FRED HUTCH
Institutional Review Board

Policy/Procedure

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9.00	09-01-2012
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8.00	05-01-2010
7.00	07-01-2009
6.00	03-21-2008
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3.00	04-27-2007
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POLICY STATEMENT

It is the policy of the Fred Hutchinson Cancer Research 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 *IRB Glossary of Terms and Acronyms* (050) for full definitions of the following:

eReview

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

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

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 Action, below).

Telephone conference: It is preferred that the majority of the IRB members physically be present at the convened meeting. IRB members may participate via telephone conference call 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.

Committees A, B, C, and D primarily are scheduled from 2:30 to 5:00 p.m. The list of IRB meeting and submission dates is posted on the IRO website at https://extranet.fredhutch.org/en/u/irb/meeting-schedule.html 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, with which they have no identified conflicts of interest. All members in attendance are expected to review, at a minimum, the Application Form (*e.g.,* the *Continuing Review Report* [045]), 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 activity and to report their findings at the convened IRB meeting.

In addition to reviewing all documents provided such as the *Application for Review* (0324, 0325, or 0326), 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 IR files are available to IRB Committee members upon request.

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 review 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 the *IRB Consultant Review Evaluation and Conflict of Interest Form* (087) (see *IRB Policy 1.5 IRB Member Conflict of Interest* [020]). 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 or in person) for the meeting for the purpose of providing additional clarification or discussion. The PI must leave the room prior to final discussion and voting by the IRB.

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

Hard copies of documents relating to a research study's review (e.g., new application) are scanned by IRB staff.

The scanned documents are then uploaded into eReview about a week before the meeting. All IRB members (including alternate members) receive the same materials posted on eReview. When an IRB member is not a primary reviewer, they are expected to review 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 *IRB Member Checklist* (071) and *IRB Member Consent Process and Documentation Checklist* (072). Any IRB member may request additional information.

When comments are provided by IRB Committee members, consultants to the IRB or PI via email, the IRB Analyst will make every effort to confirm with the owner of the email requesting permission to share his or her comments with the IRB Committee. The IRB Analyst summarizes the email correspondence(s). The summary is then scanned and uploaded unto eReview to be accessed by the IRB Members. Policies such as the *IRB Policy 2.1 New Application* (028) describe the documents provided to and reviewed by the IRB members.

5. The Agenda

Prior to every IRB Committee meeting, a full review agenda is generated (see *IRB Policy 2*.22 *Database PIRO* [013] for preparing review materials for each IRB meeting). An expedited agenda report is generated reflecting a report of items approved via the expedited review procedure which have not been previously reported to the convened IRB.

a. The Full Review Agenda includes all activities requiring full review by the IRB Committee (see Sample full agenda). 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 expedited agenda

   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 applications may be reviewed at a given meeting. The IRB Operations Manager manages the overall workload of the IRB, taking into account the number and types of items on the agenda and the committee members available for the meeting. The IRO cannot promise to schedule items received prior to the agenda cutoff date if the agenda fills up prior that date. Any item may be deferred to the next IRB Committee agenda or another IRB Committee meeting if time does not allow for a comprehensive review of agenda items or if insufficient materials are available to make sound judgment.

   viii. IRB Member Conflict of Interest (COI): The COI information provided by PIs in the new application is entered into the IRO database, PIRO. This information is screened by the IRB Analyst to determine if an IRB Member is listed on the new application. If an IRB Member is identified as having a COI with a specific study, this information is added to the detail tab in PIRO which is displayed on the 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. The Fred Hutch Office of the General Counsel or IRO Director should be consulted as necessary.

For more detailed information regarding IRB Member COI, please see *IRB Policy 1.5 IRB Member Conflict of Interest* (020).

ix. After all the review documents are uploaded onto eReview, the IRB Analyst emails the Committee members informing them that the agenda is ready for review. The agenda is typically available 4-5 days prior to the IRB meeting.

x. A supplemental agenda might be prepared if review materials are submitted after the 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 supplemental agenda item to confirm that they have sufficient time to review the material.

b. The Expedited Review Agenda report includes all activities that received expedited review by the IRB Chair or designee since the last expedited agenda was prepared and reported to the Committee.

i. When the activity involves the review of exempt research, the expedited agenda report will show the category of exemption, information to justify the exemption category, and the determination by the IRB Chair or designee that the research meets the criteria for Exempt research.

ii. New applications and continuing review reports that receive expedited review and approval by the IRB Chair or designee will include the following information:

- The specific permissible category(ies) selected by the PI and reviewed and determined by the IRB Chair or designee.
- A description of the study's objectives.
- A description of the review and action taken by the IRB Chair or designee.

iii. Any item appearing in the expedited agenda 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 Checklist* (071), which provides reviewers with guidance on the review process. The checklists are provided on eReview and in the *IRB Member Handbook.*

d. 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 before off-site members begin traveling to Fred Hutch. [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.

7. Committee Deliberations and Actions

a. Voting is done by a show of hands on each activity. If a member is attending via teleconference, the Chair requests their verbal vote for each item.

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

c. Studies undergoing IRB review may be approved, approved with minor modifications, or disapproved. Items at committee meetings may also be tabled for future consideration if circumstances warrant such action.[2]

i. Approved
The study satisfies the applicable regulatory, institutional, and IRB requirements for human subjects research. The study can begin human subject activities.

ii. Approved with minor modifications

The study satisfies the applicable regulatory, institutional, and IRB requirements for human subjects research; however, there are minor unresolved issues such that final approval documents cannot be released. The minor 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 criteria of approval. A study that is approved with minor modifications cannot begin human subject activities. [3]

An example of approved with minor modifications: Simple language changes to consent and other subject materials; clarification of issues on IRB forms; if review by external departments or committees other than the IRB is pending (e.g., Radiation Safety Committee [RSC], Institutional Biosafety Committee [IBC] or Industry Sponsored Contract), status of application is approved, however no study documents (i.e., protocol, consent forms, questionnaire) are released to the investigator.

After the meeting, the PI's response is reviewed by the Chair or designee to ensure the conditions of approval have been satisfied. 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

[1] HHS: 45 CFR 46.108(b); FDA: 21 CFR 56.108(c)
[2] HHS: 45 CFR 46.109(a); FDA: 21 CFR 56.109(a)
[3] HHS: 45 CFR 46.111; FDA 21 CFR 56.111

concerns about the information included in the response, or if the PI response includes a new Modification with substantive changes. The response is scheduled for reviewed by the same IRB Committee at its next available convened meeting.

iii. Disapproved

The study does not satisfy the applicable regulatory IRB requirements for human subjects research.

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

iv. 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.

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.

- 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 with the meeting minutes. See *Confidentiality Pledge* (0243).

  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.

iv. Votes for each activity as numbers for, against, or abstaining;[5]

v. Actions taken by the convened IRB Committee;[6]

vi. The basis for requiring changes in or disapproving the research;[7]

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

viii. A summary of the discussion of controverted issues and their resolution;[9]

ix. Document determinations required by the regulations and protocol-specific findings supporting those determinations for research involving:

[4] HHS: 45 CFR 46.115(a)(2); FDA: 21 CFR 56.115(a)(2)
[5] Ibid.
[6] Ibid.
[7] Ibid.
[8] HHS: 45 CFR 46.115(a)(3); FDA: 21 CFR 56.115(a)(3)
[9] HHS: 45 CFR 46.115(a)(2); FDA: 21 CFR 56.115(a)(2)

- 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 *IRB Policy 2.11 Informed Consent* [017])[10]
- pregnant women, human fetuses, or neonates; prisoners; children; or individuals with impaired decision-making capacity (see *IRB Policy 2.15 Research Involving Special Populations* [033]);[11]

x. Justification is provided when the IRB Committee requests a deletion or substantive modification of information concerning the risks or alternative procedures contained in the DHHS-approved sample consent document;

xi. The 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 a 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 and those with conflict of interest are noted for each agenda item. Only when a member abstains, the member's name is listed along with the reason for the abstention.

MEMBERS VOTING [to DISAPPROVE] – For: [8] Against: [0] Abstained*: [1 J. Smith first IRB Meeting]

d. Minutes are drafted by the IRO staff and routed to all members who attended the meeting and counted towards quorum. Members receive approximately 3 business days to review and comment on the minutes. Edits are incorporated by the IRO staff. Finalized minutes are then routed to the IRB chair who conducted the meeting for final review and signature. Either the signed or unsigned minutes are added to the agenda at a subsequent convened meeting for review and acknowledgement. If the unsigned minutes are acknowledged by the convened meeting and substantive revisions are made following the meeting, the final version of the minutes will be brought back to the convened meeting for acknowledgement.

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

f. A hard copy of the meeting materials is added to the agenda/minutes binder using the *Screener: Minutes Binder* (0132).

g. To provide IRB findings to Fred Hutch institutional officials per *IRB Policy 2.8 Requirements for Reporting to Institutional and External Officials* (021), the final and approved expedited and full

[10] 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*

[11] HHS: 45 CFR 46.203 – 207, 46.305 – 46.306, 46.403 – 46.409; FDA: 50.50 – 50.56

agenda, minutes and result letters are stored in a shared drive J:\IRO\IRO Minutes - For Director's Office. Requests for copies of minutes should be made with the IRO Director. Photocopying may be allowed contingent upon General Counsel's approval. See *IRB Policy 2.17 Maintenance and Retention of IRB Documents* (023).

h. Meeting minutes and agendas are archived in PIRO database after they are approved by the respective IRB Committee. This action automatically deletes the comments that were provided by IRB members and IRB staff. IRO staff with PIRO "administrative" privileges archives by clicking on the archive checkbox in PIRO in Report every three months. Additionally, the IRB Analysts shred the hard copies of the comments and notes taken at the IRB meetings.

9. Letters of Instruction to Principal Investigators (Result Letters)

a. Letters of instruction to PIs are referred to as "result letters", which will be prepared as follows:

   i. The IRB Analyst prepares the result letters for review by the IRB Operations Manager or IRO Assistant Director.

   ii. If the IRB disapproved the study or a study was closed, the IRB Analyst or IRO Assistant Director on behalf of the IRB Chair emails the PI and IRO Contact 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 in accordance with *IRB Turnaround Times* (0411).

   iii. If the IRB Committee deliberations involve individuals, e.g. General Counsel, IRO Director, or Scientific Division Heads, other than the PI, a FYI email is sent to them, describing in general the IRBs requests. Also, these individuals are cc'd in the result letter.

b. Final proofread letters are forwarded to the IRB Chair or designee for signature, no later than one week following the IRB meeting.

   Considerations:

   i. The PI is notified that the study is approved with minor modifications. That is, no documents are released if IBC, IND/IDE or other departmental approval is still pending, for example.

   ii. If a protocol is on temporary clinical hold (temporarily closed to accrual), the result letter should state that the study is approved only for data collection and no new accrual can occur.

After the IRB Chair or designee signs the letters, copies are forwarded to the PI and IRO Contact and placed in the IRB minutes' binder and in its respective IR file.

10. Response to the Result Letter

Reviewing responses to meeting result letters is a priority. Responses should be sent to the IRB Chair in accordance with *IRB Turnaround Times* (0411).

The IRB Analyst uses the *Screener: Response to Result Letter* (0141) for guidance in the screening and processing of the PIs response.

When the response involves a minor modification and is appropriate, the documents are forwarded to the IRB Chair or designee for review and signature. Each response is flagged to assist the IRB Chair or designee in their review.

When the response involves a major modification, the IRB Staff adds the appropriate review documents for the next IRB Committee meeting.

SUPPORTING DOCUMENTS

Confidentiality Pledge (0243)
Continuing Review Report (045)
IRB Policy 1.5 IRB Member Conflict of Interest (020)
IRB Policy 2.1 New Application (028)
IRB Policy 2.8 IRB Requirements for Reporting to Institutional and External Officials (021)
IRB Policy 2.11 Informed Consent (017)
IRB Policy 2.15 Research Involving Special Populations (033)
IRB Policy 2.17 Maintenance and Retention of IRB Documents (023)
IRB Policy 2.22 Database PIRO (013)
IRB Consultant Review Evaluation and Conflict of Interest Form (087)
IRB Glossary of Terms and Acronyms (050)
IRB Member Checklist (071)
IRB Member Consent Process and Documentation Checklist (072)
IRB Turnaround Times (0411)
New Application for Review Interventional Research (0324)
New Application for Review Observational Research (0325)
New Application for Review Human Specimens or Data Research (0326)
Screener: Response to Result Letter (0141)
Screener: Minutes Binder (0132)

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
Federal Register, Vol. 68, No. 119, pp. 36929-36931, June 20, 2003