

<b>SOP: FO 305</b> <b>Version No: 2</b> <b>Date: 01/01/07</b>	<b>DOCUMENTATION AND DOCUMENT MANAGEMENT</b>	<b>Supersedes Document Dated: 05/01/04</b>
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## 1. POLICY

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 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.

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

### Specific Policies

#### 1.1 Document Retention

The IRB Office (Office of Research Oversight and Compliance – OROC) must retain all records for at least three (3) years after final activity of the IRB, e.g., completion, termination, withdrawal, disapproval, etc.

##### 1.1.1 Study-related documents:

Adequate documentation of each IRB's activities will be prepared, maintained and retained in a secure location in the OROC 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 occurring to subjects and reported deviations from the protocol.
- Copies of grant applications/research proposals that have been submitted to the IRB for review, if applicable, will be maintained with the protocol file.
- 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 subjects.
- Reports of any complaints received from subjects.
- Publications.
- Copies of all correspondence between the IRB, the hospital administration, sponsors, regulatory agencies, accrediting agencies, and/or other IRB's for which the IRB has standing contractual agreements.

## **1.2 IRB Administration Documents**

The OROC office will retain the following documents:

- 1.2.1 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's deliberations; and any employment or other relationship between each member and IRB and/or the Sparrow Health System (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 OROC office.

The roster of IRB members must be submitted to OHRP. Any changes in IRB membership or organizational status must be reported to OHRP under terms of the Federal-wide Assurance (FWA).

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

## **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 the IRB Administrator. (Destroyed by placement in appropriate recycling bags provided by Sparrow Health System.)

## **1.4 Archiving and Destruction**

The OROC 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, after which the records are destroyed according to Sparrow Health System's procedure.

## **2. SCOPE**

The policies and procedures apply to all controlled documents used in the submission, initial review, and continuing review of research submitted to the IRB.

## **3. RESPONSIBILITY**

IRB Administrator is responsible for maintaining complete files on all research reviewed by or submitted to IRB and for all applicable regulatory compliance requirements.

## **4. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.103,115

21 CFR 56.115

## **5. REFERENCES TO OTHER APPLICABLE SOPS**

This SOP affects all other SOPs.

## **6. ATTACHMENTS**

None

## 7. PROCESS OVERVIEW

The OROC must retain all records regarding an application for at least three (3) years after final activity of the IRB, e.g., completion, termination, withdrawal, disapproval, etc.

## 8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

### A. Creating a Study Folder

Who	Task	Tool
<i>OROC Staff</i>	<p>Upon receipt of a new study, ensure that the study information is entered in the database.</p> <p>Assign an IRB protocol tracking ID number.</p> <p>Create a file and file label.</p> <p>Organize the submitted material in the following order:</p> <ul style="list-style-type: none"> <li>• IRB Application</li> <li>• Protocol</li> <li>• Informed Consent Document</li> <li>• Grant Proposal (if applicable)</li> <li>• Submitted Advertising</li> <li>• Human Subjects Training Verification</li> <li>• Other supporting documentation as appropriate</li> </ul> <p>Proceed as described in SOP FO 301 for administrative intake of new studies.</p>	
<i>OROC Staff</i>	<p>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.</p>	
	<p>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.</p>	
<i>OROC Staff</i>	<p>Ensure all study records (regardless of whether it is approved) are stored for the requisite time, after which documents are destroyed in the appropriate manner.</p>	