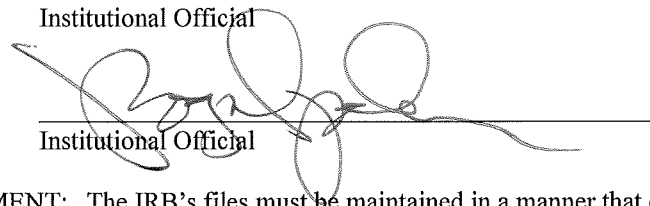


TITLE: Institutional Review Board Functions and Operations  
FO 305 Documentation and Document Management

ORIGINATOR: Institutional Official

APPROVAL:

  
Institutional Official

**POLICY STATEMENT:** The IRB's 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 (regardless of whether it is approved) must be retained in an appropriate manner as required by regulatory requirements and/or institutional policy.

Records must be accessible for inspection according to Mercy Health policy by authorized representatives of the Sponsor, funding department or agency, regulatory agencies and institutional auditors at reasonable times and in a reasonable manner. The records of the IRB are confidential and will not be released to any individuals outside of those groups described without the PI's written permission.

Required documents must be submitted to the appropriate funding entity as required.

**GENERAL PROVISIONS:**

1. Document Retention

The Office of the IRB must retain all records regarding an application (regardless of whether it is approved) for at least seven (7) years. For all applications that are approved and the research initiated, Office of the IRB must retain all records regarding that research for at least seven (7) years after completion of the research.

A. Study-related documents:

Adequate documentation of each IRB's activities will be prepared, maintained and retained in a secure location. 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 occurring to participants and reported deviations from the protocol.
- Copies of grant applications/research proposals that have been submitted to the IRB for review will be maintained with the protocol file.
- All correspondence with local hospitals will be maintained in the correspondence file with the corresponding contract or submission documents.
- Agendas and minutes of all IRB meetings.
- Copies of all submitted monitoring reports, site visit reports and other continuing review activities.
- Copies of all correspondence between the IRB and the Investigators.
- Statements of significant new findings provided to participants.
- Reports of any complaints received from participants.

B. IRB Administration Documents

The IRB Office must maintain and retain all records regarding IRB administrative activities that affect review activities for least three (3) years.

The IRB Office must retain all records regarding protocols that are approved and the research initiated for at least three (3) years after completion of the research.

- Rosters of regular, alternate IRB members, and special consultants, 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's deliberations; and any employment or other relationship between each member and IRB and/or the Mercy Health (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).
- Alternate members shall be included on the roster. In addition to the above information, the roster shall indicate the regular member for whom the alternate may substitute.
- Current and obsolete membership rosters will remain in the Office of the IRB and then archived according to Mercy Health policy.
- The roster of IRB members must be submitted to OHRP. Any changes in IRB membership must be to OHRP.

C. Maintain current and obsolete copies of the Standard Operating Policies and Procedures.

D. Delegation of specific functions, authorities, or responsibilities by the IRB Chairperson must be documented in writing and on file in the Office of the IRB.

1.3 Destruction of Copies

All material received by the IRB, which is 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 by a method deemed appropriate by Mercy Health policy.

1.4 Archiving and Destruction

Office of the IRB records are to be stored on site at Mercy Health in an IRB Storage area with badge only access or in a locked file made only accessible to Office of the IRB staff. All IRB files of active studies are kept onsite until the study file has been permanently closed by the Office of the IRB. Study files that have been permanently closed are shipped to an offsite archival storage space contracted by Mercy Health. Documents and materials germane to IRB determinations are to be destroyed according to institutional policy. Archiving policies of Mercy Health will determine when such archived records may be destroyed.

ATTACHMENTS:

- FO 305-A Hold for future use
- FO 305-B Archiving Procedure Checklist

REFERENCE:

- 45 CFR 46.103,115
- 21 CFR 56.115

PROCEDURE: All Mercy Health Campuses

Creating a Study Folder:

<u>Responsibility</u>	<u>Action</u>
IRB Coordinator	1. Will assist in maintaining all Office of the IRB records regarding a submitted study (regardless of whether it is approved) in an appropriate manner as

required by regulatory requirements and/or institutional policy.

2. Will ensure that all records are accessible for inspection and copying by authorized representatives of the Sponsor, funding department or agency, federal (FDA, OHRP) and institutional auditors at reasonable times and in a reasonable manner.

IRB Specialist

1. Upon receipt of a new study, ensure that the study information is entered in the database.

2. Create a file label.

3. Organize the submitted material in the following order:

- Signed Application
- Original Protocol, Amendments (if Any)
- Informed Consent Form(s), original & amendments (if any)
- Investigator Brochure
- Submitted Advertising
- Safety Information
- Progress Reports
- Completion Report

4. Proceed as described in SOP FO 301 for administrative intake of new studies.

IRB Manager

1. Will provide oversight of documentation creation and management as outlined in this policy.

2. May request review of records to ensure documentation and documentation management are being done according to the Office of the IRB policies and expectations.

Using Electronic Systems

Responsibility

Action

IRB Coordinator/IRB Specialist

1. Ensure that the IRB's electronic systems and records are 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. With the assistance of personnel from the Information Technology staff, oversee computerized systems used to generate documentation, track submissions and studies, and communicate with Investigators to ensure that the systems are validated and are in compliance with applicable regulations, as regards design and validation.

3. Ensure that all IRB staff members are trained on the proper use of all electronic systems used to document study review and compliance activities.

4. Maintain specific operations and procedures manuals to train staff and assure consistency of operations.

5. Oversee the security of the electronic system by conducting appropriate reviews of electronic data and audit trails at designated time periods.

6. Maintain appropriate security methods, such as issuance and revision of ID/passwords, to ensure limited access to secure areas. According to Mercy Health policies.

7. If user ID/password combination is used, they will be changed at appropriate intervals; and invalidated, stolen, lost or otherwise compromised user ID/password combinations will be replaced with a new combination. This will be done in accordance with Mercy Health policy

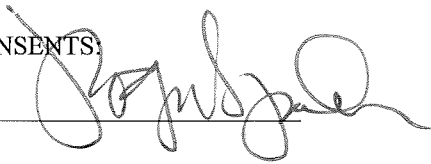
IRB Manager

1. Will provide oversight of documentation creation and management as outlined in this policy.

2. May request review of records to ensure documentation and documentation management are being done according to the Office of the IRB policies and expectations.

CONCURRENT CONSENTS:

Institutional Official

A handwritten signature in black ink, written over a horizontal line. The signature is cursive and appears to be "J. J. [unclear]".