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| | Title: HRPP Training and Education for IRB Members and Staff | Effective Date: 6/1/2006 Version Date: 09/25/2018 |

I. PURPOSE

The purpose of this standard operating procedure is to document the requirements for all personnel reviewing, approving, or supporting research involving human subjects, to demonstrate and maintain sufficient knowledge of the ethical principles and federal, state, and local requirements for protecting research participants.

Training of IRB staff and members is critical to enable the IRB to fulfill its mandate to protect the rights and welfare of research subjects in a consistent manner for research overseen by the CHOP IRB.

II. POLICY STATEMENT

IRB members, alternates, staff and others charged with the responsibility for reviewing, approving, and overseeing human subject research shall receive detailed training in the regulations, guidelines, ethics and policies applicable to human subjects' research. The required training will be appropriate to the individual's role and to the nature of the research.

III. SCOPE

These policies and procedures apply to all IRB members, alternates and staff.

IV. DEFINITIONS

AAHRPP: Association for the Accreditation of Human Research Protections Programs, an independent, non-profit accrediting body for Human Research Protections Programs (HRPP).


Alternate: An individual appointed to the IRB who serves in the same capacity as an IRB member for whom the alternate is named, who substitutes for the member at a convened meeting when the member is not voting. Alternates have the same training requirements as members.

CITI Training: Collaborative Institutional Training Initiative

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.

Director, HSR: Director, Human Subjects Research

OHRP: Office of Human Research Protections, Department of Health and Human Services


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PRIM&R: Public Responsibility in Medicine and Research

V. PROCEDURES

A. IRB Member and Alternate Training

1. The Director, HSR and Chair, CPHS are responsible for identifying training needs for IRB members. The Director, HSR will manage the development of training programs for IRB members and alternates (hereafter referred to as members).
2. New members will participate in the required training for new members.
3. All IRB staff and members of each Committee will receive initial and ongoing training regarding the responsible review and oversight of research and these policies and accompanying procedures. Training activities will include, but are not limited to the following:
 - (a) The applicable human subjects research regulations (e.g. Common Rule and 21 CFR 50 and 56), FDA Information Sheets, Belmont Report, and OHRP and FDA Guidance documents and reference materials on human subjects research topics.
 - (b) Regulatory and research ethics documents that are distributed as part of a meeting agenda as applicable.
4. The Director, HSR and the Chair, CPHS establish the educational and training requirements for members and staff who review biomedical and behavioral research involving human subjects at this institution and who perform related administrative duties.
 - (a) Educational and training activities include, but are not limited to:
 - (1) Periodic educational sessions with speakers from CHOP (e.g. at IRB meetings), as well as outside of CHOP (e.g., FDA or OHRP; PRIM&R; webinars).
 - (2) IRB staff and members are encouraged to participate in the IRB Forum, which is a listserv providing opportunity for discussion on issues and regulation throughout the IRB community.
 - (3) CITI training in the protection of human subjects, HIPAA for research, and Conflict of Interest.
 - (b) Initial and ongoing training is provided and documented.

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5. Chairpersons will receive additional training in areas germane to their additional responsibilities as Chairs. These activities include, but are not limited to, attendance at IRB conferences and receiving publications outlining updates to regulations.

6. Members are encouraged to attend outside workshops and other educational opportunities focused on IRB issues.


7. The Director, HSR will monitor participation in HRPP training requirements of members and will share observations with the Chair, CPHS. The Director and Chair will arrange for any relevant training to be provided to members before assignment of additional reviewer responsibilities.

B. IRB Staff Training

IRB staff will receive initial and continuing training in the areas germane to their responsibilities, including all Standard Operating Policies and Procedures (SOP).

1. Initial training of IRB Staff includes, but is not limited to, the following:
 - (a) Attendance at IRB meetings as an observer to learn the process of administering a meeting.
 - (b) Review the human subjects research regulations (Common Rule and FDA regulations) and the IRB SOPs.
 - (c) Shadow experienced staff members to learn IRB Office processes.
 - (d) Complete the online course curriculum for human subjects research [Collaborative Institutional Training Initiative (CITI)];
 - (e) Discussions with the Director, HSR, Assistant Director, IRB Operations and the IRB chairs related to the Analyst's assigned work.
2. Continuing Training of IRB staff includes the following:
 - (a) Attendance (in person and via webinars) at local and national conferences and presentations relevant to IRB activities.
 - (b) Review of relevant journal articles, revised regulations and guidelines circulated by the IRB chairs or Director, HSR.
 - (c) Presentations and discussions at monthly staff meetings.
3. IRB Staff members are encouraged to become Certified IRB Professionals (CIP) as soon as they qualify.

C. Documentation

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Training and continuing education shall be documented and added to the records of the IRB as described below:

1. Copies of certifications of achievement (e.g. CIP) will be maintained by IRB staff.
2. Members and staff attending the on-site, periodic educational training program may receive CME credits.
3. IRB and staff meeting minutes will reflect the members and staff who attend the meetings where the educational materials were discussed.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

21 CFR 50 and 56

VII. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs


VIII. RESPONSIBILITIES

| Title | Responsibility |
|---------------|---|
| Director, HSR | Responsible for establishing, conducting and/or supervising all relevant training programs for members and staff. |
| Chair, CPHS | Responsible for guiding the development of IRB member training programs, in collaboration with the Director, HSR and the Office of Responsible Research Training. |

IX. ATTACHMENTS

X. REVISIONS

- 6/9/10: Updated to reflect current training practices
- 2/2/13: Editorial changes
- 5/29/13: Revised to include monitoring of participation in HRPP training

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requirements of IRB members

9-25-2018

Updated CHOP logo and editorial changes

XI. APPROVAL:

 Director, Human Subjects Research

 Date

 Chair, Committees for the Protection of Human Subjects

 Date