

DOCUMENTATION AND DOCUMENT MANAGEMENT

SOP #:	304	VERSION #:	1	EFFECTIVE DATE:	05/01/09	SUPERSEDES DOCUMENT:	/ /
THIS POLICY PERTAINS TO:		ALL RESEARCH SUBMITTED TO THE IRB					
RESPONSIBILITY FOR EXECUTING POLICY:		ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB STAFF					
LAST REVIEWED ON:		/ /		RESULTS:	REVISED		
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:						DATE:	/ /

1. POLICY

The IRB 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. All records regarding a submitted study must be retained in an appropriate manner as required by regulatory requirements and/or institutional policy.

Records must be accessible for inspection and copying by authorized representatives of the Sponsor, funding department or agency, regulatory agencies, and institutional auditors at reasonable times and in a reasonable manner.

2. SPECIFIC POLICIES

2.1 Document Retention

The Research Development and Compliance office must retain all records regarding an application (regardless of whether it is approved) for at least three (3) years. For all applications that are approved and the research initiated, the Research Development and Compliance Office must retain all records regarding that research for at least three (3) years after completion of the research. If a protocol is cancelled without participant enrollment, IRB records are maintained for at least three years after cancellation.

Applications submitted to the IRB that do not meet the definition of “research” and/or “human subject” as defined in DHHS regulations and do not meet the definition of “clinical investigation” in FDA regulations will maintained for at least (1) year.

2.1.1 Study-related documents:

Adequate documentation of the IRB activities will be prepared, maintained and retained in a secure location in the Research Development and Compliance office. Retained documents include:

- Copies of all original research protocols reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents, progress reports submitted by Investigators and reports of adverse events, unexpected adverse events, unanticipated events occurring to subjects, and reported deviations or violations from the protocol.
- Agendas and minutes of all IRB meetings.

- Copies of all correspondence between the IRB and the Investigators.
- Copies of all continuing review activities, including submitted monitoring reports and site visit reports (if applicable).
- Statements of significant new findings provided to subjects as submitted by the Investigator.
- Reports of any complaints received from subjects.
- DHHS-approved sample consent documents (when they exist).
- DHHS-approved protocol (when it exists).

IRB records will be accessible for inspection and copying by authorized representatives of the IRB, OHRP, FDA and other authorized entities at reasonable times and in a reasonable manor.

2.2 IRB Administration Documents

The Research Development and Compliance office must maintain and retain for at least three (3) years all records regarding IRB administrative activities that affect review activities.

2.2.1 Rosters:

Rosters of regular and alternate IRB members identified by name, earned degrees, representative capacity, and indications of experience sufficient to describe each regular and alternate member's chief anticipated contribution to the IRB deliberations; and any employment or other relationship between each member and the University of North Dakota.

Alternate members shall be included on the roster. In addition to the above information, the roster shall indicate the regular members for whom the alternate may substitute.

Current and obsolete membership rosters will remain in the Research Development and Compliance office and then archived according to University policy on record retention.

The roster of IRB members must be submitted to OHRP. Any changes in IRB membership must be reported to the Office of Human Research Protections (OHRP).

2.2.2 Current and obsolete copies of the Standard Operating Policies.

2.2.3 Delegation of specific functions, authorities, or responsibilities by the IRB Chairperson must be documented in writing and maintained in the Research Development and Compliance office.

2.3 Destruction of Copies

All materials received by the IRB, which are considered confidential and in excess of the required original documentation and appropriate controlled forms, will be collected at the end of the meeting and destroyed.

2.4 Archiving and Destruction

After project closure, all documents and materials germane to IRB determinations will be archived by the Research Development and Compliance office. After no less than 3 years, the Office of Records Management will be contacted and the documents and materials will be destroyed.

3. RESPONSIBILITY

The IRB Coordinator and the IRB Secretary are responsible for maintaining complete files on all research reviewed by or submitted to the IRB and for all applicable regulatory compliance requirements.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.115
45 CFR 46.103, 115

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>IRB Secretary</i>	Upon receipt of a new proposal, ensure that the study information is entered in the database. Organize the submitted material in an organized manner and place all materials in a folder. Proceed as described for administrative intake of new studies.
<i>IRB Secretary, IRB Coordinator</i>	Maintain all records regarding a submitted study (regardless of whether it was approved) in an appropriate manner as required by the regulatory requirements and/or institutional policy.
<i>IRB Coordinator</i>	Report changes in IRB membership to the OHRP.