

<b>DEPARTMENT:</b> Research Compliance		<b>Reference#</b> IRB.012
<b>Effective Date:</b> 1/23/2006	<b>Page 1 of 7</b>	<b>Replaces Policy Dated:</b> 4/28/2003
<b>Description:</b>	Recordkeeping and Retention Requirements	

**A. Sunrise Health Institutional Review Board (SHIRB)**

The SHIRB maintains records of its activities for at least 3 years after completion of the research in accordance with [45 CFR 46.115\(b\)](#). The records are available, as permitted by law, for inspection and copying by the Food and Drug Administration (FDA), federal or state government agencies, or hospital accrediting agencies in the course of carrying out their respective duties.

**1. IRB Membership**

The SHIRB Office maintains a list of IRB members to include the following information:

- Name;
- Earned degree;
- Representative capacity (physician scientist; other scientist; nonscientist)
- Indications of experience, such as board certifications, licenses; and
- Affiliation, if any, to one or more Sunrise Health institutions.

The membership roster for the IRB and OHRP IRB registration is updated when there are changes in the membership. The updated OHRP IRB registration is submitted to OHRP as required.

**2. IRB Minutes**

The SHIRB Office maintains Minutes of IRB meetings to include the following information:

- Voting members (or alternates) present;
- Voting members (or alternates) absent;
- Non-voting members present;
- Guests, including consultants, present; and

For each new or continuing protocol reviewed at the meeting:

- Action taken by the IRB;

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- Votes for, against, or abstentions;
- Members attending but not present for the discussion and vote;
- Recusals of voting members;
- Period of IRB approval, i.e., one year or less;
- Findings and determinations of the IRB;
- Summary of the discussion of controverted issues and their resolution; and
- Basis for requiring changes or disapproving the research.

### 3. Research Proposals Reviewed

The SHIRB Office maintains files for every research proposal reviewed by the SHIRB to include:

- All of the documents submitted with the research proposal for review initially and subsequently including, but not limited to, the application form, protocol summary, detailed protocol, recruitment materials (letters, flyers, advertisements, etc.) consent form(s), drug/device brochures, NIH (or federal) grant, NIH cooperative group protocol, NIH cooperative group sample consent form, ancillary committee/department review, scientific evaluations, if any;
- Checklists and review documentation, including review forms signed by IRB Chair;
- IRB-approved recruitment materials;
- IRB-approved consent form;
- Progress reports, interim analyses, safety reports, DSMB reports;
- Reports of injuries to subjects;
- Reports of unanticipated problems involving risks to subjects or others;
- Reports of protocol violations;
- Proposed changes to the protocol and revised documents (amendments);
- Copies of all correspondence between the IRB and investigator;

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- Continuing review submissions for review including, but not limited to application form, protocol summary, detailed protocol, recruitment materials, NIH progress reports; and
- Statements of significant new findings provided to subjects.

#### **4. Written IRB Procedures**

The SHIRB Office maintains the IRB policies and procedures, including IRB guidance documents, and significant communications to the research community. The written policies and procedures include, but are not limited to procedures for:

- Conducting initial and continuing review of research;
- Reporting its findings and actions to the investigator and the institution;
- Determining which projects require review more often than annually;
- Determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;
- Ensuring prompt reporting to the IRB of proposed changes in the research activity;
- Ensuring that such changes in approved research, during the period for which IRB approval has already been given, are not initiated without IRB review and approval except where 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;
- Ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB;
- Ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any suspension or termination of IRB approval.

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5. Investigators

Investigators are required to maintain records of their human-subjects research activities. In general, investigators should establish a file for each subject enrolled or screened for a study in which documents are placed, including the signed and dated consent form and copies of case report forms. Good records are essential for verifying the quality of study data produced and demonstrating investigator compliance with good clinical practice guidelines and applicable regulatory requirements. Depending upon the nature of the study, a case report form (CRF) provided by the sponsor or data collection/work sheets should be used to capture all data required by protocol for each subject. All primary data should be promptly recorded in clear, adequate, original and permanent form and source documents should be retained to corroborate entries on the CRF or data collection sheets.

Research records should be retained for at least five (5) years from the time the study has been completed or longer as required by the sponsor. All such permanent records must remain in the institution's medical record department upon departure of the investigator from the institution. Consideration of alternative arrangements for copies to be kept at the institution, instead of original records, must be done with the Institutional Official or his/her designee.

HCA policy requires that all hospital research records of patients enrolled in investigational new drug or investigational device studies be retained for a period of 30 years following completion of the study. It is the investigator's responsibility to notify the institution's Medical Records Department when this retention period begins by providing the patient's name, social security number and study completion date.

1. Investigational Drugs

The investigator is expected to conduct a clinical investigation according to the plan agreed upon by the sponsor and approved by the IRB. The investigator must keep certain records of the investigation as detailed in the federal regulations 21 CFR 312.62(a)(b)(c), as quoted below:

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- (a) *Disposition of drug.* An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 312.59.
- (b) *Case histories.* An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.
- (c) *Record retention.* An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

2. Investigational Devices

The investigator is expected to conduct a clinical investigation according to the plan agreed upon by the sponsor and approved by the IRB. The investigation must be conducted under his/her supervision and he/she may not supply an investigational device for use by any investigator not authorized under the approved plan. In addition, the investigator must keep certain records of the investigation as detailed in the federal regulations 21 CFR 812.140(a)(d), as quoted below:

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- (a) *Investigator records.* A participating investigator shall maintain the following accurate, complete and current records relating to the investigator's participation in an investigation:
- (1) all correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.
  - (2) Records of receipt, use or disposition of a device that relate to:
    - (i) the type and quantity of the device, the dates of its receipt and the batch number or code mark.
    - (ii) The names of all persons who received, used, or disposed of each device.
    - (iii) Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.
  - (3) Records of each subject's case history and exposure to the device. Such records shall include:
    - (i) Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent.
    - (ii) All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering and during the course of the investigation, including results of all diagnostic tests.
    - (iii) A record of the exposure of each subject to the investigational device, including the date and time of each use and other therapy.

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- (4) The protocol, with documents showing the dates of and reasons for each deviation from protocol.
  - (5) Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.
- (b) *Retention Period.* An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.