

I. PURPOSE

The purpose of this SOP is to outline the general responsibilities of Investigators who conduct research involving human subjects at CHOP.

II. POLICY STATEMENT

Investigators conducting Human Subjects Research at CHOP must understand, accept, and fulfill their responsibilities related to the protection of human subjects.

III. SCOPE

This SOP applies to all Investigators and research staff involved in conducting Human Subjects Research, as well as all IRB Members and IRB staff reviewing research involving Human Subjects.

IV. DEFINITIONS

Principal Investigator – The individual at each institution personally responsible for the overall conduct of a specified human subjects research study or clinical investigation.

V. PROCEDURES

A. Fulfilling Ethical Obligations

Investigators conducting human subjects research will ensure that they fulfill their ethical obligations to protect the research participant via the following:

1. Obtaining IRB approval or an exempt determination prior to initiating human subjects research in accordance with **SOP 106**;
2. Obtaining the required training (as applicable), accepting their responsibilities for protecting the rights and welfare of human subjects, and complying with all applicable provisions of CHOP policies and procedures, and with federal regulations and guidelines;
3. Obtaining Department/Division approval and applicable ancillary committee approval in accordance with CHOP policies;
4. Overseeing the conduct of the research, including recruitment, obtaining consent and protocol procedures, managing data collection, storage, security and backup, and ensuring accurate analysis of study data;
 - a. If unable to direct the research personally, as when on leave or vacation, the Principal Investigator (PI) will arrange for a co-investigator to accept responsibility in his/her absence. Note: If the PI is no longer an employee of CHOP or the University of Pennsylvania, or

changes employment status to NTP, the PI will transition the study to another PI.

5. Ensuring that the research is conducted in accordance with an IRB-approved protocol, and any conditions that are set in order to receive IRB approval in accordance with **SOP 402**;
6. Reporting to the IRB all actions or processes that deviate from the protocol procedures approved by the IRB;
7. Obtaining and documenting informed consent in accordance with the regulatory requirements and **SOPs 701 and 702**, unless waived by the IRB.
8. Delegating responsibilities to qualified study team members that are commensurate with their training and qualification;
9. Ensuring that there are adequate resources available to safely conduct the research and to ensure the safety of research participants (21 CFR 312.60).
10. Ensuring that all members of the study team have a) been trained to conduct the study in accordance with the approved protocol, b) completed mandatory human subjects research training as required by CHOP's Office of Research Compliance, and c) completed all required conflict of interest disclosures in accordance with the CHOP Policies on "**Conflicts of Interest**".
11. Providing continuing review/progress update information to the IRB in accordance with relevant federal regulations and **SOP 404** and submitting closure information once human subjects research is completed (**SOP 405**).

B. Maintain Appropriate Documentation and Communications

Investigators conducting human subjects research will ensure that the following research activities are properly documented and reported to the IRB as necessary:

1. Maintaining documentation for each study that contains, at a minimum, the following (as applicable):
 - (a) IRB-approved protocol;
 - (b) IRB-approved approved informed consent documents;
 - (c) IRB-approved recruitment materials;
 - (d) IRB-approved study materials (e.g., surveys, questionnaires);
 - (e) Pertinent correspondence with the IRB, the sponsor and regulatory authorities;

2. Reporting the following to the IRB:
 - (a) Any proposed changes to the research activity including amendments to the previously approved protocol or proposed changes to study documents or procedures, in accordance with **SOP 403**.
 - (b) Study progress, in accordance with relevant regulations and **SOP 404** (at least annually for federally funded research and research involving more than minimal risk).
 - (c) All unanticipated problem involving risks to subjects or others, in accordance with relevant regulations and **SOP 408**.
 - (d) Copies of all monitoring reports received by the investigator; DSMB reports and updates; Office of Research Compliance reports and FDA reviews, if applicable, in accordance with **SOPs 403** and **408**.
 - (e) Any noncompliance with regulations, IRB-approved research, IRB conditions, and CHOP policies and procedures in accordance with the **SOP 901**.

C. Addressing Concerns That Arise During Research

Investigators conducting human subjects research are responsible for addressing any concerns arising during research, including the following:

1. Any concern or question raised by a research subject (or parent, legal guardian, Legally Authorized Representative, as applicable) before, during, or after the conduct of a research study.
2. Any concerns raised by members of their research team. This responsibility includes the following:
 - (a) Investigators should meet regularly with their research teams for the purpose of reviewing the progress of the research, and to encourage discussion of any concerns about the research in general, or about a specific research subject.
 - (b) Investigators should inform each member of the research team, individually, of their responsibility to voice any concerns they may have, without fear of repercussions.
 - (c) Investigators should investigate each expressed concern, and report back to the individual who raised it.
 - (d) Investigators may not punish an individual who brings a concern to their attention.

- (e) Investigators are responsible for reporting to the IRB any concerns that result in findings regarding subject safety or potential breaches to the rights and welfare of a research subject, compliance with the research protocol, informed consent violations, or the integrity of the research data.
3. Acting to eliminate any immediate apparent hazard to subjects, even if this deviates from the approved protocol, as permitted by relevant regulations and in **SOP 408**. A report of a deviation to eliminate such a hazard should be made promptly to the IRB in accordance with **SOP 408**.

VI. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.64	21 CFR 812.150
21 CFR 312.66	

VII. REFERENCES TO OTHER APPLICABLE SOPS

CHOP Research Institute: Institutional Review Board (IRB) Charter	SOP 701: Required Elements of Consent and Documentation of Consent
SOP 402: Criteria for Initial IRB Approval	SOP 702: Assent and Parental Permission
SOP 403: Amendments and Reports of New Findings to Approved Research	SOP 804: Qualifications to Serve as a Principal Investigator for Human Subjects Research
SOP 404: Continuing Review of Approved Research	SOP 901: Non-Compliance with Human Subjects Research Policies
SOP 405: Study Closure	CHOP Policy: Conflicts of Interest
SOP 408: Unanticipated Problems Involving Risks to Subjects	

VIII. RESPONSIBILITIES

Title	Responsibility
Investigators and Staff	Ensuring compliance with this SOP
IRB	Reviewing submissions and reports submitted by Investigators and Staff

IX. ATTACHMENTS

Investigator Responsibilities on the CHOP IRB webpage at:
<https://www.research.chop.edu/irb/pi-responsibilities>

X. REVISIONS

- 03-21-2008 Incorporated minor editing and changes in the IRB SOP numbering.
- 06-10-2010 Revised to correct minor grammatical issues for consistency across SOPs and to update the title and number of other IRB SOPs and to add the Fact Sheet link.
- 03-07-2013 Revised to reflect unchecking the box on the FWA and update titles of IRB SOPs.
- 09-25-2018 Revised to update the definition and other minor edits.
- 12-13-2022 Revised to update current processes and make other minor edits.

XI. 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