Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Meeting and Meeting Records
Version:	1.00
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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 all research activities involving human subjects must be reviewed and approved either by an Institutional Review Board (IRB) Committee at a convened meeting at which a majority of the Committee members are present or by an IRB Chair or designee before the activity can be initiated.

The Fred Hutch Institutional Review Office (IRO) supports four IRB Committees: Committees A, B, C, and D. Each Committee is responsible for the review and approval of research involving human subjects.

DEFINITIONS

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

Human Research

Quorum

Subcommittee for IRB Activity Review

PRINCIPLES/OVERVIEW

The purpose of IRB review is to ensure that ethical standards for the care and protection of human subjects have been established and that research activities are compliant with all pertinent regulations (Federal, state and local [including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe]) and with Fred Hutch policies.

The IRO coordinates activities relating to the IRB review process. The IRO is also responsible for documenting the discussion and deliberation that take place at each convened IRB Committee meeting and action taken by the IRB Chair or designee when utilizing the expedited review process.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to 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. IRB Committee Meeting

Human Research that is not classified as exempt or meeting the expedited review criteria requires review by the full IRB Committee at a convened meeting.

The IRB Chair leads the discussion of each activity at the full IRB Committee meeting. If the IRB Chair is unavailable, or conflicted, a designated alternate chair or a member of the committee

authorized to conduct expedited reviews may serve as alternate chair. The IRB Committee deliberates and takes action on each item (See Section 7 Committee Deliberation and Actions, below).

IRB members may participate remotely via telephone or video conference as long as the following two conditions are met: 1) the members receive all the pertinent material prior to the meeting and 2) the members can actively and equally participate in the discussion and vote of all the activities. The minutes must also reflect that these two conditions were met.

2. Meeting Schedule and Meeting Preparation

There are typically four regularly scheduled meetings each month:

- First Wednesday of the month: Committee D
- Second Wednesday of the month: Committee A
- Third Wednesday of the month: Committee C
- Fourth Wednesday of the month: Committee B

Actual dates may vary based on member availability, especially around holidays. A full board meeting may be canceled or rescheduled due to a) holiday; b) inability to secure a quorum; or c) other reasons as may arise that makes a scheduled meeting unnecessary or otherwise inappropriate.

Committees A, B, C, and D primarily are scheduled from 2:30 to 5:00 p.m. The list of IRB meetings is posted on the IRB Meeting Schedule webpage IRO website for access by all principal investigators (PI) and key staff members of Fred Hutch.

Several weeks prior to the scheduled meeting, the IRB staff emails the IRB members to determine their availability and confirm their attendance. The IRB staff will confirm whether a non-affiliated and non-scientific member(s) will be present to establish a quorum.

3. Review System

The IRB Committees use a primary reviewer system for activities requiring full review. Generally, two primary reviewers are assigned to each item. Each IRB member has access to all study documents submitted for full IRB review. All members in attendance are expected to review, at a minimum, the submission SmartForm and attached IRB Application Form or Supplement (*e.g., HRP-253 - FORM - Continuing Review Supplement*), the protocol summary, and consent(s) prior to the meeting in enough depth to discuss the information at the convened meeting. It is the primary reviewers' responsibility to review all the documents of their assigned item and to report their findings at the convened IRB meeting.

In addition to reviewing all documents provided such as *HRP-250 - FORM - IRB Application (Contact)* and *HRP-251 - FORM - IRB Application (No Contact)*, the primary reviewers will be primarily responsible for reviewing the funding source document(s) and the Investigator's Brochure when appropriate.

Additional materials such as past IRB minutes, Principal Investigator memos, and legacy IRB files are available to IRB Committee members upon request. Materials from past reviews submitted after the launch of Hutch IRB are available to the reviewers in the system.

The IRB Analyst determines the primary reviewers for each study based on the type of study or activity. At least one IRB member or consultant with appropriate scientific or scholarly expertise reviews each activity in-depth including the protocol. For example, a medical physician with the appropriate specialty will be assigned as the primary reviewer for a clinical intervention study, not a non-scientist.

If the study involves a special population or an activity that requires expertise and knowledge that is not found within the IRB membership (e.g., individuals with knowledge and experience working with different cultural or vulnerable populations or individuals with relevant scholarly or scientific expertise), consultants are invited to review and provide comments to the IRB Committee or IRB Chair. Consultants are required to sign and provide their comments on *HRP-284 - FORM - IRB Consultant Review Evaluation and Conflict of Interest* (see *HRP-050 - POLICY - Conflicting Interests of IRB Members*). The IRB Analyst ensures that the IRB member or consultant knowledgeable about

or experienced in working with such participants is present at the meeting or provides written comments about the item in question.

For activities requiring full review, the PI is invited to be available (by phone) for the meeting for the purpose of providing additional clarification or discussion. The PI must leave the meeting prior to final discussion and voting by the IRB.

4. Materials Submitted to the IRO and Reviewed by IRB Members

All IRB members (including alternate members) have the same materials available via Hutch IRB. When an IRB member is not a primary reviewer, they are expected to review the submission data in Hutch IRB, the application form, most current protocol, and the consent or assent forms in enough depth to discuss the information at the convened meeting for any full review activity (e.g., adverse events, unanticipated problems and modifications to an on-going activity). All IRB members have access to the *HRP-442 - CHECKLIST - IRB Member*. Any IRB member may request additional information.

If a consultant provides information outside the system, the IRB Analyst uploads the communication in the Pre-Review activity in Hutch IRB so the Committee members can see the information.

5. The Agenda

Prior to every IRB Committee meeting, a full review agenda is generated in Hutch IRB. The system automatically provides a report of the Expedited Submissions Approved in the Last 45 Days for each meeting.

a. The Full Review Agenda includes all activities requiring full review by the IRB Committee. The full agenda lists all items to be reviewed.

   The full agenda includes:

   i. A listing of the activities requiring full review

   ii. Review of the minutes from the previous IRB Committee meeting (if available)

   iii. Review of the report of Expedited Submissions Approved in the Last 45 Days

   iv. Determination of Conflict of Interest

   v. Reminder to review the confidentiality agreement for IRB members

   vi. Continuing education materials

   vii. Each full agenda is restricted to the number of items it can review. Generally, no more than five (5) new study submissions may be reviewed at a given meeting. The IRB Operations Manager manages the overall workload of the IRB, in collaboration with the Senior IRB Analyst Team Leads, taking into account the number and types of items on the agenda and the committee members available for the meeting. Items are scheduled to a meeting when they are deemed review ready by an IRB Analyst. Any item may be tabled for review at the next available Committee meeting, for example if time does not allow for a comprehensive review of agenda items.

   viii. IRB Member Conflict of Interest (COI): Submissions are screened by the IRB Analyst to determine if an IRB Member is listed on the new application or protocol. If an IRB Member is identified as having a COI with a specific study, this information is added to the Staff Data Entry activity in Hutch IRB and displays on the formal agenda, and verbally announced by the IRB Chair during the convened meeting. If an IRB Member's COI is not noted on the agenda, the IRB Member is required to notify the IRB staff of their conflict as soon as possible. For more detailed information regarding IRB Member COI, please see *HRP-050 - POLICY - Conflicting Interests of IRB Members.*

   ix. Once the agenda is ready, the IRB Analyst uses the Send Agenda activity to notify the IRB members. The agenda is typically available six days prior to the IRB meeting.

   x. An updated agenda might be prepared if an additional submission requires timely review after a meeting agenda is finalized. This could occur if, for example, a patient safety

concern was received in the IRO. The IRB Analyst emails the potential primary reviewers for the additional agenda item to confirm that they have sufficient time to review the item.

b. The Expedited Submissions Approved in the Last 45 Days report includes all activities that received expedited review by the IRB Chair or designee in the 45 days prior to the meeting. The report includes the specific Expedited category(ies) determined by the designated reviewer. Any item appearing in the Expedited Submission report can be recalled by any IRB member who feels it warrants a full review. If that occurs, the PI of the activity will be notified of the action taken and the item will appear on the next regularly scheduled meeting.

c. The IRB Chair or Member has access to the *IRB Member Handbook*, which provides reviewers with guidance on the review process.

d. For pre-Hutch IRB legacy files, the original hard copies of both the full and expedited agendas and attachments listed in the full review agenda are filed in the Agenda-Minutes binder, located in the IRO file room. Older Agenda-Minutes binders are periodically sent to archives.

6. Quorum Requirements at Convened IRB Meeting

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 IRB Member or Alternate cannot be considered to be a voting member and count toward the quorum until they have been appointed by the Institutional Official and have been added to the signed IRB roster. The IRB roster will include each member's chief anticipated contributions to the meeting. It will also specify the alternate members, including their scientific status, which determines for whom they can substitute.

Each IRB Member (or alternate as needed) should make every effort to attend IRB meetings for which they are scheduled. In order for each meeting to be in compliance with regulations, a quorum (a 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 and one unaffiliated member. The Chair is a voting member and contributes to meeting quorum. Review cannot begin until a quorum is present. If attendance 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 if attempts to obtain an Alternate were unsuccessful. [1]

Recusals are when IRB Committee Members or IRB Chairs leave voting status (the normal practice is to leave the meeting) because they have a conflict of interest. Recusals influence a quorum. If an IRB member must recuse themselves from the deliberation and the vote of a particular study, the IRB Chair or IRO staff must assess the status of the quorum. If a quorum is lost, the activity cannot be reviewed at that IRB meeting and is automatically tabled for a future meeting. This action is noted in the minutes.

An IRB roster may also include alternates for specific IRB members or class of members. This enables IRB members to share the workload associated with membership. However, if all members of a given scientific status are in voting status for a particular review item, no alternates for that scientific status may vote on that item at the same meeting.

During a convened meeting IRB staff present will be responsible for determining and ensuring quorum is established and maintained. If quorum is lost for any reason, including if required members (e.g. non-scientific, or unaffiliated) are not present, a vote will not be taken until quorum is restored.

7. Committee Deliberations and Actions

a. Voting may be done by a show of hands, verbally, or electronically.

b. The Chair and all voting members who are present (in person or by teleconference) will vote.

c. Items undergoing IRB review may have one of the following motions made:

   i. <u>Approved</u>

[1] HHS: 45 CFR 46.108(b); FDA: 21 CFR 56.108(c)

Made when IRB members have confirmed the IRB regulatory criteria for approval are met. For initial and continuing reviews, include the period of approval (if less than one year) and the level of risk.

ii. Modifications Required to Secure Approval

Made when IRB members have confirmed the IRB regulatory criteria for approval are met, but require specific modifications. When making this motion, the IRB Chair restates the modifications required.

The modifications required should be directive. The required modifications cannot be substantive clarifications or modifications regarding the protocol or informed consent process/documents that are directly relevant to the determinations related to the IRB approval criteria. When this determination is made on a study, no approval documents are released and the study cannot begin human subject activities.[2]

Generally, an IRB staff member will determine whether an investigator has made the required changes; however, the item could be referred to the Chair or designee to confirm as needed. The Chair or designee may send the item back to the fully convened IRB meeting if the approval conditions have not been met, if there are concerns about the information included in the response, or if the PI response includes a new Modification with substantive changes. The response would be scheduled for review by the same IRB Committee, at its next available convened meeting.

iii. Deferred

Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has recommendations that might make the protocol approvable. When making this motion, the IRB Chair restates the IRB's reasons for the decision and recommendations to make the research approvable.

When the convened IRB Committee defers an item, the result letter includes the reasons for its decision and gives the PI an opportunity to respond in writing. The PI's response is scheduled for review by the same IRB Committee at its next available convened meeting.

iv. Disapproved

Made when the research does not qualify for Approval, Modifications Required to Secure Approval, or Deferred and the IRB has no recommendations that might make the protocol approvable. When making this motion, the IRB Chair summarizes the IRB's reasons for the decision.

When the convened IRB Committee disapproves an activity, the result letter includes the reasons for its decision, and still gives the PI an opportunity to respond in writing. The PI's response is scheduled for review by the same IRB Committee at its next available convened meeting.

v. Tabled

If the IRB is unable to make one of the above determinations due to reasons unrelated to the research, the IRB may make a motion to Table an item. This item will be rescheduled to the next available IRB meeting. Note: If quorum is lost, the voting requirements cannot be met, so the item is automatically tabled and rescheduled to the next available IRB meeting.[3]

8. Meeting Records (Minutes) Maintained by IRB Staff

a. Written minutes of each IRB Committee meeting include:

i. Attendance (to confirm quorum)[4]

ii. Designation of alternate member(s) when replacing a primary IRB Committee member

iii. A list of guests and presenters who attended the meeting.

[2] HHS: 45 CFR 46.111; FDA 21 CFR 56.111
[3] HHS: 45 CFR 46.109(a); FDA: 21 CFR 56.109(a)
[4] HHS: 45 CFR 46.115(a)(2); FDA: 21 CFR 56.115(a)(2)

- Guests are individuals who are invited to "observe" the IRB meeting and are required to sign a confidentiality pledge. The signed confidentiality pledge(s) are then filed in the J: drive draft minutes folders. See *HRP-281 - FORM - Meeting Confidentiality Pledge*.

  Note: Guests are not present for agenda items related to potential noncompliance or potential unanticipated problems involving risks to subjects or others.

- Presenters are individuals who are invited to the IRB meetings to present their activities. Presenters also include individuals who are presenting issues that are related to the IRB, for example for continuing education.

iv. A summary of the controverted issues and their resolutions[5]

v. Risk level

vi. Determinations and findings that require documentation, including:

- a procedure which waives the requirement for obtaining a signed consent form or the waiver or alteration of some or all of the elements of consent (see *HRP-090 - POLICY - Informed Consent*)[6]

- pregnant women, human fetuses, or neonates; prisoners; children; or individuals with impaired decision-making capacity (see *HRP-125 - POLICY - Research Involving Special Populations*)[7]

vii. Length of time until the next continuing review based on the degree of risk[8]

viii. Recommended changes and reasons[9]

ix. The IRB Committee's rationale for disapproving a submission

x. Votes for each activity as numbers for, against, or abstaining[10]

xi. Name of the member who left the meeting and the reason for leaving the meeting (e.g., conflict of interest). The vote may be adjusted, if appropriate.

xii. The IRB Committee's rationale to determine the risk of an FDA regulated device is significant or non-significant.

xiii. If a consultant was present, the name of the consultant, a brief description of the consultant's expertise, and documentation that the consultant did not vote.

b. Each activity reviewed by the IRB Committee will have its own summary results of the IRB Committee's' decisions.

c. The vote on all IRB actions, including the number of members voting for, against, abstaining, absent, recused and those who are voting on behalf of a regular member. Only when a member abstains, the member's name is listed along with the reason for the abstention.

d. Minutes are drafted by IRO staff and reviewed by a manager. The minutes are added to the agenda at a subsequent convened meeting for review and acknowledgement, and members have until the end of that week to provide any feedback. If the member's feedback is substantive, or if staff identifies substantive corrections needed later, the updated minutes are brought back for IRB review and acknowledgment.

e. Also, at the beginning of each IRB Committee meeting, the IRB Chair will query the IRB members about possible conflict of interest (COI) relating to any full review items listed on the agenda.

- Any IRB Member COI will be reflected in the meeting minutes. IRB members with a COI will not be counted toward the quorum. For example, a statement such as "Member X left the

[5] HHS: 45 CFR 46.115(a)(2); FDA: 21 CFR 56.115(a)(2)
[6] HHS: 45 CFR 46.117(c)(1), 46.116(f)(3); FDA: 21 CFR 56.109(c), *FDA Guidance for Sponsors, Investigators, and Institutional Review Boards: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects*
[7] HHS: 45 CFR 46.203 – 207, 46.305 – 46.306, 46.403 – 46.409; FDA: 50.50 – 50.56
[8] HHS: 45 CFR 46.115(a)(3); FDA: 21 CFR 56.115(a)(3)
[9] Ibid.
[10] Ibid.

meeting due to a conflict of interest" is added to the minutes to document the IRB Member COI.

f. The final minutes are available in Hutch IRB. For legacy meetings pre-Hutch IRB, a hard copy of the meeting minutes is stored in agenda/minutes binders.

g. To provide IRB findings to Fred Hutch institutional officials per *HRP-117 - POLICY - Requirements for Reporting to Institutional and External Officials,* the final and approved agenda and minutes for full committee reviews are stored in a shared drive J:\IRO\IRO Minutes - For Director's Office. Requests for copies of minutes by other individuals should be made with the IRO Director. Photocopying may be allowed contingent upon General Counsel's approval. See *HRP-072 - POLICY - Maintenance and Retention of IRB Documents*.

h. Once an IRB determination is submitted in Hutch IRB, the system deletes all IRB member comments related to that submission.

9. Determination Letters to Principal Investigators (Result Letters)

a. Letters providing the IRB's determinations to PIs are referred to as "result letters," which will be prepared as follows:

i. IRB staff prepares result letters for every item reviewed by the IRB. Depending on the type of item, the letter is reviewed by another IRB staff person or manager.

ii. If the IRB disapproved or deferred a study, or a study was suspended or terminated, the IRB Analyst or IRO Assistant Director emails the PI, Primary Contact, and PI Proxies within 24 hours after the meeting to inform them of this determination. The email also informs them that the formal result letter will be forwarded to them in accordance with *HRP-150 - IRB Turnaround Times*.

iii. If the IRB Committee directives involve requests from individuals other than the PI, such as General Counsel, IRO Director, Institutional Official, or Scientific Division Heads, an email is sent to them describing the IRBs requests. Also, these individuals are cc'd in the result letter.

b. Result letters are sent to the PI, Primary Contact, and PI Proxies through Hutch IRB. The letter appears on the related submission workspace.

10. Response to the Result Letter

The PI submits the response in Hutch IRB.

If the original determination was Mods Required to Secure Approval: Generally, an IRB staff member will determine whether an investigator has made the required changes; however, the item could be referred to the Chair or designee to confirm as needed. The Chair or designee may send the item back to the fully convened IRB meeting if the approval conditions have not been met, if there are concerns about the information included in the response, or if the PI response includes a new Modification with substantive changes. The response would be scheduled for review by the same IRB Committee, at its next available convened meeting.

If the original determination was Deferral or Disapproval: The item is place on the next available agenda for the same Committee for the IRB to assess.

The IRB Analyst uses *HRP-371 - WORKSHEET - Response to Result Letter* for guidance in the screening and processing of the PI's response.

SUPPORTING DOCUMENTS

HRP-001 - Glossary of Terms and Acronyms

HRP-050 - POLICY - Conflicting Interests of IRB Members

HRP-072 - POLICY - Maintenance and Retention of IRB Documents

HRP-090 - POLICY - Informed Consent

HRP-117 - POLICY - Requirements for Reporting to Institutional and External Officials

HRP-125 - POLICY - Research Involving Special Populations

HRP-150 - IRB Turnaround Times

HRP-250 - FORM - IRB Application (Contact)
HRP-251 - FORM - IRB Application (No Contact)
HRP-253 - FORM - Continuing Review Supplement
HRP-281 - FORM - Meeting Confidentiality Pledge
HRP-284 - FORM - IRB Consultant Review Evaluation and Conflict of Interest
HRP-371 - WORKSHEET - Response to Result Letter
HRP-442 - CHECKLIST - IRB Member

REFERENCES

45 CFR 46.108
45 CFR 46.109
45 CFR 46.111
45 CFR 46.115
45 CFR 46.116
45 CFR 46.117
45 CFR 46.203-207
45 CFR 46.305-306
45 CFR 46.403-409
21 CFR 50.50-56
21 CFR 56.108
21 CFR 56.109
21 CFR 56.111
21 CFR 56.115
FDA Information Sheets: Frequently Asked Questions: IRB Membership (videoconference), IRB Records, IRB Procedures
FDA Information Sheets: Significant Risk and Nonsignificant Risk Medical Device Studies
FDA Guidance for Sponsors, Investigators, and Institutional Review Boards: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects
OPRR, Meetings Convened via Telephone Conference Memo, dated March 28, 2000
OHRP compliance Activities: Common Findings and Guidance #3, # 8, #9, #10, #14, #15, #20, #43, #48, #49, #68, #69, #70, #71(d), #72
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VERSION HISTORY

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