**Informed Consent in Human Subject Research**

**Section Notes:**

- It is the responsibility of the principal investigator to assess the comprehension of the consent process and only enroll subjects who can demonstrate informed understanding of the research study (45CFR46.116). Federal regulations require that consent be in a language understandable to the subject. If subjects do not comprehend English, translated consent forms are required. Translated consent forms must be prepared by a certified translator.

- Permission (consent) of a parent or legally authorized representative must be obtained. Under certain limited conditions it may be possible for the minor to consent on her/his own behalf, without the need for parental permission. For example, research concerning neglect and abuse.

- Consider the environment and location where informed consent will be solicited. The timing of the process, *(example: in relation to hospital admission, surgery, medication, stressful events, etc.)* the involvement of someone other than the principal investigator to help explain the research, the opportunity for the perspective subjects/representative to discuss participation in the research with family, friends, or their advisors before signing the consent form.

*Following are the required elements of informed consent that must be included on each informed consent form:*

**Required Elements of Informed Consent:**

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary; refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

**Additional Elements, as appropriate:**

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the principal investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- The approximate number of subjects involved in the study