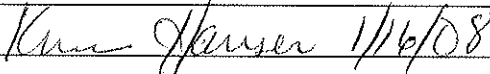


Title:	IRB Member Conflict of Interest
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	<i>Signature/date</i>  1/16/08
Effective Date:	January 14, 2008
Policy:	1.5

POLICY STATEMENT

Fred Hutchinson Cancer Research Center (FHRC) is committed to avoiding or managing any possible financial and non-financial conflict of interest (COI) of Institutional Review Board (IRB) Members, Consultants to the IRB, and Research Staff for all IRB-approved research activity in order to assure that the rights and welfare of research participants are adequately protected. It is the responsibility of the Institutional Review Office (IRO) and the IRB to ensure that members and consultants who review research have no conflicting interest.

DEFINITIONS

Conflict of Interest:

Non-Financial Interest:

- Personal Relationship: The IRB member or consultant has a personal relationship (e.g., spouse, domestic partner, immediate family member or close friend) with the principal investigator or key personnel (e.g. involved in the design, conduct or reporting) of a research protocol under review
- Relationship to the Research Study: The IRB member or consultant (or his/her spouse, domestic partner or immediate family member) is involved in the design, conduct or reporting of the research protocol under review
- Business Relationship or Affiliation: The IRB member or consultant to the IRB (or his/her spouse, domestic partner or immediate family member) serves as a trustee, director, officer, owner or partner of a for-profit entity that could be affected by the outcome of the research protocol under review by the IRB

Financial Interest: The IRB member or consultant (or his/her spouse, domestic partner or immediate family member) has a financial interest that could be affected by the outcome of the research protocol under review. Included in the definition of financial interests are equity interests (e.g. stock, stock options or other ownership interests) other than interests held in a publicly traded, diversified mutual fund; payment or expectation of payment derived from intellectual property rights (e.g., patent royalties); and payments received from a for-profit entity for consulting or other services for the current and or preceding year (i.e., salary, honoraria, fees) or expectation of future payments or benefits. An example of a financial interest that could be affected by the outcome of the research protocol under review by the

IRB is stock held in a company sponsoring the research study under review or whose product or service is being tested as part of the study

Research Staff: persons responsible for the design, conduct or reporting of this research

REFERENCES

DHHS - Final Guidance Document: "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection

45 CFR 46.107(e)

21 CFR 56.107(e)

OHRP Compliance Activities: Common Findings and Guidance # 10

PRINCIPLES/OVERVIEW

No research subject to the FHCRC 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. All members of the IRB are expected to make decisions and conduct their oversight responsibilities in an independent manner, free from bias or undue influence. IRB members and consultants to the IRB (and members of their immediate families) may be involved in activities both at the Center and in the larger community that could be perceived as conflicting with their IRB responsibility. The integrity of the IRB review process can be compromised if such conflicts of interest are not disclosed and avoided. Federal regulations provide that "no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB." [45 CFR Section 46.107(e)].

IRB members or consultants to the IRB must disclose any relationship, interest or other circumstance which could reasonably be perceived as creating a conflict of interest (COI). The following are to be disclosed and are automatically considered to be a conflict of interest.

- Personal relationships
- Relationship to the research study
- Business relationship or affiliation
- Financial interest

This policy applies to all IRB review by the convened IRB and review using the expedited procedure. This policy applies to all review, such as:

- Initial Review/Continuing review
- Review of modifications
- Review of unanticipated problems involving risks to subjects or others
- Review of non-compliance with the regulations or the requirements of the IRB

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to IRO staff, IRB members, and consultants to the IRB reviewing FHCRC and University of Washington Consortium investigator studies. This policy is posted on the IRO website.

PROCEDURES

1. IRB Members & Consultants to the IRB

Disclosures. IRB members or consultants to the IRB are required to disclose only those personal, and business relationships and financial interests that (a) they (or their spouse,

domestic partner or immediate family member) have or receive or may receive that could be affected by the research which is the subject of the research protocol, or (b) that might otherwise reasonably be perceived to affect their independent, unbiased judgment with respect to the IRB's review of the protocol or related matters. If an IRB member is uncertain whether to disclose a particular relationship or interest, the member should consult with FHCRC's Office of the General Counsel (OGC). Consultants to the IRB who discloses that he/she has a COI related to the specific activity to which he/she has been assigned, will be removed as a consultant.

Determination. Disclosures shall be made by IRB members or consultant to the IRB Chair or Co-Chair. Disclosures shall be made by IRB Chairs or Co-Chairs to the IRO Director or designee. The IRB Chairs, Co-Chairs or IRO Director shall determine whether a conflicting interest exists. If the reviewer determines that any of the above four situations are met, the IRB member will automatically be considered to have a conflicting interest. The determination of whether or not a conflict exists will be reflected in the IRB minutes. FHCRC's Office of the General Counsel (OGC) should be consulted as necessary.

Recusal. IRB members who have a COI related to any research protocols that the IRB is about to consider (a) must refrain from participating in any discussion of the protocol or related matters except to the extent necessary to provide relevant, factual information requested by the IRB, and (b) may not deliberate or vote on those protocols or related matters. Unless requested by the IRB to provide information to the IRB, the IRB member or consultant with a conflict will be required to leave the room for the final discussion and vote. An IRB member assigned as a primary or secondary reviewer for a protocol or related matters with respect to which a COI has been identified must notify the IRB Chair or IRO Director so that the protocol may be reassigned.

- At the time that research documents are submitted for IRB review, the IRB Analyst will screen the documents to determine if any IRB members are listed as key personnel for the study. If it is determined that an IRB member has a COI, that member will not be assigned as a reviewer. The COI information will be entered into the database.
- Upon receiving the IRB agenda one week prior to the IRB meeting, IRB members are encouraged to notify the IRB staff if they have any COI with studies on the agenda.
- At the beginning of each IRB meeting, the IRB Chairperson will query the IRB members of possible COI for any of the full review items listed on the agenda.
- Any COI will be reflected in the meeting minutes. IRB members with a COI will not be counted toward the quorum. FHCRC's Office of the General Counsel should be consulted as necessary.

Consultants to the IRB who have a COI related to any research protocols that they are asked to review must immediately disclose the conflict and will be removed as a consultant from the research activity.

Annual Certification. The IRO Assistant Director informs all new IRB members of the COI Policy at the time of New Member Orientation. FHCRC requires that each IRB member annually certify that he/she (a) has reviewed and understands the terms of *IRB Policy 1.5 IRB Member Conflict of Interest*; (b) agrees to disclose to the IRB Chair, Co-Chair or IRO Director, as applicable, any relationship, interest or other circumstance which might reasonably be perceived as creating a COI; and (c) acknowledges by his/her signature that he/she is in compliance with the letter and spirit of the policy. Each IRB member must review *IRB Policy 1.5 IRB Member Conflict Of Interest*. Each Member will then sign the *Annual Certification Form*. Consultants to the IRB will be provided with *IRB Policy 1.5 IRB*

Member Conflict of Interest when his/her review is requested by the IRB. However, a consultant is not required to sign the *Annual Certification Form*, but is required to sign the *Consultant Review Evaluation and Conflict of Interest Form* at the time of each review.

The signed Annual Certifications forms are kept in the IRB member binder (IR File 6378). Two months before the Annual Certification expires for an IRB member, the IRB staff will forward a memo to the IRB member along with *IRB Policy 1.5 IRB Member Conflict of Interest* and an *Annual Certification Form*.

If an IRB member does not sign the Annual Certification form, he/she may not take part in the review process. The IRB staff will notify the IRO Assistant Director and the appropriate IRB Analyst(s) that an IRB member can not be assigned as a reviewer until that IRB member provides a signed Annual Certification form.

2. Research Staff

The new application for review (*Protocol Disposition Form*) and the *Continuation Review Report (CRR Form)* require that the principal investigator disclose whether he/she or any other person responsible for the design, conduct or reporting of this research have a financial interest in or act as an officer or director of any for-profit entity whose financial interest could reasonably affect or be affected by the research. Research Staff must comply with FHCRC's Conflict of Interest policy located at:

http://www.fhcrc.org/intranet/general_counsel/conflict_interest_2002.pdf

Research Staff may appear at the convened IRB meeting and respond to questions of the IRB members but will not be present during the final discussion and vote of the activity. This action is documented in the minutes.

SUPPORTING DOCUMENTS

IRB Member Annual Certification Form
IRB Consultant Review Evaluation and Conflict of Interest Form
Continuing Review Report Form
Protocol Disposition Form
FHCRC Conflict of Interest Policy