Informed Consent Process

I. Procedure Title: Informed Consent Process

II. Overview/Procedure Description:

In this procedure "investigator" means a principal investigator or an individual authorized by the principal investigator to obtain consent for the specific protocol, such as a co-investigator, research assistant, or study coordinator.

1. In this procedure "subject/representative" means:
    a. The subject, an adult capable of providing consent;
    b. Legally authorized representative (LAR) when the subject is an adult unable to give consent. This is an individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the protocol.
    c. One or both biologic or adoptive parents when the subject is a child or in the absence of a parent a person other than a parent authorized under applicable law to consent on behalf of the child to general medical care.

2. If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative.

3. If the subject is an adult unable to consent:
    a. The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.
    b. Permission is obtained from a legally authorized representative

4. If the subject is a child:
    a. The IRB must have specifically approved the protocol to allow the enrollment of children.
    b. Permission is obtained from both parents unless:
        a. One parent is deceased, unknown, incompetent, and not reasonably available;
        b. Only one parent has legal responsibility for the care and custody of the child; or
        c. The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
    c. In the absence of a parent, permission may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care.

5. If the subject/representative cannot speak Spanish:
    a. The IRB must have specifically approved the protocol to allow the enrollment of subjects able to speak the language that the subject understands.

6. Conduct all discussions in a private and quiet setting.

7. Any well-informed individual may:
    a. Review the study with subject/representative to determine preliminary interest.
    b. If the subject/representative is interested, notify an investigator.
    c. If the subject/representative is not interested, take no further steps regarding recruitment or enrollment.

A. Purpose:

1. This procedure establishes the process to obtain informed consent from subjects, the legally authorized representatives of adults unable to consent, or the parents or guardians of children.
2. The process begins when an individual identifies a subject as a potential candidate for a research study.
3. The process ends when a subject or the subject's legally authorized representative declines to take part in the research study.
4. The informed consent process does not end with the initial review and signing of the informed consent document; it is an ongoing, interactive process that continues throughout the participant's involvement in the research study.

III. Area(s) of Responsibility:

The principal investigator (PI) is responsible to ensure these procedures are carried out, and also applies to all clinical personnel involved in the informed consent process, Regulatory Knowledge and Support Core, PRCTRC Nursing Staff.

IV. Procedure Details:

1. If the consent process will be documented in a written form:
    a. Obtain the current IRB approved consent form;
    b. Verify that you are using the most current IRB-approved version of the study specific consent form and that the consent form is in language understandable to the subject/representative;
    c. Provide a copy of the consent form to the subject/representative. Whenever possible provide the consent form to the subject/representative in advance of the consent discussion;
    d. If the subject/representative cannot read, obtain an impartial witness – a person to be present during the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness may be a family member or friend. **The witness may not be** a person involved in the design, conduct, or reporting of the research study.

e. Read the consent document with the subject/representative. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

2. If the requirement for written documentation of the consent process has been waived by the IRB:
    a. Obtain the current IRB approved script.
    b. Verify that you are using the most current IRB-approved version of the study specific script and that the script language is understandable to the subject/representative;
    c. When possible provide a copy of the script to the subject/representative in advance of the consent discussion;
        i. Read the script with the subject/representative. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

3. Invite and answer the subject/representative's questions;

4. Give the subject/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate;

5. Invite and encourage the subject/representative to take the written information home to consider the information and discuss the decision with family members and others before making a decision;

6. Ask the subject/representative questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the subject/representative is incapable of consent:
    a. The subject/representative understands the information provided.
    b. The subject/representative does not feel pressured by time or other factors to make a decision.
    c. The subject/representative understands that there is a voluntary choice to make.
    d. The subject/representative is capable of making and communicating an informed choice.

7. If the subject/representative has questions about treatments or compensation for injury, provide correct information and avoid statements that imply that compensation or treatment is never available.

8. Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops;

9. If the subject/representative agrees to take part in the research study:
    i. If the subject is an adult able to consent:
        1. Obtain written documentation of the consent process
    ii. If the subject is a child:
        1. Whenever possible explain the research to the extent compatible with the child's understanding.

2. **Request the assent** (affirmative agreement) **of the child** unless:
    a. The capability of the child is so limited that the child cannot reasonably be consulted.
    b. The IRB determined that assent was not a requirement.

3. Once a child indicates that he or she does not want to take part in the research study, this process stops.

iii. If the subject is an adult unable to consent:

1. Whenever possible explain the research to the extent compatible with the adult's understanding.

2. Request the affirmative agreement of the adult unless:
    a. The capability of the adult is so limited that the adult cannot reasonably be consulted.
    b. The IRB determined that acceptance was not a requirement.

3. Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.

REMEMBER:

- The subject (or legal representative) should have ample opportunity to ask questions and to decide whether or not to participate in the study. **The subject should not be coerced to participate or continue to participate in a project.**
- ICD process must be consistent and conducted by a **qualified person**
- Ensure that all subjects or legal representative **personally sign & date** the appropriate and complete version of the Informed Consent Document (ICD) prior to beginning of the study.
- The subject or legal representative should receive a **copy** of the signed ICD and any subsequent amendments.
- **Document** the ICD procedure followed with each subject in source document.
- If a **new version of the IDC** was available, re-consent the subject on the next visit.
- **All** signed versions of the ICD must be filed in the subject record.
- **You never:** discard an ICD, sign an ICD retrospectively, and sign or date the ICD instead of the subject.

V. References:

21 CFR §50.20, 21 CFR §50.25 and 45 CFR §46.116