

SOP: Number GA 107 Version No: Effective Date: 01/01/07	IRB ADMINISTRATIVE RECORDKEEPING	Supersedes Document Dated: 05/04
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1. PURPOSE

The purpose of this policy is to define the guidelines for IRB Administrative recordkeeping.

2. POLICY

A. The SHS OROC shall prepare and maintain adequate documentation of IRB activities including:

- Copies of all research proposals reviewed,
- Scientific evaluations, if any, that accompany the proposals,
- Approved sample consent documents,
- Progress reports submitted by investigators,
- Reports of injuries to subject.
- Minutes of IRB meetings which shall be in sufficient detail to:
 - Show attendance at the meetings (members and guests),
 - Actions taken by the IRB,
 - The vote on these actions including the number of members voting for, against, and abstaining,
 - The basis for requiring changes in or disapproving research,
 - A written summary of the discussion of controverted issues and their resolution.
- Records of continuing review activities,
- Copies of all correspondence between the IRB and the investigators, as well as correspondence between SHS administration and federal agencies.
- A list of IRB members identified by:
 - Name
 - Earned degree
 - Representative capacity
 - Indications of experience such as board certifications, licenses, etc, sufficient to describe each member's chief anticipated contributions to IRB deliberations
 - Any employment or other relationship between each member and the institution (for example, full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant).
- Written procedures for the IRB as required by 45 CFR § 46.108 (a) and (b),
- Statements of significant new findings provided to subjects, as required by 45 CFR § 46.116 (General Requirements for Informed Consent), or in specific cases of FDA approved studies, 21 CFR § 50.25 (Elements of Informed Consent).

- B. Maintain and update as appropriate all documentation pertaining to the SHS Federal Wide Assurance (FWA), IORG institution registration and IRB membership through the DHHS Office of Human Research Protection (OHRP)
- C. Records shall be retained in the OROC for at least 3 years after completion of the research and be available for inspection and copying by the authorized representatives of the department or agency (OHRP or FDA), at reasonable times and in a reasonable manner.

2. SCOPE

The SHS OROC will maintain a copy of each research proposal, including all documentation pertaining to said proposal, for a period of at least 3 years after receipt of written confirmation from the principal investigator of the completion of the research locally, at which time the documents may be destroyed.

3. RESPONSIBILITY

- IRB Administrator (or IRB Coordinator)
- IRB Chairperson (or designee)
- Institutional Official

4. APPLICABLE REGULATIONS AND GUIDELINES

- 45 CFR 46.018(a) and (b)
- 45 CFR 46.115
- 21 CFR 56.115
- 21 CFR 50.25
- OHRP Guidelines and FDA Information Sheets

5. REFERENCES TO OTHER APPLICABLE IRB SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

Describe the IRB documents to be prepared and maintained by the OROC.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Administrator</i>	Ensure the appropriate handling and storage of all documents pertaining to research proposals reviewed (approved and/or denied), including initial application, consent forms, progress reports, injury reports, amendments, and other documentation pertaining to research project(s). Ensure accurate IRB meeting agenda, minutes, and correspondence.	

<i>IRB Administrator</i>	Ensure FWA and IORG registration through OHRP is accurate and renewed as necessary.	
<i>Institutional Official</i>	Sign updated and/or renewed FWA and IORG documentation as necessary.	
<i>IRB Coordinator</i>	Prepare IRB meeting agendas, minutes, and correspondence for investigators. Adequately maintain research project document files (approved and/or denied).	