

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 036
SECTION: INFORMED CONSENT PROCESS
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.116, 117

SUBJECT: Waiver of Informed Consent

1. The IRB must ensure that provisions are made to obtain legally effective informed consent prospectively from each research subject or the subject's legally authorized representative. However, the regulations do permit an IRB to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent entirely provided the IRB finds and documents that:
 - a) the research involves no more than minimal risk to the subjects;
 - b) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - c) the research could not practicably be carried out without the waiver or alteration; and
 - d) whenever appropriate, the subjects be provided with additional pertinent information after participation.

2. Additionally, as documentation of informed consent, an 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 shall 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 that "minimal risk" means that the probability and 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.

3. When the IRB approves a procedure which alters or waives the requirement for informed consent, the minutes of the IRB meeting shall document that the Committee made the required findings as set out above, and should document discussion of the risks and benefits of the research as required by regulation.