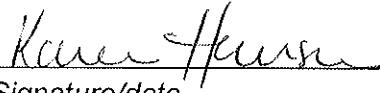


Title:	Meeting and Meeting Records
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	 July 1, 2009
	Signature/date
Effective Date:	July 01, 2009
Policy:	1.6

POLICY STATEMENT

It is the policy of the Fred Hutchinson Cancer Research Center (FHCRC) that all research activities involving human subjects must be reviewed and approved 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 FHCRC Institutional Review Office (IRO) supports three IRB Committees: IRB Committee A, IRB Committee B, and, IRB Committee C. Each Committee is responsible for the review and approval of research involving human subjects.

DEFINITIONS

eReview: A secure, web-based, electronic archive for IRB document review and comments.

Quorum: One more than half of the voting members identified on the approved IRB Committee roster.

SubCommittee for IRB Activity Review: A subCommittee typically involves two or more IRB Members and includes the original primary and secondary reviewers of an activity.

REFERENCES

- 45 CFR 46.108(b)
- 21 CFR 56.108(c)
- FDA Information Sheets: Frequently Asked Questions: IRB Membership (videoconference), IRB Records, IRB Procedures
- FDA Information Sheets: Significant Risk and nonsignificant Risk Medical Device Studies 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
- 45 CFR 46.115(a)(2)
- 45 CFR 46.116(c)-(d)
- 45 CFR 46.117(c)
- 45 CFR 46.204-207
- 45 CFR 46.305-306

45 CFR 46.404-408
45 CFR 46.103(b)(4) and 46.109(e)
45 CFR 46.111
21 CFR 50.51-56
21 CFR 56.109(c)
21 CFR 56.115(a)(2)

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 research activities are in compliance with all pertinent regulations (federal, state and local) and with FHCRC 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 Institutional Review Office (IRO) staff, IRB members, employees of FHCRC and investigators from other institutions who submit research studies to the FHCRC 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 make 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 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 three regularly scheduled meetings each month:

- IRB Committee A meets on the 2nd Wednesday
- IRB Committee B on the 4th Wednesday
- IRB Committee C meets on the 3rd Wednesday.

In November and December, historically, due to the holidays, IRB Committee B meets on the 3rd Wednesday and IRB Committee C meets on the 4th Wednesday.

Each IRB meeting typically takes place in the Yale Building, in Conference Room J6-102 from 2:30 to 5:00 p.m.

The list of IRB meeting and submission dates is posted on the IRO website at <http://www.fhcrc.org/intranet/iro/irb/meetings.html> for access by all principal investigators (PI) and key staff members of FHCRC.

Two weeks prior to the scheduled meeting, the IRB Analyst emails the IRB members to confirm their attendance. This email confirms whether a non-affiliated and non-scientific member(s) will be present to confirm a quorum.

The IRB Administrative Assistants use the *IRO Meeting Checklist* to confirm that all items needed for a meeting have been ordered (e.g. catering).

3. Review System

The IRB Committees use a primary and secondary reviewer system for activities requiring full review. Each IRB member has access to all study documents submitted for full IRB review. All members are expected to review, at a minimum, the Application Form (e.g., the *Continuation Review Report*), the protocol summary, consent(s), and recruitment materials prior to the meeting. It is the primary and secondary 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*, the primary reviewer will be 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 and secondary 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. 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 vulnerable population or an activity that requires expertise and knowledge that is not found within the IRB membership (i.e. 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 *Consultant Review Form* (see *IRB Policy 1.5 IRB Member Conflict of Interest*). The IRB Analyst ensures that the IRB member or consultant knowledgeable about or experienced in working with such participants are present at the meeting.

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 the IRB staff.

The scanned documents are then uploaded onto eReview a week before the meeting. All IRB members (including alternate members) receive the same materials posted on eReview. When an IRB member is neither the primary or secondary reviewer, h/she is expected to review the application form, most current protocol, 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* and *IRB Member Consent Process and Documentation Checklist*. 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 first confirms with the owner of the email requesting permission to share his or her comments with the IRB Committee. After receiving permission, 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* describes the documents provided to and reviewed by the IRB members.

5. The Agenda

Prior to each IRB Committee meeting, two agendas (full and expedited) are generated (see *IRB Policy 2.22 Database PIRO* for preparing review materials for each IRB meeting).

- 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
- iii. Review of the expedited agenda
- iv. Determination of Conflict of Interest
- v. Review of confidentiality agreement for IRB members
- vi. Determination of frequency of review for each new application and continuation review reports (CRR) based on the Studies That May Require IRB Review More Often Than Once a Year list included in the *IRB Member Checklist*.
- vii. Continuing education materials
- viii. Each full agenda may be restricted to fifteen (15) items. The IRO cannot promise to review items received prior to the agenda cutoff date if the agenda fills up prior to 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.
- ix. Each IRB Committee has its own specialty. See *IRB Policy 1.3 Committee Structure*. However, if there is a patient care, patient risk concern or a funding agency certification request, an activity may be reviewed by any of the three IRB Committees, regardless of its specialty. If warranted, consulting reviewers may be asked to assist in the review. The IRB Committee conducting the review of the activity may determine that future review related to the study will be conducted by the appropriate Committee.
- x. 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 to have a COI with a specific study this information is added to the detail tab of PIRO, is displayed on the agenda, and is verbally announced by the IRB Chair during the convened meeting. If an IRB member's COI is not noted on the agenda, IRB members are required to

notify the IRB staff if they have a COI with an activity. The FHCRCs 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*.

- b. The Expedited Review Agenda includes all activities that received expedited review by the IRB Chair or designee.
- i. When the activity involves the review of exempt research, the expedited agenda 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, that the ethical standards for conducting the research are met, and that participants are protected.
 - ii. New applications and continuation 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.
 - A description of the study's objections.
 - A description of the review and action taken by the IRB Chair or designee.
 - Any findings required under the DHHS regulations.
 - iii. When the IRB Chair or designee approves a procedure which waives the requirement for obtaining a signed consent form; approving the alteration of the elements of informed consent; approving research involving pregnant women, human fetuses, or neonates; approving research involving prisoners; or approving research involving children, the IRB will document such findings in its agenda, including protocol-specific information justifying each IRB finding. Chair for example, for a new minimal risk application, the expedited agenda may document that one of the four criteria for a waiver of consent as "The research could not practicably be carried out without the waiver, because most of the participants are deceased or cannot be located."
 - iv. Any item appearing in the expedited agenda 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 agenda.
 - v. 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 available a week prior to the IRB meeting.
 - vi. 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 and secondary reviewers for the supplemental agenda item and confirms that they have sufficient time to review.
 - vii. After the expedited agenda is uploaded to eReview, the Administrative Assistant II formats the document into a PDF document. It is stored in the shared drive, j:iro/iro/irb/agd/year. If there are minor changes made to the expedited agenda, then the changes must be reflected in the minutes or a memo which is placed in the minutes-agenda binder. If the post date is after the IRB Committee meeting, then an explanation must be included in the minutes-agenda binder.
- c. The IRB Chair or Member has access to the *IRB Member Checklist* to provide reviewers guidance in 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.
- e. After each meeting, the IRB Analyst converts all documents relating to the meeting into PDF documents.

6. Quorum Requirements at Convened IRB Meeting

The IRB Member or Alternate can not be considered to be a voting member and count toward the quorum until they have been added to the IRB Roster and their membership reported to OHRP. 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, who they can substitute for a member.

Each IRB member (or alternate as needed) and non-voting member should make every effort to attend IRB meetings. In order for each meeting to be in compliance with regulations, a quorum (one more than half of voting members) must be present with at least one member present whose primary concerns are in a nonscientific area. 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 can not be achieved, the meeting is cancelled before off-site members begin traveling to FHCRC.

Recusals (e.g. an IRB Committee Member or IRB Chair recuses him/herself if he/she has a conflict of interest) and abstentions (e.g. a new Committee member refrains from voting at his/her first meeting) influence a quorum. If an IRB member must recuse or abstain himself/herself from the deliberation and the vote of a particular study, the IRB Chair or staff must assess the status of the quorum. If a quorum is lost, the activity cannot be reviewed at that IRB meeting and this action is noted in the minutes.

An IRB roster may also include alternates for specific IRB members or class of primary 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
- b. Studies undergoing IRB review may be:

- i. Approved

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.

- ii. Require modifications.

Minor modifications are those requested by the IRB and would require expedited review of the investigator's response by the IRB Chair or designee. The Committee may also request a subcommittee consisting of the primary and secondary reviewers to review the changes only when the changes fall in the minor modification category. If the subcommittee decides that the PIs response is appropriate, the response is forwarded to the IRB Chair or designee for final approval.

Examples of minor modifications are:

Simple editorial changes to the consent form that are clearly described in a meeting result letter.

Simple editorial correction to the application form.

Simple confirmation from the PI such as whether a funding source is active or not.

Major Modifications are those requested by the IRB and would require Full Review of the PI response at a convened meeting. When the IRB Committee uses the word "clarification", the PIs response receives full review.

Examples of major modifications are:

The IRB Committee questions the eligibility criteria (e.g., why are minors included or not included in the study)

The IRB Committee requests a "consultant" for additional review

Requests for supplemental information that may impact the risks/benefits ratio

Major and substantive changes to the consent form

When more information is needed to adequately review the risk/benefits or alternatives for the study

The IRB Committee does not fully understand the objectives/purpose of the study

The PI does not provide adequate response to the IRB Committee's request

The IRB Committee requests another Committee (e.g. SRC/IBC) to review

Protocol noncompliance was reported and the IRB Committee requests additional information about steps to be taken to prevent a reoccurrence of such noncompliance in the future. The full IRB Committee would review the investigator's response.

iii. Disapprove.

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 PIs response is reviewed by the same IRB Committee at its next convened meeting. The FHCRC IRB does not recognize an appeal process.

8. Meeting Records (Minutes) Maintained by IRB Staff

a. Written minutes of each IRB Committee meeting include:

- i. Attendance (to confirm quorum);
- ii. An alternate member 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 *IRB Meeting Confidentiality Pledge*.
 - 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 such as eReview.
 - iv. Votes for each activity as numbers for, against, or abstaining;
 - v. Actions taken by the convened IRB Committee;
 - vi. The basis for requiring changes in or disapproving the research;
 - vii. The length of time until the next review based on the degree of risk;
 - viii. A summary of the discussion of controverted issues and their resolution;
 - ix. Document determinations required by the regulations and protocol-specific findings supporting those determinations for research involving:
 - a procedure which waives the requirement for obtaining a signed consent form or the waiver of some or all of the elements of consent (see IRB *Policy 2.11 Informed Consent*)
 - pregnant women, human fetuses, or neonates; or children (*IRB Policy 2.15 Research Involving Vulnerable Populations*);
 - prisoners (*IRB Policy 2.15 Research Involving Vulnerable Populations*).
 - 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;
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.
 - xi. The IRB Committee’s rationale to determine the risk of a FDA regulated device is significant or non-significant.
- b. On all minutes, items are listed in the order in which they appeared on the full review agenda. Each activity reviewed by the IRB Committee will have its own summary results of the IRB Committee’s decisions. If a consultant provided comments to a study, the name of the consultant and his/her comments are noted in the minutes and also entered into the comments field in PIRO, the database. Copies of the signed result letters containing the IRB Committee’s contingencies are attached.
- 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. When a member abstains, the member’s name is listed along with the reason for the abstention. For example, the minutes will be recorded in the following format:
- MEMBERS VOTE - For: 8 Against: 0 Abstained: 1 (J. Smith – first IRB meeting)
- d. When a Committee “switch” occurs, e.g., when an activity is first reviewed by IRB Committee A and then the continuation review report of the study is reviewed by IRB Committee B, a reason or explanation must be documented in the minutes and in PIRO (database).

- e. At the beginning of each IRB Committee meeting, the IRB Committee reviews and approves the minutes from the last meeting. After the IRB meeting, minutes are edited, if needed and forwarded to the Chair or designee for signature. After the minutes are approved, the expedited agenda is added to the minutes. The minutes document is then formatted into a PDF document and stored in the shared drive, j:\iro\iro\irb\agd\year.
- f. A hard copy of the minutes/agenda, any confidentiality pledge(s), education materials are added to the agenda/minutes binder using the Screener: *Meeting Minutes/Agenda Binder*.
- g. To provide IRB findings to the Center's institutional officials, the IRB Analyst electronically forwards the approved IRB agenda outline, minutes, and result letters in J:\OffDir\EXECUTIVE - IRB DOCS. The IRB Analyst emails the Center's President and Director and Deputy Director's Assistant when the documents are placed in the respective IRB Committee's folder.
- h. When the Meeting Minutes/Agenda have been signed and final the IRB Analyst or Admin Asst. II will follow the *IRB Policy 2.17 Maintenance and Retention of IRB Documents* for storage and retention.
- i. 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*.
- j. 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. The IRO staff with PIRO "administrative" privileges archives by clicking on the archive checkbox in PIRO in Report every three months. Additionally, the IRB Analysts shreds the hard copies of the comments and notes taken at the IRB meetings.
- k. After an IRB Committee approves the minutes, the IRB Analyst shreds all handwritten and electronic notes.
- l. 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.
- m. 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 is a PI and was not present during the final discussion and vote of the protocol." is added to the minutes to document the IRB Member COI.
- n. Special Consulting members for Cooperative Group studies such as Gynecological Oncology Group (GOG) receive excerpted approved minutes only involving GOG/PSOC/NSABP studies. The excerpted minutes are mailed to the appropriate parties next time their review is required.

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

The FHCRC IRO calls the letters of instruction to PIs "result letters" Timeline: The day after an IRB meeting:

- i. The IRB Analyst and the IRO Assistant Director will meet to review each item discussed by the IRB Committee to ensure that any follow up items to be handled by the IRB staff receive attention.
- 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/contact person within 24 hours after the meeting to inform them of this determination. The email also informs them that the meeting result letter will be forwarded to them within two (2) business days.

- 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.

The result letters are reviewed by one of the three IRB Analysts or IRO Assistant Director for editorial purposes prior to routing to the IRB Chair for review and signature.

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

Considerations:

- i. The PI is notified that the study is approved, pending accrual – no documents released if IBC, IND/IDE or other departmental approval are still pending.
- 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 contact person and placed in the IRB minute's binder and in its respective IR file.

10. Response to the Result Letter

Reviewing meeting result letter response is a priority. Response should be sent to IRB Chair within 3 working days of receipt.

The IRB Analyst uses the *Screener: Response To Result Letter* 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 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

IRB Policy 1.3 Committee Structure
IRB Policy 1.5 IRB Member Conflict of Interest
IRB Policy 1.6 Meeting and Meeting Records
IRB Policy 2.1 New Application
IRB Policy 2.11 Informed Consent
IRB Policy 2.15 Research Involving Vulnerable Populations
IRB Policy 2.17 Maintenance and Retention of IRB Documents
IRB Policy 2.22 Database PIRO
IRO Meeting Checklist
Invite Email
Meeting Conf Pledge
Screener: Response to Result Letter
Screener: Meeting Minutes/Agenda Binder
Consultant Review Form