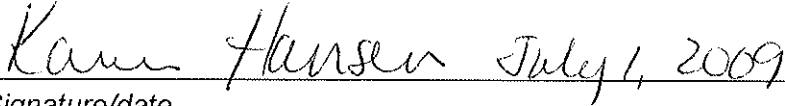


Title:	IRB Committee Structure
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	 Signature/date
Effective Date:	July 01, 2009
Policy:	1.3

POLICY STATEMENT

It is the policy of Fred Hutchinson Cancer Research Center (FHCRC) 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.

DEFINITIONS

IRB: Institutional Review Board (IRB) - A review body established by the organization to protect the rights and welfare of research participants recruited to participate in research activities. An IRB is organized in accordance with the Department of Health and Human Services (DHHS) at 45 CFR 46 and for studies involving products regulated by the Food and Drug Administration (FDA), the IRB complies with the requirements set forth in 21 CFR 50, 21, CFR 56, 21 CFR 312, and 21 CFR 812.

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

Affiliated: IRB members are considered affiliated if they, their spouse, domestic partner, or dependent children are an employee, contractor, student, board member, or have any other similar affiliation with FHCRC, UW, SCCA, or Seattle Children's.

REFERENCES

- 45 CFR 46.103(b)(3)
- 45 CFR 46.107
- 45 CFR 46.108(b)
- 45 CFR 46.304
- 21 CFR 56.107
- 21 CFR 56.107(e)
- 21 CFR 56.107(f)
- 21 CFR 56.108(c)
- 21 CFR §56.115(a)(5)
- 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: Frequently Asked Questions: IRB Membership, FDA

Information Sheets: Frequently Asked Questions: IRB Procedures

PRINCIPLES/OVERVIEW

All IRB Members are appointed by the FHCRC Institutional Official. No 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 Center department or official. The IRB is responsible for:

- protecting the research participant's capacity for self-determination;
- maximizing possible benefits and minimize possible harms;
- treating people fairly so that risks of research do not fall unfairly on one group while the potential benefits are given to another group;
- assuring that the consent process is voluntary and fully informs the potential participant about the research study;
- providing additional protection to vulnerable individuals who may not have the capacity to consent;
- determining that the research is designed to respect the individual's privacy and confidentiality of identifiable information; and
- assuring 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, disapprove, or require modifications to 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 to determine that the risks and potential benefits remain reasonable for the protection and welfare of its research participants.

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. Name and Types of Committee

At FHCRC, there are 3 IRB Committees known as Committee A, Committee B, and Committee C. Each Committee is responsible for the review of any and all research submitted by FHCRC and the Fred Hutchinson/University of Washington Cancer Consortium investigators.

Each committee may review clinical interventions and behavioral studies studies. In addition, based on the composition of its members, each committee has its own unique expertise for review of certain types of studies:

- IRB Committee A - reviews studies involving prisoners;
- IRB Committee B - reviews studies involving vaccine and HIV trials; and
- IRB Committee C - reviews studies involving prisoners and behavioral studies;

2. Responsibilities and Purpose of the IRB

The responsibilities and purpose of the FHCRC IRB are described in the *IRB Mission Statement*. The specific responsibilities of an IRB member are outlined in the *IRB Committee Member Service Description, Authorities and Responsibilities of the IRB Chairperson, and Authorities and Responsibilities of Individual IRB members*. All documents are included in the IRB Member's Handbook (See *IRB Member Handbook TOC*) which is given to the new member during the new member's orientation.

3. The Type and Numbers of Members on the IRB

The FHCRC IRBs will include:

- a. Both men and women of varying professions.
- b. At least one member whose primary concerns are in the nonscientific areas (e.g., lawyers, ethicists, members of the clergy.)
- c. At least one member whose primary concerns are in the scientific areas.
- d. At least one member who is not affiliated with FHCRC and who is not part of the immediate family of a person affiliated with FHCRC.
- e. Members who are knowledgeable in the applicable regulations, applicable law, and standards of professional conduct and practice.
- f. Alternates may serve on the IRB for any voting member with the same scientific status (e.g., nonscientist). See Section 8 below.
- g. 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.
- h. Consultants: An IRB Committee or IRB Chair may invite individuals as consultants when their expertise or experience is currently lacking within an IRB Committee to review and provide comments to the IRB Committee or IRB Chair. See Sections 10 and 11 below.
- i. Individuals from the FHCRCs Office of Sponsored Research or IRO, can not serve as voting IRB members.

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 (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 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 Chairperson recuses him/herself if h/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 /abstain himself/herself 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.

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 from any individual. The IRO Director will contact the FHCRC President and Director and the Office of the General Counsel to determine the appropriate corrective action to be taken.

The IRO Director will also report to the FHCRC President and Director and the Office of the General Counsel of any concerns about the independent functioning or undue influence or coercion of the IRB and thereafter determine the appropriate corrective action to be taken.

6. Appointment and Term Duration

At FHCRC, each member is appointed for a term of two years, normally beginning on August 1 and ending on July 31. 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.

The IRO Director requests recommendations of potential members from scientific division directors, the Community Outreach Program, 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. Candidates who offer the expertise and experience sought for the relevant IRB committee are recommended for IRB membership.

The FHCRCs President and Director makes the appointments to the IRB Committees based on the recommendations made by the IRO Director.

A letter of invitation (See *Sample Membership Invite Letter*) from the FHCRCs President and Director is forwarded to a potential new member or current members that are invited to extend their term on the IRB Committee.

On an annual basis, the IRO Director will use findings from the *IRB Member Evaluation of IRB Members and Chairs* evaluation tool to assist in the evaluation of the experience, expertise, contributions, and attendance of each IRB Committee member. The IRO Director will review the *Authorities and Responsibilities of IRB Chairperson* and *Individual IRB Member* found in the *IRB Member Handbook* to ensure IRB members continue to meet the *IRB Member Service Description* and *Authorities and Responsibilities of Individual Members*. The evaluation process may include discussions with the respective IRB chairs, IRB members, staff and others.

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

At the end of a two-year term, an IRB chairperson 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 FHCRCs President and Director are provided to the member.

IRB members are encouraged to attend at least half of the scheduled IRB 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 FHCRCs President and Director 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, please see Section 7 below.

Each IRB member is required to provide his/her current curriculum vitae when they first accept an appointment and when they are re-appointed every two years. The curriculum vitae confirms that each IRB Committee has the appropriate experience and expertise.

Changes in IRB membership are reported to the Office for Human Research Protections (OHRP) by an IRO Staff. See *IRB 1.2 Policy Federal Wide Assurance* for further information.

7. Chairs and Expedited Reviewers

The IRB Chair must be a scientist and have served on an IRB Committee for at least one term.

Members must serve on the IRB Committee for at least six months in order to review expedited items, sign on behalf of the Committee and serve as an alternate Chair.

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., an alternate physician scientist for a primary physician scientist) 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, s/he receives and reviews 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.

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.

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 might be recruited as subjects in a research study. At FHCRRC, IRB Committees A and C have appointed a prisoner advocate alternate Committee members.

10. Consultants

When it is determined that expertise and knowledge are needed that does not exist currently with 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 from within or outside FHCRRC are invited to review and provide comments to the IRB Committee or IRB Chairperson. Consultants are required to review and sign the *Consultant Review Evaluation and Conflict of Interest Form* prior to reviewing IRB materials in order to determine if a conflict of interest exists. In addition, if the consultant is not an employee of FHCRRC, he/she is required to sign a *Confidentiality Agreement - Unaffiliated*.

For full review: The consultant's comments are provided to the IRB via eReview 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.

For expedited review: In the expedited agenda, in the description section of the activity would indicate that a consultant was also obtained for review of the research activity.

11. Consultants (special consideration for PSOC and WSCR)

Currently the FHCRRC IRB recognizes two organizations, Puget Sound Oncology Consortium (PSOC) and Washington State Cancer Registry (WSCR) that require the use of consultants.

Appointment: The two organizations mentioned above identify the individuals to act as the non-voting reviewers. A letter of invitation from the FHCRCs President and Director is forwarded to a potential new consultant or current consultant to extend their term on the IRB Committee.

Term: Each consultant is appointed for a one year term, beginning normally on August 1 and ending on July 31.

Materials provided to consultants:

- PSOC related studies. The PSOC coordinator manages the Gynecologic Oncology Group (GOG), National Surgical Adjuvant Breast and Bowel Project (NSABP) and PSOC studies. When a specific activity (e.g., new application) is submitted, the PSOC Coordinator provides the name(s) of the non-voting reviewer(s). The IRB Analyst emails the consultants that review materials are available in eReview and request that their comments be posted onto eReview.
- Excerpted minutes only involving GOG/PSOC/NSABP studies are emailed to the consultants after they are approved by the IRB Committee.
- WSCR related studies. If the study involves the WSCR, the IRB Analyst follows the instructions included in the *Screener: WSCR Form*.

12. Compensation

The IRB Chairpersons are compensated for their time and effort dedicated to the IRB process. The IRO budget compensates 20% of the Chairpersons' salaries.

IRB membership is a voluntary position and there is no financial payment for service on the IRB.

13. Roster

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

- Last name, first name, and middle initial;
- Earned degree(s)/credentials
- Specialty - The member's specialty (e.g., clergy, pediatric oncology, representative of a vulnerable population)
- Gender
- Scientific status:
 - PS = Physician Scientist – any member with M.D. credentials, or equivalent medical degree from institutions outside the U.S.
 - OS = Other Scientist – any member with scientific training, or who has sufficient expertise to evaluate scientific issues.
 - NS = Non-Scientist – any member who's primary concern is non-scientific.
- Expedited Reviewer – Members with sufficient experience who are authorized 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.
- Affiliation with the institution (Y or N) and their relationship to FHCRC (e.g., employee)

14. Training and Education

a. New Member

- New members undergo a two-hour orientation with the IRO Assistant Director and the respective IRB Analyst prior to their first meeting. A New Member's Handbook is given to each new member. See *New Member Orientation Outline*.
- New IRB members who have not completed any human subjects training must attend the Human Subjects Key Personnel training offered at FHCRC or complete the web based CITI module, "What Every New IRB Member Needs to Know" available at www.citiprogram.org.
- The IRO Director with 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 and secondary reviewers. The area(s) of expertise will be added to the IRB Committee Roster.

b. Continuing Training and Education

- IRB chairpersons are provided opportunities to attend national conferences every other year.
- IRB members and chairpersons are provided opportunities to attend local IRB conferences, training programs and seminars.
- IRB members and IRB chairpersons are provided with information and are encouraged to complete other training such as CITI's three core courses, IRB 101 on CDrom, etc.
- One option as a refresher is serving on the IRB Committee.
- Educational materials are available, if applicable with the IRB meeting materials and IRB members are encouraged to discuss them at each IRB meeting. Hard copies are available at the IRB meetings. All members have access to these education materials for up to four (4) months in eReview after first receiving them.

15. Documentation Requirements

The following are documents that each member must complete:

a. Confidentiality Pledge

- **Affiliated Members** – members who are employees of FHCRC and SCCA are required to sign a FHCRC Confidentiality Pledge. These members do not need to sign another confidentiality pledge.
- **Non-affiliated Members** – members who are not affiliated with FHCRC must sign the *Confidentiality Agreement – Unaffiliated* form.

b. Conflict of Interest: Each member must review the *IRB Policy 1.5 IRB Member Conflict of Interest* and if agreeable, sign the *Conflict of Interest Annual Certification* form. See *IRB Policy 1.5 IRB Member Conflict of Interest* for further details.

c. Affiliation status: When reviewing the *Conflict of Interest Annual Certification* form, each member is also asked to verify their affiliation status.

16. Annual Joint IRB Committee Meeting

The three IRB Committees will hold a joint meeting annually and the FHCRCs President and Director and Deputy Director will be invited to attend. It is an opportunity for the FHCRCs President and Director and Deputy Director 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 Assistant Director oversees the coordination of the Joint IRB Committee Meeting. One of the three IRB Analysts will act as recording secretary. The draft minutes are reviewed by the IRO Director and General Counsel before they are forwarded to the FHCRC President and Director. The finalized minutes are then forwarded to the three IRB Committees for review and approval.

In the event a joint IRB Committee Meeting cannot be scheduled, the FHCRCs President and Director and Deputy Director 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 three Committees and if appropriate, individuals with expertise regarding the topic. The IRB Subcommittee is formed to provide an opportunity to discuss an issue more in depth such as developing a new policy. The IRB Subcommittee may only forward its recommendation to the IRB Committees for final review and approval. For more details regarding IRB Subcommittee, see *IRB Subcommittee Procedures*.

SUPPORTING DOCUMENTS

IRB Policy 1.2 Federalwide Assurance
IRB Policy 1.5 IRB Member Conflict of Interest
 Screener: New Application
Consultant Review Evaluation and Conflict of Interest Form
Annual Certification
IRB Subcommittee Procedures
IRB Committee Member Service Description
Authorities and Responsibilities of the IRB Chairperson
Authorities and Responsibilities of Individual IRB Members
 Screener: WSCR Form
IRB Mission Statement
Confidentiality Agreement – Unaffiliated
Sample Membership Invite letter
IRB Committee Roster Template
New Member Orientation Outline
IRB Member Handbook TOC
Evaluation of IRB Members and Chairs