

DEPARTMENT: INSTITUTIONAL REVIEW BOARD  
POLICY NUMBER: 033  
SECTION: INFORMED CONSENT PROCESS  
REVIEW RESPONSIBILITY: IRB  
EFFECTIVE DATE: AUGUST 13, 2003  
REVISION DATE:  
LAW IMPLEMENTED: 45 CFR 46.116

SUBJECT: General Requirements for Informed Consent

1. Except as provided elsewhere in 45 CFR 46.116, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. Informed consent is a process that takes place between the Investigator and the prospective subject.
2. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.
3. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the 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, in the institution or its agents from liability for negligence.
4. 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. There are limited circumstances under which the regulations give the IRB authority to waive the required informed consent. Documentation of informed consent must be obtained unless alternate procedures are approved by the IRB. The IRB must review all informed consent documents and assure the adequacy of the information contained in the consent document.
5. Each subject or his/her authorized representative must sign, date, and receive a copy of the current IRB approved consent form prior to enrollment or any participation in any phase of the study, unless the requirement is waived by the IRB.
6. A "legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure involved in the research. Example: A parent or a minor child or a legal guardian may be a legally authorized representative.

7. The IRB may approve a consent procedure in which a surrogate consents on behalf of a subject who is unable to give informed consent and for whom the proposed intervention reasonably appears to offer a therapeutic gain. The surrogate is deemed to be a legally authorized representative. A surrogate consent can only be used when the subject faces a high likelihood of death or serious bodily injury from standard of care alone and the window or opportunity for employing the investigational agent would be too brief to allow obtaining consent by an alternative legal representative. In such circumstances, if the IRB otherwise approves the protocol and a surrogate consent document, the approval recommendation will be forwarded after committee review and before final approval to the Associate Vice President for Research or IRB Chair for administrative approval of the use of surrogate consent. The person acting as a surrogate must execute the document in the presence of a witness who should also execute the consent document.
  
8. Studies involving subjects who are decisionally impaired may take place over an extended period. Therefore, the IRB shall consider whether periodic reconsenting of individuals should be required to ensure that a subject's continued involvement is voluntary. The IRB may require that investigators reconsult subjects after taking into account the study's anticipated length and the condition of the individuals to be included (such as subjects with progressive neurological disorders), and whether or when to require a reassessment of decisionmaking capacity.