

SOP: QA 902 Version No: Effective Date: 01/01/07	AUDITS BY REGULATORY & ACCREDITING AGENCIES	Supercedes Document Dated:
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1. POLICY

Sparrow Health System acknowledges that certain regulatory agencies have the authority to audit the operations of IRBs, and supports such audits as part of its continuing effort to maintain high standards for human research protections.

Sparrow Health System also acknowledges that accrediting agencies may audit the operations of the IRB if invited to do so by the Institutional Official.

Entities that may audit IRBs include: FDA, OHRP, JCAHO, and appropriate certified auditors of foreign countries where data from clinical research has been submitted in an application for drug or device approval. Sponsors or funding entities of research may also be authorized to audit specific documents and procedures.

Specific Policies

1.1 Preparing for an Audit

1.1.1 For external audits involving OHRP or FDA, the following must be notified immediately:

- Vice President of Medical Affairs (Institutional Official)
- IRB Chairperson and IRB Administrator
- IRB staff designated to participate in the audit are required to follow the steps outlined by this institution for preparing the site for an audit.

1.2 Participating in an Audit

1.2.1 IRB staff is expected to know and follow the procedures outlined by this Institution for the conduct of a regulatory audit.

1.2.2 Prior to being granted access to IRB documentation, inspectors or auditors must exhibit proof of their authority or authorization to conduct the audit and to access IRB documents, and no entity other than those listed on the consent forms may have access to any document that includes subject identifiers.

1.2.3 Auditors will be provided with adequate working area to conduct an audit and IRB staff and members must make every reasonable effort to be available and to accommodate and expedite the requests of such auditors.

1.2.4 Documents may be copied and taken off-site only by individuals authorized in writing by the IRB Chairperson or Institutional Official to do so. Such copied materials may not contain subject identifiers.

1.3 Follow-up After an Audit

Reports of the audit, either verbal or written, should be addressed by the IRB Chairperson and IRB Administrator (with the assistance and support of Sparrow Health System Administration), as soon as possible after the audit.

2. SCOPE

These policies and procedures apply to the IRB in the Sparrow Health System.

3. RESPONSIBILITY

Institutional Official is responsible for serving as the responsible institutional official in all regulatory agency matters regarding regulatory compliance, participating as needed in regulatory agency audits, and providing support in responding to and correcting audit findings.

IRB Administrator is responsible for all formal regulatory agency correspondence and interactions, establishing logistical support during regulatory agency audits, serving as key institution contact during such audits, and drafting responses to regulatory agency correspondence received following such audits.

IRB Chairperson, Members and Staff are responsible for participating in regulatory agency audits as determined by IRB Administrator, and in fully cooperating with government officials during their participation in such audits.

IRB Chairperson is responsible for assisting the IRB Administrator in formal responses to regulatory agency audits and in implementing policy and procedure changes indicated by such audits.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.115

45 CFR 46.115

FDA Compliance Program Guidance Manual 7348.809, Institutional Review Boards

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

QA 902-A FDA’s A Self-Evaluation Checklist for IRBs

7. PROCESS OVERVIEW

Provide guidelines concerning preparation for regulatory audits of the IRB and appropriate behavior toward regulators.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Administrator</i>	Upon being notified of an impending audit, notify all IRB staff, and staff of any other institutional entity designated.	
<i>IRB Administrator</i>	Using the Audit Preparation Checklist, assign responsibilities as indicated on the checklist.	FDA’s A Self-Evaluation Checklist for IRBs.