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	Title: Maintenance of Standard Operating Procedures	

I. PURPOSE

Written operating procedures compliant with federal regulations and guidance, and CHOP policies, must be in place to ensure the highest quality and integrity of the review and oversight of research involving human subjects and for the adequate documentation of such oversight.

Compliance with these operating procedures ensures that the rights and welfare of human subjects participating in clinical research will be overseen and protected in a uniform manner, regardless of changes in personnel.

II. POLICY STATEMENT

Standard operating policies and procedures (SOPs) will be developed, reviewed and maintained in accordance with CHOP policies. These SOPs provide the framework for the ethical and scientifically sound conduct of human research.

III. SCOPE

These policies and procedures apply to all IRB staff.

IV. DEFINITIONS

Director, HSR: Director, Human Subjects Research


Chair, CPHS: The Chair functions as the executive chair of all of the IRB committees and subcommittees and provides input for IRB policies and educational training requirements. The Chair works with the Director, Human Subjects Research and the AVP, Research Compliance and Regulatory Affairs on procedural matters pertaining to the IRB. The Chair serves as Chair or Vice-Chair for one or more of the CHOP IRBs.

V. PROCEDURES

A. Review, Revision, Approval of Policies & Procedures

1. The Director, HSR with input from the Chair and Vice-Chair CPHS, the Assistant Vice President, Research Compliance and Regulatory Affairs and the IRB Analysts, determines when a new or updated SOP must be generated. The following may warrant changes or additions to the SOPs:

- a. Changes to federal regulations;
- b. New or revised federal guidelines;
- c. Changes to CHOP research practice;
- d. Modifications to CHOP policies and procedures; or
- e. Recommendations from external auditors or inspectors.

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2. Policies will be reviewed by the Director, HSR at intervals not less than every two years, in order to determine whether or not they are current.
3. New and updated SOPs are drafted in collaboration with the appropriate members of the IRB Office, the IRB Chairs and in consultation with the Assistant Vice President, Research Compliance and Regulatory Affairs.
4. The Director HSR reviews the SOP for consistency, accuracy and ability for those affected by the SOP to easily and effectively implement.
5. The Director HSR and the Chair, CPHS will approve all new or revised SOPs. The signature of the Director HSR and Chair are evidence of approval.

B. SOP Dissemination and Training

1. When a new or revised SOP is approved, notice of the changes will be disseminated to all appropriate individuals and departments and the revised SOP will be made available on the CHOP IRB Internet page.
2. Training will be provided to all members of the IRB and IRB staff, as appropriate, on applicable new or revised SOP. Evidence of training will be documentation in meeting minutes. (**SOP 102**)
3. Each new IRB member or staff employee must review the applicable SOPs, prior to undertaking a related IRB responsibility. Evidence of training must be documented following the same procedures as noted in V.B.2.


C. Archiving of Previous Versions

1. Upon approval of a new version of a SOP, the previous version will be archived but will be available for review.
2. If changes to the SOPs address new regulations, guidance, laws or institutional policies that affect only submissions reviewed after implementation, the prior version of the SOP will be available with the current version to support the continued review of older studies that are not subject to these changes.

D. Forms and Checklists

The electronic reviewer forms and checklists may be used to facilitate compliance with the regulatory requirements and IRB SOPs. These tools are reviewed periodically and updated as necessary.

1. *Reviewer forms and checklists, as applicable*, are used by the IRB reviewer to ensure compliance with the regulations. They include space for written comments, and for recording recommendations for IRB action (e.g., indication of approval or

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requested modifications).

2. *Analyst's checklists* are job aids that IRB Office staff may use to ensure that submissions are complete and ready for review.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45CFR46.108	21 CFR 56.108
45 CFR 46.109	21 CFR 56.109
45 CFR 46.113	21 CFR 56.113

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 102: HRPP Training and Education for IRB Members and Staff	
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VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.
Chair, CPHS	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.

IX. ATTACHMENTS

X. REVISIONS:

6/9/2010	Revised to update titles and editorial changes for clarity.
2/2/2013	Editorial changes.
9/25/2018	Revised to include reference to the archiving of previous SOP versions.

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XI. APPROVAL

 Director, Human Subjects Research

 Date

 Chair, Committees for the Protection of Human Subjects

 Date