

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 014
SECTION: IRB REVIEW PROCEDURES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.103,111, 117

SUBJECT: IRB Audits and Monitoring

1. The Institutional Review Board is charged with the responsibility for internal and external auditing and monitoring efforts in order to ensure the protection of human subjects and compliance with federal regulations and IRB policies. The IRB has the authority to observe, or appoint a designee to observe, the informed consent process and the IRB approved research.
2. The Vice President of Research, Associate Vice President of Research, and/or the Chair of the IRB may direct an experienced designee to initiate periodic and/or directed audits when deemed necessary.
 - a) A periodic audit is a systematic method to audit IRB approved research on a regular basis.
 - b) A directed audit is an audit conducted in response to identified concerns that require an IRB determination.
3. Monitoring and/or auditing activities may include, but are not limited to the following:
 - a) Request progress reports from investigators.
 - b) Examine research records, including copies of signed consent forms.
 - c) Contact research subjects.
 - d) Assign observers to sites where research involving human subjects and/or the informed consent process is being conducted.
 - e) Audit advertisements and other recruiting materials as deemed appropriate by the IRB.
 - f) Review projects to verify from sources other than the investigator that no unapproved changes have occurred since previous IRB review.
 - g) Other monitoring or auditing activities deemed appropriate by the IRB.
4. The IRB may suspend or terminate research if the information gained during the monitoring or auditing process indicates that human subjects in a research project were exposed to unexpected serious risk or harm, or that the federal regulations or the policies of the IRB were not met.

5. The IRB may request additional safety monitoring or the creation of an independent data safety monitor.
6. For research activities involving vulnerable populations such as fetuses, children, pregnant women, prisoners, or the decisionally impaired, the IRB shall determine that adequate provisions have been made by the investigator for monitoring the actual consent process. The IRB may oversee the actual informed consent process, not limited to the following:
 - a) verifying that subject selection is appropriate and observing the actual informed consent process by which individual consents are obtained, or
 - b) monitoring the progress of the activity and intervening as necessary, including visits to the activity site and continuing evaluation to determine whether any unanticipated risks have developed.
7. The results of any auditing or monitoring activity by the IRB shall be reported in writing to the Chair of the IRB. The IRB Chair shall determine the need for full IRB Committee review. The results will be placed on the agenda or the next regularly scheduled meeting for action as appropriate. In addition, all auditing and monitoring information will be maintained in the IRB file and provided to the primary reviewer at the time of the next continuing review.
8. If the auditing or monitoring of a research activity reveals that a human subject has been exposed to unexpected serious harm, such finding shall be reported to the Chair of the IRB, the Vice President of Research, and Associate Vice President of Research. The finding and related study shall be placed on the agenda of the next regularly scheduled meeting for discussion and action. However, a decision may be made to suspend or terminate the research prior to the next regularly scheduled IRB meeting as circumstances may require.
9. The IRB may determine which projects require verification from sources other than the investigator to ensure that no unapproved changes have occurred since the previous IRB review. To accomplish this task, the IRB may conduct audits or inquiries to collect information and/or observe or utilize a designee to observe, the informed consent process and conduct of the research.