SOP 201: Composition and Management of the IRB

SOP

I. PURPOSE

To describe the procedures used to ensure that CHOP provides the appropriate number of IRBs each with a membership properly composed for the volume and types of human subjects research to be reviewed and in accordance with the terms of institutional commitments and policies, federal regulations, applicable law, and standards of professional conduct and practice.

II. POLICY STATEMENT

The Chair, Committees for the Protection of Human Subjects at The Children's Hospital of Philadelphia and the Senior Director, Human Subjects Research, will ensure that a diverse membership is appointed to the IRBs, with the scope of expertise required to promote complete and adequate review of research activities commonly conducted by the institution.

III. SCOPE

These policies and procedures apply to the membership of the IRB.

IV. DEFINITIONS

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 responsibilities as members.

Committees for the Protection of Human Subjects (CPHS): The committees of the medical staff at The Children's Hospital of Philadelphia under which its duly constituted IRBs function.

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 Senior Director, Human Subjects Research and the VP, Research Compliance & 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.

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).

ECMS: Executive Committee of the Medical Staff; Medical Staff committees, including the IRB, are responsible to the ECMS.

IRB: Institutional Review Board

President: The person appointed by the Board to act on its behalf as chief executive officer in the overall management of CHOP;

President of the Medical Staff: The Medical Staff Member selected in accordance with the CHOP Medical Staff Bylaws who serves as President of the Medical Staff

V. IMPLEMENTATION

A. Membership Selection Criteria

1. Each IRB shall consist of at least 5 regular, voting members and may include a variable number of alternates.

(a) Members will be solicited from both CHOP and from the local communities.

(b) IRB members are nominated by the Chair, CPHS in consultation with the Vice-Chair, CPHS/IRB Chairs (as applicable) and the Senior Director, Human Subjects Research.

(c) The IRB Chairs are nominated by the Institutional Official (or designee), Chair CPHS, and Senior Director, Human Subjects Research..

(d) All appointments of IRB members and IRB Chairs are made in accordance with the CHOP Medical Staff Bylaws.

2. The members of the IRB shall be sufficiently qualified through experience in their relevant field and expertise for reviewing research proposals with regard to federal regulations, applicable law and standards of professional conduct and practice, and institutional policies and commitments.

3. In order to adequately assess all aspects of research submitted for review, the membership shall be diverse and selection shall include consideration of race, gender, cultural background, clinical expertise, other relevant healthcare experience and sensitivity to such issues as community attitudes.

4. Individuals whose primary responsibility is grant management or business development are prohibited from serving as members on the IRB and from carrying out day-to-day operations of the review process.

5. A curriculum vitae that is current at the time of an IRB member's initial appointment, and updated approximately every 5 years, will be maintained in the IRB Office.

6. An IRB Confidentiality Agreement signed by the IRB member will be maintained in the IRB Office.

B. Alternates

1. Alternates will be appointed to the committee to substitute for specific members based on expertise.

2. Members may serve as a member of one committee and as an alternate of another.

3. When a member serves as an alternate, the individual will be allowed to vote

only if the member for whom they are serving as an alternate is not voting.

4. Members and alternates receive and review the same materials.

5. IRB members may be paired with alternates who have similar scientific or non-scientific backgrounds (e.g. physician scientific members are paired with physician alternates).

C. Composition of the Board

1. There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. There shall be at least one member who is not otherwise affiliated with the Children's Hospital of Philadelphia, who is not part of the immediate family of a person who is affiliated with CHOP. Regular members must include:

(a) Non-affiliated member(s): The member(s), who can be either scientific or non-scientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration is given to recruiting individuals who speak for the communities from which CHOP draws its research subjects. The non-affiliated member typically represents the general perspective of the research participants.

(b) Scientific member(s): Members whose training, background, and occupation would qualify them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline are considered scientists. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

(1) When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as described below and provided by 45 CFR 46.107(f) and 21 CFR 56.107(f).

(2) When FDA-regulated products are reviewed, the convened meeting must include a licensed physician member, therefore, at least one (1) member of each IRB must be a physician.

(c) Non-scientific member(s): The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline are considered non-

scientists.

(d) Representatives of special groups of subjects: Certain types of research may require members or consultants who are knowledgeable about the concerns of certain groups. For example, when the IRB reviews research involving prisoners, a member who can represent the interests of this group, either an ex-prisoner or an individual with specialized knowledge about this group, must be included on the IRB.

(e) Chairs: The individual IRB Chairs will be highly respected individuals from within CHOP, fully capable of managing the IRB and the matters brought before it with fairness and impartiality.

2. The IRBs comply with requirements of the CHOP Medical Staff Bylaws for the majority of the membership to be made up of members of the medical staff.

D. Committees

1. All IRB Committees review all human research studies as well as issues of alleged non-compliance.

2. The Executive IRB Committee will also be charged with serving as an IRB to meet for rapid reviews.

3. An evaluation of whether the number of IRBs and member experience and expertise is appropriate to the volume and types of human research reviewed will be conducted at least annually. This is to ensure that reviews are accomplished in a thorough and timely manner. This evaluation is conducted via reviews of IRB submission volume and internal benchmarking reports completed by the IRB staff.

4. The CHOP IRBs are registered with the Office of Human Research Protection (OHRP) and the FDA. Any changes in membership are reported promptly by the IRB Office to the OHRP and the FDA in accordance with regulatory requirements. The Senior Director, Human Subjects Research, is responsible for reviewing and adjusting (if necessary) the composition of the IRB to meet regulatory and organizational requirements.

5. A list of IRB members for each IRB will be maintained in the IRB office in accordance with **IRB SOP 304.**

E. Term

Members will generally serve on the IRB for a term of three years. Reappointment for additional terms may occur, by mutual agreement of the IRB Chairs, the Institutional Official or their designee, and the President of the Medical Staff or Vice President of the Medical Staff after consultation with the President, or the President's designee.

F. Appointments

All appointments of IRB members and IRB Chairs are made in accordance with the CHOP Medical Staff Bylaws: a) The Chair, CPHS will be appointed by the President of the Medical Staff or Vice President of the Medical Staff; b) Medical Staff members and Vice chairs are appointed by the Chair, CPHS after consultation with the President of the Medical Staff; c) Non-medical and administrative members are appointed by the Institutional Official, acting pursuant to delegation from the President of CHOP, and after consultation with the President of the Medical Staff.

G. Resignations and Removals

1. A member may resign before the conclusion of his/her term. The vacancy will be filled as quickly as possible.

2. Members of the IRB or their alternates are required to attend at least 80% of assigned meetings each fiscal year. Failure to meet attendance requirements may result in removal from the IRB.

3. The IRB Chair, after consultation with the Senior Director, Human Subjects Research and the Institutional Official or their designee, may remove a member of the IRB.

H. Compensation

1. Members of the IRB will be compensated, for their service as IRB members, provided the member fulfills his/her agreed upon responsibilities.

2. Members not affiliated with CHOP shall receive compensation for their service on the IRB provided the member fulfills his/her agreed upon responsibilities.

3. CHOP consultants engaged for additional expertise will not be compensated for their consulting.

I. Liability Insurance

Members have liability insurance coverage as part of their IRB membership in their capacity as agents of CHOP.

J. Initial and Continual Training Requirements

IRB Chairs, members and staff will receive continuing education and training in accordance with **IRB SOP 102**. Completion of training requirements will be one of the items included as part of performance evaluations.

K. Performance Evaluation

1. IRB member performance will be evaluated, on a no less than annual basis, by the IRB Chair and Vice Chair(s) and the Senior Director of Human Subjects Research. Formal written feedback will be provided annually by the Chair, CPHS. The evaluation will include:

   (a) Attendance at IRB meetings;

   (b) The number of reviews conducted as primary or secondary reviewer at IRB meetings;

   (c) Attendance at training/educational sessions (in accordance with the initial and continual training requirements outlined above);

   (d) Whether the assigned reviews/reviewer forms were completed in a timely fashion; and

   (e) Whether they contributed to the discussions during the IRB meeting.

In addition, if there are any specific concerns about a member, the Chair will communicate confidentially with the individual member.

2. In addition to IRB member reviews (as outlined above), IRB members are encouraged to provide feedback regarding the administrative support they receive from the IRB office, how the committee functions as a whole and perceived needs for additional education.

3. The IRB Chair, with input from the Senior Director, Human Subjects Research, will compile an annual report outlining the IRB's activities during the past fiscal year (including, but not limited to, number of submissions, expedited versus full board reviews, aggregate member evaluation results, and IRB Office and Chair staffing). To facilitate any discussions and make improvements (as necessary), this information will be shared with the Institutional Official (IO) and the President of the Medical Staff, either directly or through presentations to committees of which the IO or the President of the Medical Staff are members.

4. IRB staff who may also serve as IRB members undergo annual performance evaluations as part of their CHOP employment. Input will be solicited from the Lead IRB Analyst, IRB Operations Supervisor, IRB Operations Manager, Assistant Director of IRB Operations, Senior Director, Human Subjects Research and the IRB Chairs during the evaluation process.

5. IRB Chair performance will be evaluated on a no less than annual basis by the Institutional Official, with input from the Senior Director, Human Subjects Research, IRB staff and members. Formal feedback will be provided to the IRB Chair and Vice Chairs by the Institutional Official.

L. IRB Registration

The IRBs will be registered as required under 45 CFR 46, Subpart E and 21 CFR 56.106 (January 15, 2009) using the OHRP electronic portal at http://ohrp.cit.nih.gov/efile.

1. Initial registration has already been performed and the institution holds an approved Federalwide Assurance (FWA);

2. The Registration of the IRBs will be renewed at least every 3 years and updated within 30 days of changes to the institution's registration information (e.g., addition of an IRB, new roster of members, a change in IRB Chair).

3. The FWA of the institution will be renewed at least every 3 years and updated within 30 days of changes in the institution's assurance information on record with OHRP (e.g., change in Signatory Official, addition of an IRB, change is mailing addresses);

4. OHRP will also be notified within 30 days

   (a) of the IRB's decision to permanently cease review of HHS-conducted or FDA-regulated research;

   (b) of the IRB's decision to review new types of FDA-regulated research (e.g., drugs products, biologics, devices, food additives).

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103(b)(2)	21 CFR 56.103(b)(2)
45 CFR 46.103(d)	21 CFR 56.103(d)
45 CFR 46.107	21 CFR 56.107
45 CFR 46.501 - 505	21 CFR 56.106
	FDA Guidance for Institutional Review Boards and Clinical Investigators – Institutional Review Boards Frequently Asked Questions, Section II questions 14, 15

VII. REFERENCES TO OTHER APPLICABLE SOPS AND OTHER POLICIES

IRB SOP 102: HRPP Training and Education for IRB Members and Staff	IRB SOP 906: IRB Office Quality Control and Improvement Activities
IRB SOP 304: Documentation and Document Management	CHOP Medical Staff Bylaws

VIII. ROLES AND RESPONSIBILITIES

Title	Responsibility
President of the Medical Staff	Responsible for appointing the Chair, CPHS. The President of the Medical Staff may receive input from faculty, department chairman, staff of the Research Institute, or current members of the IRB.
President	Responsible for appointing the non-Medical Staff and administrative staff members of the IRB. The President may receive input from faculty, department chairman, staff of the Research Institute, or current members of the IRB.
Institutional Official	Responsible for ensuring the IRB has adequate resources to identify and recruit qualified potential members.
Medical Staff	Physicians and dentists who have been appointed as members of the Medical Staff pursuant to the terms of the CHOP Medical Staff Bylaws.
Senior Director, HSR	Responsible for recruiting and installing new IRB members. Responsible for registration of the CHOP IRB with OHRP and the FDA as well as renewing/updating the FWA.
Chair, CPHS	Serves as the Executive Chair for all of the CHOP's IRBs. Responsible for recruiting and evaluating new IRB members, and for appointing the Medical Staff members of the IRB, after consultation with the President of the Medical Staff.

IX. REVISION HISTORY:

06-16-2006	Initial approval date
07-07-2006	Revised to update Section V.A(1)
04-30-2009	Revised to incorporate AAHRPP recommendations, changes in IRB office staff responsibilities, revisions of language and format, added IRB C and D, references to the position of Vice-Chair, CPHS, and adds the requirement for IRB registration to meet the requirements published in the Federal Register January 15, 2009.
06-09-2010	Minor wording changes and deletion of section on consultants to the IRB, which are discussed in IRB SOP 105.
07-12-2010	Revised to incorporate training requirements and timeframes, monitoring of educational requirements, and other related edits.
01-11-2013	Revised to reflect compensation of IRB Members as of July 1, 2012.
01-24-2017	Revised for consistency with the CHOP Medical Staff Bylaws.
03-16-2018	Revised to include editorial revisions, to clarify when an alternate may be allowed to vote, and member feedback from the IRB Chair.
11-20-2018	Revised to reflect content of annual IRB member evaluation and include annual report
10-15-2021	Revised to clarify details of content and recipients of the annual report
04-25-2023	Revised for consistency with the CHOP Medical Staff Bylaws and to reflect the current processes regarding IRB Confidentiality Agreements
12-01-2023	Revised for consistency with the IRB Charter regarding IRB member appointments, to add the requirement for updated CVs, and to reflect updated job titles

X. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 12/01/2023

Amy Schwarzhoff, Senior Director, Human Subjects Research and Barbara Engel, Chair, CPHS