

<b>Title:</b>	Multi-Center Study Coordination - IRB Review and Oversight
<b>Responsible Office:</b>	Institutional Review Office (IRO)
<b>Responsible Official:</b>	Karen Hansen, IRO Director
	<i>Signature/date</i>
<b>Effective Date:</b>	January 14, 2008
<b>Policy:</b>	2.14

---

## POLICY STATEMENT

It is the policy of Fred Hutchinson Cancer Research Center (FHCR) IRB that a principal investigator (PI) responsible for coordinating a multi-center study is responsible for the oversight and management of IRB approval for each performance site and individual investigator engaged in research they oversee.

---

## DEFINITIONS

**Engaged in Research:** An institution becomes “engaged” in human subjects research when its employees or agents (all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility) (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)]. Solicitation of consent by performance site staff would be considered engagement.

**Performance Site:** A site whose staff, facilities or private records of identifiable individuals are engaged in the conduct of research; or, a site that receives HHS funds. The performance site is the actual place where the research activity takes place (e.g., clinic or hospital). The performance site’s location may be different from the location where the IRB review takes place.

**Operations Center or Coordinating Center Involving No Interaction or Intervention with Research Participants:** FHCR investigators and their employees or agents may maintain “operations centers” or “coordinating centers” for multi-site collaborative research. Where institutional activities involve no interaction or intervention with research participants, the FHCR IRB need not review each collaborative protocol. However, the FHCR IRB will determine and document that the operations or coordinating center has sufficient mechanisms in place to ensure that (i) management, data analysis, and Data Safety and Monitoring (DSM) systems are adequate, given the nature of the research involved; (ii) sample protocols and informed consent documents are developed and distributed to each collaborating institution; (iii) each collaborating institution holds an applicable OHRP-approved Assurance; (iv) each protocol is reviewed and approved by the IRB at the collaborating institution prior to the enrollment of research participants; (v) any substantive modification by the collaborating institution of sample consent information related to risks or alternative procedures is appropriately justified; and (vi) informed consent is obtained from each subject in compliance with HHS regulations.

**Federalwide Assurance:** A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved [Federal Policy §\_\_\_\_.103]. Since December 31, 2005, OHRP only recognizes Federalwide Assurances.

**Multi-Center Study:** A study involving more than one performance site engaged in research.

**IRB of Record:** The IRB responsible for review of research involving a performance site.

---

## REFERENCES

---

45 CFR 46.114  
21 CFR 56.114  
FDA Information Sheets: Non-Local IRB Review  
OHRP Guidance on Engagement in Research

---

## PRINCIPLES/OVERVIEW

---

When the FHCRC IRB reviews a multi-center study where the principal investigator is responsible for the operations center or coordinating center that may have or may not have interaction or intervention with research participants, the FHCRC IRB determines whether the oversight responsibilities of the coordinating center are managed properly to safeguard the rights and welfare of its research participants and in accordance with *OHRP Guidance on Engagement in Research*.

Additionally, the FHCRC IRB confirms that the appropriate IRB approval certification documents are submitted to the FHCRC IRB before the performance sites or collaborating investigators can engage in multi-center research coordinated by FHCRC investigators.

---

## 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 Approval of Operations Centers or Coordinating Centers That Have No Interaction or Intervention with Research Participants

The investigator submits a new IRB application for IRB review that overviews the operations center or coordinating center responsibilities. The application also includes a completed *Coordinating Center / Operations Center Supplement*.

### 2. IRB Approval of Operations Centers or Coordinating Centers That Have Interaction or Intervention with Research Participants

The investigator submits a new IRB application for IRB review that overviews the research study(ies) and the operations center or coordinating center responsibilities. The application also includes a completed *Coordinating Center / Operations Center Supplement*.

This application also describes the mechanisms for documenting the IRB of record for the performance site(s) or individual investigators engaged in research using one or more of the following mechanisms:

- a. IRB Authorization Agreement – This agreement may be used by performance sites engaged in research with FHCRC that elects to rely on the FHCRC IRB as the IRB of record for the multi-center study coordinated by FHCRC. For specific information

regarding IRB Authorization Agreement, please see *IRB Policy 2.24 IRB Authorization Agreement*.

- b. Cooperative Review Agreement – This agreement may be referenced and relied upon for certain performance sites in the state of Washington who are engaged in frequent research collaborations with FHCRC investigators and wish to avoid duplicate IRB review. See *IRB Policy 2.3 Cooperative Review Agreements* for current Cooperative Review Agreements and stipulations relating to IRB review and oversight.
- c. Individual Investigator Agreement – This agreement is used for investigators collaborating on research overseen by the FHCRC IRB and who are not aligned with a performance site that has an IRB of record. An individual investigator can agree to abide by the FHCRC IRB review requirements using the *Individual Investigator Agreement* form.
- d. IRB Certification of Approval – Performance sites engaged in research may rely upon an IRB of record independent of the FHCRC IRB for review and approval of the multi-center study coordinated by FHCRC. Each performance site submits the *Assurance Identification/IRB Certification/Declaration of Exemption* form.

The Principal Investigator is responsible to contact the Office of the General Counsel to determine if additional agreements and documentation are required for engaging in research with a performance site.

IRO staff are responsible for confirming that IRB approved multi-center study files coordinated by FHCRC investigators include the appropriate documentation for performance sites and individuals investigators as described above. IRO Staff use the  *Screener: New IRB Authorization Agreement*, *Screener: Assurance Identification / Declaration of Exemption / Multi-Center IRB Documentation*, and *Screener: New Individual Investigator Agreement* to confirm that the appropriate documents were submitted.

For Ongoing Studies: The FHCRC PI submits a completed *Protocol Modification Form* (see *IRB Policy 2.5 Modification to Ongoing Activities*) adding the collaborating investigator to the study and describing his/her role to the study. Any documents (e.g., consent forms, protocols), should be revised, if appropriate.

---

## SUPPORTING DOCUMENTS

---

IRB Policy 1.2 Federal Wide Assurance  
IRB Policy 2.1 New Application  
IRB Policy 2.2 Continuing Review  
IRB Policy 2.3 Cooperative Review Agreements  
IRB Policy 2.24 IRB Authorization Agreement  
IRB Policy 2.5 Modification to Ongoing Activities  
RTO Data and Safety Monitoring Plan  
IRB Authorization Agreement  
Screener: New IRB Authorization Agreement  
Screener: CRR IRB authorization  
Sample Email for IRB Certification Form  
Sample Assurance Update Email to FHCRC PI  
Assurance Identification/IRB Certification/Declaration of Exemption  
Sample CRR Email  
Screener: Assurance Identification / Declaration of Exemption / Multi-Center IRB Documentation  
Individual Investigator Agreement  
Screener: New Individual Investigator Agreement  
Screener: Continuation Review — Individual Investigator Agreement  
Sample Letter of Support from the Collaborating Investigator's Institution