I. PURPOSE

The purpose of this standard operating procedure 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 – An individual who conducts human subjects research and, in case of the human subjects research being conducted by a team of individuals, is the responsible leader of that team (generally referred to as the “Principal Investigator”).

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 the review and approval of the IRB prior to initiating Human Subject Research in accordance with SOP 106;

2. Obtaining the necessary training, 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. Overseeing the conduct of the research, including recruitment, obtaining consent and protocol procedures, managing data collection, storage, security and backup, and ensuring accurate of analysis of data;

4. 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: Criteria for Approval;

5. Reporting to the IRB all actions or processes that deviate from the protocol
procedures approved by the IRB;

6. Obtaining and documenting informed consent in accordance with the regulatory requirements and IRB SOPs (SOPs 701 and 702), unless waived by the IRB.

7. Delegating responsibilities to qualified study team members that are commensurate with their training and qualification;

8. Ensuring that there are adequate resources available to safely conduct the research and to ensure the safety of research participants. (21 CFR 312.60).

9. 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 Protection training as required by the Research Education department, and c) completed all required financial disclosures in accordance with the CHOP Policies on “Conflicts of Interest” and “Conflicts of Interest in the Research Setting.”

10. Providing continuing review information to the IRB in accordance with relevant federal regulations and IRB SOP 404.

B. Ensuring 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:
   (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 (if applicable) and regulatory authorities (if applicable);

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 problems related to research, in accordance with relevant regulations and SOP 408.

(d) Copies of all external monitoring reports received by the investigator; DSMB reports and updates; and FDA reviews, if applicable, in accordance with SOP 403 and 408.

(e) Any noncompliance with regulations or Hospital policies and procedures in accordance with the SOP 901: Noncompliance with Human Subjects Research Policies.

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 before, during, or after the conduct of a research study.

2. Any concerns raised by any member 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 his or her responsibility to voice any concerns he or she may have, without fear of repercussions.

   (c) Investigators must take seriously any concern raised. Investigators should investigate each expressed concern, and report back to the individual who raised it. No concern should be dismissed.

   (d) Investigators may not punish an individual who brings a concern to their attention.
(e) Investigators are responsible for reporting to the IRB any expressed 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

<table>
<thead>
<tr>
<th>21 CFR 312.64</th>
<th>21 CFR 812.150</th>
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VII. REFERENCES TO OTHER APPLICABLE SOPS

<table>
<thead>
<tr>
<th>CHOP Research Institute: Institutional Review Board (IRB) Charter</th>
<th>SOP 701: Required Elements of Consent and Documentation of Consent</th>
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<td>SOP 403: Amendments and Reports of New Findings to Approved Research</td>
<td>SOP 702: Assent and Parental Permission</td>
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<td>SOP 404: Continuing Review of Approved Research</td>
<td>SOP 408: Unanticipated Problems Involving Risks to Subjects</td>
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VIII. RESPONSIBILITIES

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<th>Responsibility</th>
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<td>Investigators and Staff</td>
<td>Ensuring compliance with this SOP</td>
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<tr>
<td>IRB</td>
<td>Reviewing submissions and reports submitted by Investigators and Staff</td>
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IX. ATTACHMENTS

Investigator Responsibilities on the CHOP IRB intranet at:
https://intranet.research.chop.edu/display/cmtirb/Investigator+Responsibilities

X. REVISIONS

3-21-2008 Incorporated minor editing and changes in the IRB SOP numbering.

6-10-2010 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.

3-07-2013 Revised to reflect unchecking the box on the FWA and update titles of IRB SOPs.

XI. APPROVAL:

________________________________________________________________________
Director, Human Subjects Research                                            Date

________________________________________________________________________
Chair, Committees for the Protection of Human Subjects                      Date