Informed Consent Requirements

Informed consent is a process in which the researcher provides sufficient information, in an understandable format, to the research subjects so that they can make a voluntary decision whether or not to participate in the study. The informed consent process is fundamental in ensuring respect for persons and should serve to educate the subject about the research, the benefits and risks, and the voluntary nature of their participation. The informed consent should be in language understandable by the study subjects. The informed consent should also be revised when deficiencies are discovered or when additional information will improve the process. The regulations under section 28 CFR §46.116 describe the elements or information that must be contained in the informed consent provided to the study subjects. Below is a brief listing of the basic items to be included in the informed consent:

- A statement that the study involves research.
- The name(s) of the funding agency(ies).
- An explanation of the purposes of the research.
- The expected duration of the subject's participation.
- A description of the procedures to be followed and what the subjects will be required to do in the study.
- Identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject. Risks are not limited to physical injury, but also include psychological, social, financial, legal, and others.
- A description of any benefits to the subject or to others that may reasonably be expected from the research; there may be none other than a sense of helping the public at large when balanced by the appropriate level of risk.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. In most NIJ studies the alternative will be to not participate in the study.
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained. For studies sponsored by NIJ the subject should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the subjects need to be explicitly notified. If the investigator intends to disclose any information, the subject needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The subject must be informed of any potential risks which may result from this disclosure and must explicitly provide prior written consent.
- 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 questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. This should include name and telephone number or other appropriate methods.
- 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 CFR §46.117 Documentation of Informed Consent

As a general rule, informed consent should be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

An IRB may waive the requirements to obtain a signed consent form as described in section 46.117(c) if it determines:

1. That 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; or
2. That 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 written consent documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research and obtain their oral consent to participate.