

IRB Policy #:	260
Policy Title:	<i>Informed Consent</i>
Date Approved:	
Date Reviewed:	

Purpose: To describe the requirements for informed consent.

Policy:

Informed consent must be sought from each prospective subject or the subject’s legally authorized representative before research is begun. Consent is a continuing process and subjects always retain the right to withdraw from participation in a research project. Federal policy requires that investigators inform subjects of any important new information that might affect their willingness to continue participating in the research.

The basic elements of the informed consent (45 CFR 46.116) are:

- A statement that the study involves research. (45 CFR 46.116(a)(1))
- An explanation of the purpose of the research. (45 CFR 46.116(a)(1))
- The expected duration of the participation. (45 CFR 46.116(a)(1))
- A description of the procedures to be followed and, if appropriate, identification of any procedures that are experimental (e.g., therapies that are being tested). (45 CFR 46.116(a)(1))
- A description of any reasonably foreseeable risks or discomforts to the subject. (45 CFR 46.116(a)(2))
- A description of any benefits to the subjects or to others which may reasonably be expected from the research and how that will contribute to the field of study or may benefit others. (45 CFR 46.116(a)(3))
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subject, description of foreseeable risks or discomforts to the subject. (45 CFR 46.116(a)(4))
- A statement describing the extent, if any, to which confidentiality of records identifying the subject is maintained. This includes the matter and place of data storage. (45 CFR 46.116(a)(5))
- For research involving more than minimal risk, an explanation as to whether any compensation is available, and an explanation as to whether any medical treatments are available if injury occurs and what they consist of or where further information may be obtained. (45 CFR 46.116(a)(6))
- 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. (45 CFR 46.116(a)(7)) (SIUC consent forms should include the address, phone number and email addresses for the PI and the IRB.)

- 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. (45 CFR 46.116(a)(8))

Additional requirements may include:

- 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. (45 CFR 46.116(b)(1))
- Anticipated circumstances under which participation may be terminated by the investigator without regard to the subject's consent. (45 CFR 46.116(b)(2))
- Any additional costs to the subject that may result from participation in the research. (45 CFR 46.116(b)(3))
- The consequences of a subject's decision to withdraw from the research and procedures for orderly closure of participation by the subject. (45 CFR 46.116(b)(4))
- A statement that significant new findings developed during the course of the research, which may relate to subjects' willingness to continue participation, will be provided to the subject. (45 CFR 46.116(b)(1))
- The approximate number of subjects involved in the study. (45 CFR 46.116(b)(1))

Where the potential for the need to report information to authorities exists (e.g., information arises in the course of the research that suggests a subject may intend to harm to him or herself or others, thus breaking confidentiality), subjects shall be informed before agreeing to participate in the study. (45 CFR 46.103(b))

The IRB may waive written documentation of informed consent if: (i) the research represents no more than minimal risk of harm to subjects, (ii) the waiver or alteration will not adversely affect the rights and welfare of the subject, (iii) the research could not be carried out without the waiver or alteration, and, (iv) where informed consent constitutes the only threat to anonymity, and (v) whenever appropriate, the subject will be debriefed. When consent is waived, the IRB may require the investigator to offer subjects written information about the study. [45 CFR 46.116(c) and (d)]

Consent forms avoid jargon and should be written in the second person (e.g., If you agree to the research....) in a language and at a level that is understandable to the subject. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the

institution or its agents from liability for negligence. Informed consent will not be accomplished unless the requirement is met that the subject understands the components of the consent form.

Only the current IRB-approved watermarked version of the consent form may be used for consenting subjects.

The person who signs the consent form must be given a copy as a reference and reminder of the information conveyed by the researcher. Non-written methods of administering consent are also possible.

The IRB may waive written documentation of informed consent as stated above but will not allow a passive consent process. Participants must actively participate in the consent process. Sometimes passive consent is also called “opt-out” consent. “Opt-out” or passive consent is any procedure where the participants are in the study unless they say they do not want to participate.