

SOP: QA 901 Version No.: 02 Effective Date: 10/24/05	AUDITS BY REGULATORY AGENCIES	Supersedes Document Dated: 01/27/04
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1. POLICY

Aurora Health Care 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.

Entities that may audit IRBs include: FDA, OHRP, Office for Civil Rights (OCR), Joint Commission on Accreditation of Healthcare Organizations (JCAHO), other voluntary accreditation organizations, 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 if deemed appropriate by the RSPP Manager.

Specific Policies

The definitions of terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

1.1. Preparing for an Audit

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

- The RSPP Manager, Director, and the Signatory Official
- IRB Chair

1.2. Participating in an Audit

1.2.1. 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.

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

1.3. Follow-up After an Audit

Reports of the audit, either verbal or written, should be addressed by the RSPP Director in consultation with the Signatory Official, (with the assistance and support of the appropriate Aurora administrator) as soon as possible after the audit.

2. SCOPE

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These policies and procedures apply to all Aurora IRBs

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.115

45 CFR 46.115

FDA Compliance Program Guidance Manual 7348.809, Institutional Review Boards

4. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.