

SOP 202: Duties of IRB Members

I. PURPOSE

The purpose of this standard operating procedure is to outline the duties of each IRB Member.

II. POLICY STATEMENT

CHOP IRB Members must fulfill the responsibilities outlined below in order to maintain their membership on the IRB at CHOP.

III. SCOPE

These policies and procedures apply to all IRB members.

IV. DEFINITIONS

Chair: A chair for one or more of the convened IRBs.

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 VP, 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

IRB: Institutional Review Board

Non-affiliated member: Member who is not otherwise affiliated with the institution and who is not an immediate family member of a person who is affiliated with the Children's Hospital of Philadelphia.

Non-scientific member: IRB Member with no scientific expertise.

Scientific member: Member who has scientific expertise in a given area(s).

Vice-Chair, CPHS: The Vice-Chair function is responsible for assisting the Chair, CPHS and serving as a Chair or Vice-Chair of one or more of the CHOP IRBs (IRB Chair).

V. PROCEDURES

A. General Duties

The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the members and the IRB staff. The IRB must be perceived to be fair and impartial, immune from pressure either by CHOP leadership or administration, investigators whose protocols are brought before it, or other professional and non-professional sources.

1. The Committees for the Protection of Human Subjects are a committee of the Medical Staff of The Children's Hospital of Philadelphia. As such, the IRB members serve CHOP, rather than a particular department. Therefore, members must not allow their own interests or those of their department to supersede their duty to protect the rights and welfare of research subjects.
2. IRB members are expected to commit to a 1-year term and, during that time, to fulfill certain duties. These duties will be described prior to appointment and each IRB member is expected to fully understand the responsibilities of membership prior to accepting appointment as an IRB member.
3. IRB members shall attend at least 80% of the assigned meetings per year.
4. IRB members shall be versed in the federal regulations governing human subjects protection, biomedical and behavioral research, research ethics, and CHOP policies relevant to the protection of human subjects.

B. Specific Duties

1. Non-scientific members:
 - (a) Non-scientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise.
 - (b) Non-scientific members should advise the IRB when additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of subjects.
2. Scientific members:
 - (a) Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of clinical practice.
 - (b) Scientific members should advise the IRB when additional expertise in a scientific area is required to assess if the protocol adequately protects the rights and welfare of subjects.

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3. IRB Chairs (Chair, CPHS and Vice Chair(s), CPHS):
 - (a) In addition to the above responsibilities as a member, the Chairs moderate convened meetings of the IRB.
 - (b) Chairs perform or can delegate to one or more experienced IRB member(s) (designees) review of research eligible under expedited review procedures in accordance with **SOP 401**.
 - (c) Chairs are empowered to suspend human subjects research when deemed urgent to protect the rights and welfare of participants. (**SOP 410**).
4. Designees of the IRB Chair
 - (a) Designees of the IRB Chair are identified on the IRB Membership Roster and are empowered to perform IRB reviews using expedited review procedures and to make exempt determinations in accordance with **SOPs 401** and **302**.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.108, 46,100, 46.113 OHRP Human Research Protection Program (HRPP) Resources (Educational Resources for IRB Members)	21 CFR 50.108 50.110, 50.113 FDA Guidance for Institutional Review Boards and Clinical Investigators – Institutional Review Boards Frequently Asked Questions, Section II, question 17.
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VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 201: Composition and Management of the IRB	SOP 402: Criteria for Initial IRB Approval
SOP 302: Research Meeting the Criteria for Exemption	SOP 404: Continuing Review of Approved Research
SOP 303: IRB Meeting Administration	SOP 410: Suspensions and Terminations of IRB Approval
SOP 401: Expedited Review Procedures	

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VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for clearly articulating the scope of IRB members' duties to potential and current IRB members.
Chair, CPHS	Responsible for clearly articulating the scope of IRB members' duties to potential and current IRB members.

IX. ATTACHMENTS

X. REVISIONS

- 06-19-2006 Initial approval date
- 06-09-2010 Revised to update to current titles of positions within the IRB
- 02-13-2013: Editorial updates
- 09-25-2018 Revised to include new CHOP Log and update the referenced SOP listing
- 10-18-2021 Revised to make updates to current titles of positions within the Research Institute and the referenced guidelines and SOP listing

XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 10/18/21
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, IRB Research