

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 042
SECTION: RECORDS AND DOCUMENTATION
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.115

SUBJECT: IRB Office Records

1. The IRB Office files must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments and adverse event reports.
2. The IRB Office must retain all records regarding an application (including those which did not receive approval) for at least 3 years. For all applications that are approved and the research initiated, the IRB Office must retain all records regarding that research for at least three (3) years after completion of the research. Records may be archived as provided by State Law.
3. The IRB Office must make all records available for inspection and copying by authorized representatives of the sponsoring Department or Agency at reasonable times and in a reasonable manner.
4. The IRB Office must prepare and/or maintain the following documents:
 - a) Applications - copies of all research applications reviewed, scientific evaluations, approved sample consent documents, data safety monitoring board reports, progress reports submitted by investigators, and reports of injuries or adverse events to subjects.
 - b) Minutes - the complete minutes of all IRB Committee meetings.
 - c) Continuing Review - records of continuing review activities.
 - d) Correspondence with Investigators - copies of all correspondence between the IRB and the investigators.
 - e) Listing of IRB Committee Members - A list of the membership identified by name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, sufficient to describe each member's chief anticipated contributions to IRB deliberations, and any employment or other relationship between each member and FSU, such as full or part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Note that changes to IRB Committee membership need to be updated periodically with OHRP by the IRB Office.
 - f) Written policies and procedures which the IRB Office and the IRB Committee will follow for :

- conducting initial and continuing review of research and for reporting its finding and actions to the Investigator and the institution (FSU);
 - determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since the previous IRB review.
 - ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject;
 - ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and any suspension or termination of IRB approval.
- g) Statements of any new significant findings developed during the course of the research which may relate to the subject's willingness to continue participation provided to subjects.