory and ethical responsibilities for obtaining the informed consent of participants in a human subject research study and assent from parents and guardians of research participants who are not competent to give consent.

**APPLICABLE REGULATIONS AND UC POLICIES**

Policy II.01 *Obtaining Informed Consent*

Policy V.06 *Participants Vulnerable to Coercion or Undue Influence Because of Cognitive Impairment*

Policy III.05 *IRB Review of Emergency Use of an FDA Regulated Test Article*

Policy V.04 *Research Involving Minors*

21 CFR 50.25 45 CFR 46.116

**DEFINITIONS**

Assent: a child’s affirmative agreement to participate in research. Assent may be verbal or in writing, depending on what the IRB approved protocol requires. Failure of the child to object to participating is not assent.

Guardian: An individual who is authorized by law to consent on behalf of a child to general medical care.

Informed Consent: A process by which a potential participant in a research voluntarily agrees to participate in the study after having been informed of all aspects of the study relevant to the subject’s decision to participate and having all questions answered to the participant’s satisfaction. The process continues throughout the study and is documented by means of a written, signed, and dated informed consent form approved by the IRB.

Informed Consent Document: The written document, meeting all legal and regulatory requirements and approved by the IRB, which is signed by the participant or the participant’s legally authorized representative demonstrating the participant’s consent to participate. The required elements of informed consent are listed in University Research Policy *II.01 Obtaining Informed Consent in Human Subjects Research*

Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Parent: A child's biological or adoptive parent.

Vulnerable Subjects:Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent. (ICH 1.61) Mentally disabled individuals are a vulnerable population.

**PERSONS RESPONSIBLE**

*Principal Investigator:* The Principal Investigator is responsible and accountable for gaining participants’ informed consent to participate in the study in accordance with federal and local law, rules, regulations and university policy. The PI may delegate responsibility for the informed consent process to another qualified researcher involved in the study, but may not delegate accountability. Examples of qualified researchers to whom the PI may delegate responsibility for obtaining informed consent include Clinical Research Coordinators, Clinical Research Nurses, Research Assistants, and Regulatory Affairs Assistants.

**TRAINING**

The PI and all research personnel who are involved in the informed consent process or in documenting informed consent must be able to demonstrate competency in understanding the ethical obligations of informed consent. Competency is demonstrated by satisfactorily completing UC’s online testing for informed consent. The PI and individual(s) to whom informed consent is delegated shall have sufficient clinical training to understand and explain study related procedures to potential participants.

**NOTES**

1. The university’s IRB or other compliance official may observe the consent
process for any study.

2. The PI may delegate responsibility for obtaining the informed consent of potential research participants to another member of the research team; however the IRB will attribute any deficiency in obtaining the informed consent of any participant which is discovered through audit or monitoring to the PI.

3. If the research participant does not speak English, the informed consent must be in the participant’s language and the form must approved by the IRB.

4. Only the most recently IRB approved, stamped and dated version of the informed consent document may be used to consent potential participants.

5. Capacity to Consent**.**

a. As a general rule, all adults, regardless of their diagnosis or condition, are presumed competent to consent unless there is evidence of serious mental disability that would impair reasoning or judgment. Even those who do have a diagnosed mental disorder may be perfectly able to understand the matter of being a research volunteer, and quite capable of consenting to or refusing participation. Mental disability alone should not disqualify a person from consenting to participate in research; rather, there should be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent.

b. Persons judged incompetent by a court of law have a court-appointed guardian who must be consulted and to consent on their behalf. The guardian must present a copy of the court’s order of guardianship, which should be filed with the signed informed consent, and picture identification.

6. Vulnerable Subjects**.**  If the IRB approved protocol has special protections for participants who may be vulnerable, the person designated by the PI to obtain informed consent must follow the consent process approved by the IRB. These special protections may require the use of a comprehension tool which is IRB approved, an objective third party to witness the consent process, allowing the participant additional time to discuss the consent with family members, or other measures.

**PROCEDURE FOR OBTAINING INFORMED CONSENT**

1. A completed Informed Consent Document must be obtained from every participant who takes part in a study prior to performing any study-related activities, including screening laboratories, vital signs, or questionnaires. On occasion, a separate *screening consent,* approved by the IRB, may be used to document consent for screening procedures only.

2. When a potential protocol candidate is identified, the investigator or research coordinator discusses the study in detail with the potential participant. An explanation of the study, its risks and benefits, and what would be required of the subject is discussed. The subject is given a copy of the informed consent document to read in a quiet environment without distraction. The subject is encouraged to take the consent form home so that he or she may discuss it with family members. All questions and concerns are addressed throughout this process by the consenter and/or PI.

3. If a person decides to participate, he/she is asked to sign the informed consent document

only after all questions and concerns have been addressed and the consenter is satisfied that there is a clear understanding of the trial.

4. The informed consent document must be signed and dated by the participant or legal representative along with the coordinator or investigator obtaining consent.

5. The original signed informed consent is kept in the patient’s research chart (i.e., source documents) or in the patient’s medical record as required by the research unit.

6. The participant is given a copy of the signed informed consent document.

7. Documentation of the Informed Consent process will be entered in the subject’s source documents (see Documentation Section below).

**REVISED INFORMED CONSENT FORMS AND RE-CONSENTING**

If, during the course of the trial, the protocol has been modified in such a way that changes are made to the Informed Consent, participants who have already given their informed consent may be required by the IRB to be re-consented using the updated form with the changes bolded. All participants currently enrolled in the study must sign the bolded copy of the updated informed consent form to acknowledge the changes. The participant may be re-consented at the next patient contact unless otherwise stated by the IRB or study sponsor.

For potential participants who are not yet enrolled in the study, the revised Informed Consent replaces all previous versions for the Informed Consent and is used in its clean format. Informed Consent is obtained as described above.

**OBTAINING INFORMED CONSENT FROM PARTICIPANTS UNABLE TO SPEAK ENGLISH**

Individuals unable to speak English may not be excluded from participating in a study. If the potential subject does not speak English, study related information will be presented verbally to the person in the person’s native language. Unless the researchers are fluent in the subject’s language, a qualified translator must be included in the consent process and then sign his or her name at the end of the approved translated consent form. The informed consent document must be translated into a language the person can read and understand, and the translation must be approved by the IRB. Family members may not be used as interpreters for the informed consent process.

**OBTAINING INFORMED CONSENT FROM A PARTICIPANT WHO CANNOT READ**

1. If an investigator wishes to include a subject who is illiterate or cannot read, the informed consent document will be read to the subject in the presence of an impartial witness. Whenever possible, accommodations should be made to permit subjects to read the

consent form if possible; e.g., large type for individuals with visual impairments, rather than relying on verbal consent routinely.

2. The information presented to the subject must include all of the required elements of consent and should be at least as extensive as found in the written consent form.

3. An impartial witness will observe and/or take part in the consent process and then sign the consent form.

4. The person who is illiterate will also sign her/his mark on the signature line. When a study is expected to include illiterate subjects, the investigator will describe during initial review how the consent process is to be carried out and will submit a “short form” for approval.

**SHORT FORM CONSENT**

1**.** If the IRB has approved use of a short form written informed consent document, the IRB will approve both the summary that is to be presented to the participant verbally and the short form informed consent document.

2. The verbal summary shall be presented to the participant in the presence of an impartial witness.

3.Only the short form itself is to be signed by the subject. However, the witness will sign both the short form and a copy of the summary, and the person actually obtaining the consent will sign a copy of the summary.

4.A copy of the summary will be given to the subject or the representative in addition to a copy of the short form.

5.It is recommended that a progress note documenting the informed consent process be placed in the subject’s medical record and signed by the investigator. At a minimum, the progress note should include the name of the study, the person consenting the subject, a statement that the study was explained to the subject or the subject’s representative, a statement that the subject was given the opportunity to ask questions, and documentation that consent was obtained before any subject procedures were performed. The witness will sign both the short form and a copy of the summary.

**PROCEDURES FOR RESEARCH INVOLVING CHILDREN**

1.Where minors (those who are less than 18 years of age) are involved in research, consent of one or both parents must be obtained, as required by the IRB approved protocol.

1. The IRB may require the assent of the child. The IRB approved protocol will specify whether assent is required, and when it is required, whether assent may be verbal or must be written and signed the minor. If assent is required, the child should be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition. This explanation should include a discussion of any discomforts and inconveniences the child may experience if he or she agrees to participate.

3.If the parents consent but the child does not wish to participate, the researcher must contact the IRB before including the child in the research.

4. The IRB may require additional protections when minors participate in research, such as requiring that an independent third party or an advocate of the child be present during the informed consent process.

5.Individuals who are “mature minors” or “emancipated minors” under the law of the state may be able to give informed consent. If a participant is a mature minor or emancipated minor, the researcher should contact the IRB before allowing the minor to give informed consent for participating in the study.

**DOCUMENTATION RELATED TO THE INFORMED CONSENT PROCESS**

1. The PI/study coordinator will maintain documentation of the decision to delegate the responsibility for informed consent, including the qualifications of the individual(s) selected. This may be done via a Delegation of Duties Form which is filed in the regulatory files. This documentation shall be made available for auditing/monitoring.

2. The original IRB approval letter and the stamped copies of the consent form will be maintained in the regulatory file and copies forwarded to the sponsor. (See Regulatory Preparation Section of this Manual)

3. The researcher obtaining informed consent should note in the source documents the following information pertinent to The Informed Consent Process:

• Name and title of person who explained the study

• Name and title of person who obtained Informed Consent (if different than above)

• The actual date and clock time Informed Consent was obtained

• Individual(s) present when Informed Consent was obtained

• Name of staff, if any, who witnessed Informed Consent

• Name of individual who signed the Informed Consent document