

28.0 Informed Consent

Last Revised on 12 December 2003

Informed consent is a process rather than merely a document. Any individual invited to participate in a research study should be given a description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate. The informed consent process should be designed to provide potential subjects with readily understandable information in an amount and timing appropriate to the level of risk in participating.

The subject's consent must follow and not precede receipt of this information unless the IRB approves a waiver or alteration of informed consent (as in some behavioral research that would be compromised by full disclosure in advance). Consent must be obtained from each subject who is legally, mentally, and physically able to provide it unless waived by the IRB. Consent should be in writing unless the IRB finds that written documentation of informed consent may be waived. Consent forms and other informational documents should be written in simple language so as to be easily understood by persons with no technical background in the field.

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the subject's authorized 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.

The standard expectation is that all subjects will sign a document containing all the elements of informed consent, as specified in the federal regulations and noted below. Some or all of the elements of consent, including signatures, may be waived under certain circumstances.

28.1 Basic Elements of Informed Consent

Unless the IRB approves exceptions, the following information must be provided to the subject when seeking informed consent:

- 28.1.1 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 that are experimental;
- 28.1.2 A description of any reasonably foreseeable risks or discomforts to the subject;
- 28.1.3 A description of any benefits to the subject or to others that may be reasonably expected from the research;
- 28.1.4 A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- 28.1.5 A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained; (see 29.0: HIPAA and IRB Review and 24.6 Privacy of subjects and confidentiality of data)

- 28.1.6 For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- 28.1.7 An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject, if relevant. Typically, questions concerning a research project should be referred to the PI for that project, whereas questions concerning the rights of human subjects should be referred to the IRB.
- 28.1.8 A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

28.2 Additional Elements of Informed Consent

For some studies, one or more of the following elements or information may be appropriate and required by the IRB:

- 28.2.1 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) that are currently unforeseeable;
- 28.2.2 Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- 28.2.3 Any additional costs to the subject that may result from participation in the research;
- 28.2.4 The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject (particularly when potentially therapeutic experimental interventions are being administered and unscheduled cessation of the intervention may pose health risks to subjects);
- 28.2.5 A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
- 28.2.6 The approximate number of subjects involved in the study.

28.3 Exceptions to informed consent requirements

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- 28.3.1 The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: