

I. PURPOSE

This document establishes that the IRB will institute and maintain a formal quality control and improvement program to improve the functioning of the IRB Committees and the IRB staff. The goals of the program are to ensure that the IRB meets its regulatory responsibilities and conducts its activities efficiently and in keeping with the highest standards.

II. POLICY STATEMENT

The IRB will maintain active quality control and improvement programs.

III. SCOPE

These operating procedures apply to the activities within the IRB Office and to the Director, Human Subjects Research (HSR); the Chair, Committees for the Protection of Human Subjects (CPHS); and all IRB Office staff.

IV. PROCEDURES

A. Quality Control

The IRB will maintain an active quality control program whose aim will be to assess the IRB and IRB Office activities. The goal of the quality control program will be to assess the effectiveness of IRB procedures, to identify problems and to target issues for quality improvement initiatives by tracking the following:


1. Processing Metrics
 - (a) To ensure that the IRB provides timely review of protocols, amendments, continuing review materials, and unanticipated problems related to research as listed on the IRB intranet. To ensure transparency regarding review timelines for the initial review of studies, protocol review times will be posted to the study workspace after initial approval. Investigators will be able to see how much time was spent with the IRB, the investigator, in Department/Division review, and in review with ancillary committees; and
 - (b) To ensure that the IRB communicates its decisions back to investigators within 3 business days of the review being complete;
 - (c) Metrics data is collected continuously and will be reviewed on an at least quarterly basis as part of the electronic reporting dashboard. This information is used to ensure there are appropriate resources and balanced workloads. The data will be analyzed by the Director, HSR or their designee.
2. IRB documentation – to ensure that all required materials are maintained and documented as required by IRB SOPs and federal regulation. Documentation is reviewed at least annually by the Director, HSR. The IRB Director may coordinate with the Office of Research Compliance to support these activities.

3. Correspondence with investigators
 - (a) To ensure that proper advice was provided; and
 - (b) To ensure that the IRB staff adhere to IRB Office standards;
 - (c) Correspondence is reviewed by the Director, HSR or their designee by checking a random sampling of studies at least annually.
 - (d) The IRB Director may coordinate with the Office of Research Compliance to support these activities.
4. Compliance with CHOP Policies
 - (a) To confirm that investigative team members have completed mandatory education training; and
 - (b) To confirm that investigative team members have completed financial disclosure forms;
 - (c) Investigator training are checked by the IRB Analyst at least annually for each study for which continuing review is required.
5. IRB Committee Members – to ensure that committee members and chairs are evaluated annually
6. Policies and Procedures
 - (a) To ensure that IRB SOPs undergo review at least annually; and
 - (b) To ensure that IRB SOPs are consistent with federal regulations and guidelines and reflect the IRB's actual practice.

B. Quality Improvement

The Director of Human Subjects Research, in consultation with the Chair, CPHS, has the authority to implement a quality improvement program. Quality improvement programs will seek to correct identified deficiencies or weaknesses. The quality improvement program could include but would not be limited to the following:

1. Revisions to IRB policies, procedures, forms and guidance documents;
2. Revision of educational activities including lectures, web-based training, email, or other appropriate forms of communication with the relevant segments of the CHOP research community and the IRB staff members;
3. Additions or revisions to the IRB website;
4. Remedial training for IRB staff, which could include but would not be limited to human subjects protection, computer literacy, writing skills, clinical epidemiology, management science or other areas that relate to the staff person's job and function;

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5. A request for additional resources for the CHOP Human Research Protection Program, including but not limited to requests for additional medical or legal expertise, IRB staff, or office/meeting/training space.

V. RESPONSIBILITIES


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

VI. ATTACHMENTS

The IRB maintains information regarding its timelines for investigators on its web site at: <https://at.chop.edu/research/irb/irb-timelines>

VII. REVISIONS:

- 10-03-2006 Initial approval date
- 06-10-2010 Revised to correct minor grammatical issues for consistency across SOPs and to change the number of this SOP from 901 to 906
- 07-8-2010: Revised in response to AAHRPP suggestions.
- 05-29-2013: Revised to include resource requests for the HRPP
- 12-13-2022: Revised to reflect current processes

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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