

I. PURPOSE

This document outlines the operating procedures related to the preparation for external regulatory audits of the IRB, and appropriate interactions with regulators.

II. POLICY STATEMENT

This policy describes the IRB's procedures for interacting and cooperating with a federal regulatory authority, funding agency, or external accrediting agency.

III. SCOPE

These operating procedures apply to the Director, HSR; the Chair, CPHS; and all IRB Office staff.

IV. PROCEDURES

A. Preparing for an audit

Certain regulatory authorities, funding agencies, and accrediting agencies have the authority to audit the operations of IRBs.

1. Auditing agencies can be conducted by representatives of the following: FDA, OHRP, AAHRPP, JCAHO, industry sponsors, entities funding research, or others specifically authorized by regulations or agreement with CHOP to audit specific documents and procedures.
2. The following individuals must be notified immediately upon being informed of an external audits involving OHRP or FDA:
 - (a) Institutional Official or their designee
 - (b) Chair, CPHS

B. Participating in an audit

1. Prior to being granted access to any of the IRB's records, electronic systems, or documents, the inspector(s) or auditor(s) must provide proof of their identity and their authority or authorization to gain access to IRB documents.
 - (a) The IRB staff shall be responsible for redaction of information from files prior to an audit, as may be required.
2. Auditors will be provided with a secure, private area to conduct the audit. IRB staff and IRB members will make every reasonable effort to be available as required and to accommodate and expedite the requests of such auditors.
3. Documents from the IRB's records may be copied and taken off-site only by individuals authorized in writing by the Chair, CPHS, Director, Human Subjects Research, Office of General Counsel or the Institutional Official.

C. Follow-up after an audit

1. Reports of the audit, either verbal or written, and directed to the operation of the IRB, will be shared with the Director, HSR, Chair, CPHS, the Institutional Official and any other individuals or offices as appropriate.
2. Specific findings identified in an audit report, that require a response to the auditing authority, will be addressed promptly, by the Chair, CPHS, the Director, HSR and any other individuals or offices as appropriate.

V. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all SOPs

VI. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for establishing and periodically reviewing and modifying (as appropriate) the IRB audit program.
Chair, CPHS	Responsible for working with Director, HSR on maintaining a compliant audit program.

VII. REVISIONS:

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| 06-10-2010 | Revised to correct minor grammatical issues for consistency across SOPs. |
| 03-11-2013 | Updated to include AAHRPP as an authorized entity to audit the IRB. |
| 07-29-2014 | Updated to delete reference to internal or external audits of specific studies or study sites. |
| 12-13-2022 | Minor administrative edits |

VIII. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 12/13/22
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS