Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	IRB Committee Structure
Version:	1.00
Effective Date:	February 3, 2025
Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

POLICY STATEMENT

It is the policy of the Fred Hutchinson Cancer Center (Fred Hutch) that the structure and composition of the Institutional Review Boards (IRB) are appropriate in the review of all of its research activities to ensure the welfare and protection of its research participants. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.[1]

DEFINITIONS

See *HRP-001 - Glossary of Terms and Acronyms* for full definitions of the following:

Affiliated

Institutional Review Board

PRINCIPLES/OVERVIEW

All IRB Members are appointed by the Fred Hutch Institutional Official (IO). No human research subject to the HRPP may proceed without review and approval by one of the IRBs even if it has been approved by some other Fred Hutch department or official.

The IRB is responsible for ensuring research plans:

- protect the research participant's capacity for self-determination;
- maximize possible benefits and minimize possible harms;
- treat people fairly so that risks of research do not fall unfairly on one group while the potential benefits are given to another group;
- assure that the consent process is voluntary and fully informs the potential participant about the research study;
- provide additional protection to vulnerable individuals who may not have the capacity to consent;
- are designed to respect the individual's privacy and confidentiality of identifiable information; and
- assure that ethical standards for care and protection of research participants in research are in compliance with all pertinent regulations – international, federal, state, and, local.

To ensure that these responsibilities are met, the IRB may approve, require modifications to secure approval, defer, or disapprove research studies. It may also suspend or terminate its approval of ongoing (previously approved) research. The IRB is responsible for the review of ongoing studies where required by regulation, to determine that the risks and potential benefits remain reasonable for the protection and welfare of its research participants.

[1] HHS: 45 CFR 46.107(a); FDA: 21 CFR 56.107(a)

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to Institutional Review Office (IRO) staff, IRB members, employees of Fred Hutch and investigators from other institutions who submit research studies to the Fred Hutch IRB for review and approval.

PROCEDURES

1. Name and Types of Committees

At Fred Hutch, there are four IRB Committees: Committees A, B, C, and D. Each Committee is able to review any type of research submitted by Fred Hutch investigators or by investigators from other institutions who submit research studies to the Fred Hutch IRB.

2. Each committee has sufficient expertise to review all types of clinical intervention and behavioral studies. Responsibilities and Purpose of the IRB

The responsibilities and purpose of the Fred Hutch IRB are described in the *HRP-163 - IRB Mission Statement*. The specific responsibilities of an IRB member are outlined in *HRP-152 - IRB Member Service Description, HRP-165 - Authorities and Responsibilities of the IRB Chairperson,* and *HRP-164 - Authorities and Responsibilities of Individual IRB Members*. All documents are included in the IRB Member's Handbook which is given to the new member during the new member's orientation.

3. The Type and Numbers of Members on the IRB

Each IRB Committee has at least five members with varying backgrounds to promote complete and adequate review of research commonly conducted by Fred Hutch and the Cancer Consortium.

The Fred Hutch IRBs will include:

a. Members of varying professions.[2]
b. Members not all of the same gender.
c. At least one member whose primary concern is non-scientific (e.g., lawyer, clergy, community member) and who represents the general perspective of participants and the community.
d. At least one member with M.D. credentials (or equivalent medical degree from outside the United States), scientific training, or sufficient expertise to evaluate scientific issues involving biomedical or behavioral research.[3]
e. At least one member who is not affiliated with a Cancer Consortium institution and who is not part of the immediate family of a person affiliated with a Cancer Consortium institution.[4]
f. When reviewing research that involves special populations, such as children, at least one member who is knowledgeable about or experienced in working with such participants.
g. Members who are knowledgeable in the applicable regulations, applicable law, and standards of professional conduct and practice.
h. Alternates may serve on the IRB for any voting member with the same scientific status (e.g., nonscientist). See Section 8 below.
i. Prisoner Advocate: When a review item involves the inclusion of prisoners, the prisoner advocate is invited to attend the IRB Committee meeting to review, provide comments and vote on the review item. See Section 9 below. [5]
j. Consultants: If certain expertise or experience necessary to the review of a submission is lacking from an IRB Committee, a consultant may be requested to review and provide comments to the IRB Committee or IRB Chair. See Section 10.[6]
k. Individuals from the Fred Hutch Office of Sponsored Research, the Business Development & Strategy office, and the office of Ethics and Compliance, including IRO, cannot serve as voting IRB members.

[2] FDA: 25 CFR 56.107(b)
[3] HHS: 45 CFR 46.107(b); FDA: 25 CFR 56.107(c)
[4] HHS: 45 CFR 46.107(c); FDA: 25 CFR 56.107(d)
[5] HHS: 45 CFR 46.107(a); FDA: 25 CFR 56.107(a)
[6] HHS: 45 CFR 46.107(e); FDA: 25 CFR 56.107(f)

4. Quorum Requirements

IRB members are encouraged to attend **at least** half of the scheduled IRB meetings. In order for each meeting to be in compliance with regulations, a quorum (majority of the voting members) must be present, with at least one member present whose primary concerns are in a nonscientific area and who represents the general perspective of participants and the community. The Chair is a voting member and contributes to the quorum. Review cannot begin until a quorum is present. If complications arise, the member should attempt to notify the IRO not less than four hours prior to the meeting. If a quorum cannot be achieved, the meeting is cancelled before off-site members begin traveling to Fred Hutch.[7]

An IRB Committee Member or IRB Chairperson must recuse themselves if they have a conflict of interest, and such a recusal affects quorum. If an IRB member must recuse themselves from the deliberation and the vote of a particular study, the IRB Chair and staff must assess the status of the quorum. If a quorum is lost, the study cannot be reviewed at that IRB meeting and this action is noted in the minutes. The IRB may vote after the quorum is restored.

In order for the study to be approved, it has to receive the approval of a majority of members present at the meeting.[8]

5. Action taken when there is perceived coercion or undue influence towards any IRB Committee member or IRB Committee

An IRB Committee member must immediately report to the IRO Director any behavior involving coercion or undue influence of the IRB from any individual. The IRO Director will contact the IO, Vice President and Chief Compliance Officer, and the Office of the General Counsel to determine the appropriate corrective action to be taken.

The IRO Director will also report to the IO, Vice President and Chief Compliance Officer, and the Office of the General Counsel any concerns about the independent functioning or undue influence or coercion of the IRB and thereafter determine the appropriate corrective action to be taken including disciplinary action in accordance with Fred Hutch policy.

6. Appointment and Term Duration

At Fred Hutch, each member is appointed for a term of three years, normally beginning on August 1 and ending on July 31. Any member joining off-cycle will have a first term duration of less than three years.

The IRO Director reviews the IRB rosters in the month of April of each year, or when a member resigns, to determine if:

- the composition of each committee is appropriate; and
- any need for the identification of new members is required.

When additional membership is needed:

- The IRB Operations Manager discusses with the IRO Director or Assistant Director any need to identify additional IRB members (e.g., to replace retiring members or to meet the needs of the committee roster requirements).
- The IRO Director requests recommendations of potential members from the IO, scientific division directors, the Office of Community Outreach and Engagement, IRB members, staff, and other external resources.
- Potential IRB members will submit a copy of their *curriculum vitae* (CV) and participate in an interview with the IRO Director. The potential member is asked to review *HRP-152 - IRB Member Service Description* prior to the interview.
- Candidates who offer the expertise and experience sought for the relevant IRB Committee are recommended for IRB membership. The IO makes the appointments to the IRB Committees based on the recommendations of the IRO Director. The IRB member is asked to confirm in writing his/her willingness to serve and commitment to the requirements of membership.

[7] HHS: 45 CFR 46.107(b); FDA: 25 CFR 56.115(a)(2)
[8] HHS: 45 CFR 46.108(b); FDA: 25 CFR 56.108(c)

A letter of invitation (See *HRP-560a - TEMPLATE LETTER - IRB Member Appointment*) from the IO is forwarded to a potential new member or current members who are invited to extend their term on the IRB Committee.

IRO Staff follows *HRP-377 - WORKSHEET - Onboarding IRB Members* to complete administrative onboarding steps.

On an annual basis, the IRB Operations Manager or designee will follow *HRP-935 - PROCEDURE - IRB Member Evaluation* to complete the *HRP-327 - WORKSHEET - IRB Member Evaluations (All Members)* evaluation tool for each IRB member and IRB Chair who attended at least 3 IRB meetings in the evaluation period. Evaluations are typically conducted in the spring. The IRO Director will use findings from the *HRP-327 - WORKSHEET - IRB Member Evaluations (All Members)* evaluation tool and attendance records to assist in the evaluation of the experience, expertise, contributions, and attendance of each IRB Committee member. The IRO Director will review the *HRP-165 - Authorities and Responsibilities of the IRB Chairperson* and *HRP-164 - Authorities and Responsibilities of Individual IRB Members* found in the *IRB Member Handbook* to ensure IRB members continue to meet *HRP-152 - IRB Member Service Description* and *HRP-164 - Authorities and Responsibilities of Individual IRB Members*. The evaluation process may include discussions with the respective IRB chairs, IRB members, staff and others. IRB Members and IRB Chairs will be provided feedback regarding their evaluations using *HRP-563 - TEMPLATE LETTER - IRB Member Evaluation Feedback.* The IRO Director may discuss issues or concerns raised during the evaluation process directly with the IRB Member or IRB Chair as appropriate.

The IRO Director and the IO recommend whether a member's appointment on the IRB Committee should be renewed. If a renewed appointment is recommended, reappointment is made by the IO.

At the end of a three-year term, an IRB Chair or member may retire their position or may be invited to renew their appointment. Recruitment for replacement or additional Chairperson(s) and/or members progresses through the summer. If a member resigns from the IRB, a thank you letter and a certification of appreciation signed by the IO are provided to the member.

Full IRB members are generally required to attend at least half of the scheduled IRB meetings (normally this means attending a minimum of 6 meetings per year, excluding any emergency or supplemental meetings).

An IRB member may also be invited to serve as an alternate for another IRB Committee member on another IRB Committee. The letter of invitation from the IO will describe the alternate status (e.g., expectation to serve as an alternate for an individual or a specialty, e.g., community member). For specific information about alternate status, please see Section 8 below.

Each IRB member is required to provide their current *curriculum vitae* when they first accept an appointment, whenever any significant changes in their *curriculum vitae* occur, and when they are re-appointed every three years. At the time of re-appointment, if no changes have been made to the *curriculum vitae* in the previous three years, an email confirmation from the member is saved in the IRB member file instead. The *curriculum vitaes* together confirm that each IRB Committee has the appropriate experience and expertise.

7. IRB Chair, Alternate Chair, and Expedited Reviewers

The IRB Chair, and any designated Alternate Chair, must be a scientist and have served on an IRB Committee for at least one term, unless otherwise approved by the IO. The duties of the Chair are outlined in the *HRP-165 - Authorities and Responsibilities of IRB Chairperson*.

Members must serve on an IRB Committee for at least six months before they may be designated by the IRB Chair as an Expedited Reviewer who can review and approve items qualifying for expedited review, sign documents on behalf of the Committee, and serve as Alternate Chair if needed.

8. Alternate Members

Individuals are invited to serve on the IRB Committees as alternate members. An alternate member serves for a member of the same scientific status (e.g., nonscientist) and therefore can serve as an alternate for more than one IRB Committee member. This enables IRB members to share the workload associated with membership.

When the alternate member is requested to attend a meeting, they receive and review the same material that the member for whom they are serving as alternate would have received. The alternate member provides comments and votes at the meeting.

If all voting members of the IRB for a given scientific status are present and in voting status for a particular review item, no alternates for that scientific status may vote on that item at the same meeting.

9. Prisoner Advocate Member

A prisoner advocate is an individual with the appropriate background and experience to represent the best interests of the prisoners who become subjects in a research study. At Fred Hutch, all IRB Committees have appointed prisoner advocate Committee members.[9]

10. Consultants

When it is determined expertise and knowledge are needed that does not exist currently with the IRB membership (e.g., individuals with knowledge and experience working with different cultural or special populations or individuals with relevant scholarly or scientific expertise), consultants from within or outside Fred Hutch are invited to review and provide comments to the IRB Committee or IRB Chair. Consultants are required to review and sign the *HRP-284 - FORM - IRB Consultant Review Evaluation and Conflict of Interest* prior to reviewing IRB materials in order to determine if a conflict of interest exists.

For full review: The consultant's comments are provided to the IRB through Hutch IRB for consideration. Consultants may attend the IRB meeting in person or by way of conference call. Consultants may not vote with the IRB. The minutes of the IRB meeting will reflect that a consultant was utilized in the review of a protocol/activity for full review.

11. Compensation

IRB membership is voluntary. IRB members may receive a small amount of salary support, or a fixed stipend, in recognition of their time. Salary support and stipends are determined based on membership status or attendance at IRB meetings according to the *HRP-166 - IRB Member Compensation Schedule.* The amount of salary support or stipend is not influenced by the number of items reviewed or how a member votes on a particular item.

12. Roster

The IRB roster must include the following information about its voting, non-voting, regular and alternate members:

- Last name and first name
- Earned degree(s)/credentials if any
- Specialty - The member's specialty (e.g., clergy, pediatric oncology, representative of a special population)
- Gender
- Scientific status:
    - Scientists – members whose training, background, and/or occupation (current or prior) is in any scientific area (e.g., MD, RN, MPH, pharmacists, biomedical health professionals, laboratory staff, etc.).
    - NS = Non-Scientists – members with little or no scientific or medical training, background, and/or occupation (current or prior) (e.g., lawyer, clergy, ethicist).

  Some members have training in both scientific and non-scientific disciplines, such as a J.D., R.N. While such members are of great value to an IRB, other members who are unambiguously non-scientific should be appointed to satisfy the non-scientist requirement.
- Expedited Reviewer – Members with sufficient experience who are appointed by the IRB Chair to conduct expedited review on behalf of the committee. Members with this designation can also serve as alternate chairs as needed and have signature authority for the Committee.

[9] HHS: 45 CFR 46.304(b)

- Alternate Chair – Any member designated as an alternate chair.
- Affiliation with a Cancer Consortium institution (Y or N) and their relationship to Fred Hutch (e.g., employee)[10]

13. Updating IRB Membership Roster

The IRB Committee Roster is updated when a new member joins the IRB, a member resigns from a Fred Hutch IRB Committee, or the status of a member changes (e.g., member to alternate).

The IRB Member or Alternate cannot be considered a voting member and count toward the quorum until they have been added to the IRB Committee Roster. The IRB Committee Roster will include each member's chief anticipated contributions to the meeting. It will also specify the alternate members, including their scientific status. See *HRP-601 - TEMPLATE - IRB Committee Roster*.

The IRO Director, with input from the new member, will identify the new member's area(s) of expertise. This determination will assist the IRB Analyst in selecting the appropriate primary reviewers. The area(s) of expertise will be added to the IRB Committee Roster.

When updating the IRB Committee Roster, the IRO staff follows the instructions in the *HRP-376 - WORKSHEET - Committee Roster Update.*

14. Training and Education

See *HRP-062 - POLICY - Training*, for information about training and continuing education for IRB members.

15. Documentation Requirements

The following are documents that each member must complete:

a. Confidentiality Pledge, signed as part of their onboarding in Workday. (A meeting confidentiality pledge is also required to observe an IRB meeting for training purposes.)

b. Conflict of Interest: Each member must review the *HRP-050 - POLICY - Conflicting Interests of IRB Members* and sign *HRP-283 - FORM - IRB Member Annual Certification*. See that policy for further details.

c. Affiliation status: When reviewing *HRP-283 - FORM - IRB Member Annual Certification*, each member is also asked to verify their affiliation status with the Cancer Consortium institutions (Fred Hutch, University of Washington, and Seattle Children's).

d. Member Contact Form: To provide contact information.

16. Annual Joint IRB Committee Meeting

The four IRB Committees will hold a joint meeting annually and the IO will be invited to attend. It is an opportunity for the IO to acknowledge the IRB members and offer them an opportunity to share their views. It is also a forum to provide additional training to IRB members, hold discussion about relevant issues, discuss any resource needs, and share experiences with members of the other Committees.

The IRO Director oversees the coordination of the Joint IRB Committee Meeting. A member of the IRO staff will act as recording secretary. The draft minutes are reviewed by the IRO Director before they are forwarded to the IRB Chairs for review and signature. The finalized minutes are then forwarded to the four IRB Committees and the IO.

In the event a joint IRB Committee Meeting cannot be scheduled, the IO will be invited to attend a regularly scheduled meeting of each Committee.

17. IRB Subcommittee – Special Topics

The IRB Committees may request a subcommittee be formed consisting of IRB members from the four Committees and if appropriate, individuals with expertise regarding the topic. The IRB Subcommittee is formed to provide an opportunity to discuss an issue in more depth, such as developing a new policy. The IRB Subcommittee may only forward its recommendation to the IRB Committees for final review and approval.

[10] HHS: 45 CFR 46.108(a)(2); FDA: 21 CFR 52.115(a)(5)

SUPPORTING DOCUMENTS

HRP-001 - Glossary of Terms and Acronyms
HRP-050 - POLICY - Conflicting Interests of IRB Members
HRP-062 - POLICY - Training
HRP-152 - IRB Member Service Description
HRP-163 - IRB Mission Statement
HRP-164 - Authorities and Responsibilities of Individual IRB Members
HRP-165 - Authorities and Responsibilities of the IRB Chairperson
HRP-166 - IRB Member Compensation Schedule
HRP-283 - FORM - IRB Member Annual Certification
HRP-284 - FORM - IRB Consultant Review Evaluation and Conflict of Interest
HRP-327 - WORKSHEET - IRB Member Evaluations (All Members)
HRP-376 - WORKSHEET - Committee Roster Update
HRP-377 - WORKSHEET - Onboarding IRB Members
HRP-560a - TEMPLATE LETTER - IRB Member Appointment
HRP-563 - TEMPLATE LETTER - IRB Member Evaluation Feedback
HRP-601 - TEMPLATE - IRB Committee Roster
HRP-935 - PROCEDURE - IRB Member Evaluation

REFERENCES

45 CFR 46.107
45 CFR 46.108
45 CFR 46.304
21 CFR 56.107
21 CFR 56.108
21 CFR 56.115
OHRP Compliance Activities: Common Findings and Guidance #10
OHRP Compliance Activities: Common Findings and Guidance #47, #71
FDA Information Sheets: Non-Local IRB Review, IRB Membership
OHRP Compliance Activities: Common Findings and Guidance #8, #9, #48, #49
FDA Information Sheets: Institutional Review Boards Frequently Asked Questions: II. IRB Membership; III. IRB Procedures
FDA Guidance for Institutions and IRBs: Minutes of Institutional Review Board (IRB) Meetings

VERSION HISTORY

Version	Effective Date
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