

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 011
SECTION: IRB REVIEW PROCEDURES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.103

SUBJECT: Amendments to Previously Approved Applications

1. For previously approved applications that were approved within the last year, all planned changes in the conduct of a study and/or changes to the consent document must be approved by the IRB prior to initiation.
2. Investigators must submit the exact text of an amendment or other revision to the protocol and any proposed changes to the consent document to the IRB. When there are numerous changes to the research protocol, a summary of the changes should also be included.
3. Changes to the informed consent document must take into account both prospective research subjects and, if applicable, research subjects already enrolled in the study. The latter may be addressed by using an addendum to the initial informed consent document or, less preferably, by re-consenting the subject using the modified informed consent document.
4. Minor changes proposed for previously approved research may be reviewed in an expedited manner. A minor modification is defined to mean a change that would not materially affect an assessment of the risks and benefits of the study, or does not substantially change the specific aims or design of the study.
5. If major changes are proposed for previously approved research, then the IRB Committee must review and approve changes at a convened meeting before such changes can be implemented. A major modification is defined as any change which materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.