INFORMED CONSENT

INFORMED CONSENT DEFINITION

Informed consent is a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights or release or appear to release the investigator, the sponsor, the institution, or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25].

IRB CONSIDERATIONS

Investigators may seek consent only under circumstances that provide the prospective subject or his/her representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. Furthermore, the information must be written in language that is understandable to the subject or representative. The consent process may not involve the use of exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence [Federal Policy §___.116].

FEDERAL REGULATIONS

Federal regulations require that certain information must be provided to each subject: [Federal Policy §___.116(a)]

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) 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.

The regulations further provide that the following additional information be provided to subjects, where appropriate: [Federal Policy §___.116(b)]

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 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.

As per CFR §46.117 (c), the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it determines either of the following:

The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.
(2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

**ASSENT**

Assent is defined as an “agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.” [IRB Guidebook](http://www.hhs.gov/ohrp/irb/irb_glossary.htm). Assent is generally required if

1. subjects are minors between the ages of 7 and 17 (children below the age of 7 are generally not asked to provide assent);
2. subjects 18 or older are intellectually or emotionally impaired and not legally competent to give their informed consent.

In the case where the minor subjects are able to read and understand the informed consent document, they may provide assent on a form with a separate signature line for their parents/guardians.

The assent form must include:

1. Study title
2. Study purpose (provide a brief explanation of the purpose of the study)
3. Procedures (describe what the subject is being asked to do)
4. Withdrawal privilege (describe how a subject can stop participation later even if he/she agrees to start)
5. Voluntary participation (include a statement that the subject does not have to participate)
6. Confidentiality statement (indicate that the experimenter will not tell anyone – e.g., parents, teachers – what the subject says or does in the study)
7. Signature lines (include a signature line for the subject and for the investigator)
8. Date line

It is important that the form be written using language that is appropriate for the age level and mental capacity of the subjects.