

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 035
SECTION: INFORMED CONSENT PROCESS
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.117

SUBJECT: Documentation of Informed Consent

1. Except as provided in paragraph (3) of this policy, informed consent shall 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 of the consent form shall be given to the person signing the form. Consent form pages shall be consecutively numbered inclusively.
2. Except as provided in paragraph (3) of this policy, the consent form may be either of the following:
 - a) A written consent document that embodies the elements of informed consent required by IRB Policy. This form may be read to the subject or the subject's legally authorized representative, but in any event the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed, and the form should utilize language understandable to the subject; or
 - b) A short form written consent document stating that the elements of informed consent required by IRB Policy have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. The person obtaining consent may not be the witness to the consent. Also, the IRB shall approve a written summary (script) of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form. Where informed consent is documented using the short form for non-English speaking subjects, the oral presentation and the short form consent form must be in a language understandable to the subject, and the witness shall be fluent in both English and the language of the subject.
 - c) The IRB committee must receive all foreign (non-English) language versions of the written consent form or short form documents as a condition of approval.
3. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- a) 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
 - b) 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. Note: "Minimal Risk" is defined to mean that the probability and the magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
 - c) In cases in which the consent documentation requirement has been waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
4. The IRB may approve that the written informed consent document be delivered to the potential subject or legally authorized representative by mail or by facsimile, and to conduct the consent interview by telephone provided the potential subject or the legally authorized representative can read the consent document as it is discussed. Note: All other applicable requirements for documentation of informed consent must be met when using this delivery procedure.