

<b>SOP: FO 305</b> <b>Version No.: 05</b> <b>Effective Date: 12/2/10</b>	<b>DOCUMENTATION AND</b> <b>DOCUMENT MANAGEMENT</b>	<b>Supersedes</b> <b>Document</b> <b>Dated: 7/1/08</b>
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## 1. POLICY

Steering Committee approved 4/6/11

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 (regardless of whether it is approved) must be retained in a secure manner as required by regulatory requirements and/or the policy of the Aurora IRB.

Records must be accessible for inspection and copying by authorized representatives of the sponsor, funding department or agency, accrediting or 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

Terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

#### 1.1. Document Retention

The RSPP 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 RSPP office must retain all records regarding that research for at least three (3) years after completion of the research (i.e., after all requisite follow-up is completed). If a protocol is withdrawn without subject enrollment, IRB records are maintained for at least three (3) years after withdrawal.

##### 1.1.1. 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, reports of adverse events and injuries occurring to subjects, and reported deviations from the protocol.
- Protocol amendments.
- Documentation of noncompliance.
- Most current copy of the Investigator Brochure, if applicable.

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- DHHS-approved sample consent document and protocol, when they exist.
- For initial and continuing review of research by the expedited procedure:
  - The specific permissible category;
  - Description of action taken by the reviewer; and
  - Any findings required under the regulations.
- For each protocol's initial and continuing review, the frequency for the next continuing review.
- Determinations required by the regulations and protocol-specific findings supporting those determinations for:
  - Waiver or alteration of the consent process;
  - Research involving pregnant women, fetuses and neonates;
  - Research involving prisoners; and
  - Research involving children.
- For exemption determinations, the specific category of exemption.
- Agendas and minutes of all IRB meetings.
- Records of continuing review activities.
- Data safety monitoring reports, if any.
- Copies of all correspondence between the IRB and the investigators.
- Statements of significant new findings provided to subjects.
- Written complaints received from subjects or reports of misconduct.
- Any certification documents from other committees of the applicable Facility or Aurora Health Care.
- Texts of advertisements (recruitment materials) submitted to the IRB.

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- Any documentation pertaining to emergency use of an investigational article, including, but not limited to the approval or disapproval of emergency research.
- IRB Authorization Agreements/Unaffiliated Investigator Agreements.

## **1.2. RSPP Administration Documents**

The RSPP office must maintain and retain all records regarding IRB administrative activities that affect review activities for least three (3) years, as follows:

1.2.1. Maintain current and obsolete rosters of regular and alternate IRB members (form RO 201-A). A current roster of IRB members will be on file with OHRP.

1.2.2. Maintain current and obsolete copies of the Policies.

## **1.3. Destruction of Copies**

Copies of meeting materials distributed to IRB members will be destroyed upon completion of the IRB meeting per Policy FO 303 section 1.6.

## **1.4. Archiving and Destruction**

After three (3) years, all documents and materials germane to IRB determinations will be archived according to the applicable institutional policy. Archiving policies of Aurora Health Care will determine when such archived records may be destroyed.

## **2. SCOPE**

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

## **3. APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS**

45 CFR 46.103, 46.115

21 CFR 56.115

AAHRPP Standard II-5, Elements II.5.A. and II.5.B.

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

This SOP affects all other SOPs.