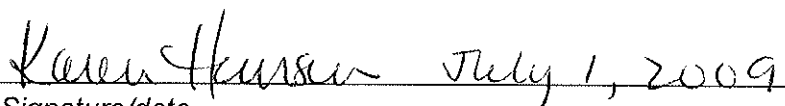


Title:	Federal Wide Assurance
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	 Signature/date
Effective Date:	July 01, 2009
Policy:	1.2

POLICY STATEMENT

It is the policy of Fred Hutchinson Cancer Research Center (FHCRC) that it will comply with its Federal Wide Assurance with the Office for Human Research Protections (OHRP).

DEFINITIONS

Federal-Wide Assurance (FWA): 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 §45CFR46.103]. Since December 31, 2005, OHRP only recognizes Federalwide Assurances.

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.

IRB Authorization Agreement: An agreement used when FHCRC engages in research with a participating site who may or may not rely on FHCRCs IRB review in order to avoid dual review.

IRB Certification: A document used when FHCRC acts as the coordinating center of a multi-center study. It assures the FHCRC IRB that each performance site's IRB of record conducts its own review and approval of the research activity.

REFERENCES

- 45 CFR 46.103
- OHRP Compliance Activities: Common Findings and Guidance #72
- OHRP Assurance FAQs
- OHRP Engagement of Institutions in Research
- FDA Information Sheet, FAQs

PRINCIPLES/OVERVIEW

The purpose of this policy is to describe the Federal Wide Assurance (FWA) of the FHCRC and its Institutional Review Boards (IRB). This policy also describes the responsibilities of the

FHCRCs IRB office to maintain and update the FHCRC FWA as well as ensuring that all FWAs and IRB registrations associated with the FHCRC FWA have current approval dates with the OHRP.

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. Federal Wide Assurance (FWA)

FHCRC has an approved Federal Wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP) under assurance number 00001920. Registration numbers for IRB Committee A is 00000021, 00000022 for IRB Committee B, and 00005619 IRB Committee C.

The FWA is maintained in IR File 5710B. The OHRPs website at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR> lists all the IRBs linked to this assurance. A copy of the FWA is available to research staff by contacting the IRO Assistant Director.

2. Updating IRB Membership Roster

When a new member joins the IRB, a member resigns from a FHCRC IRB Committee or the status of a member changes (e.g. member to alternate), the IRB Membership Roster is updated. The OHRP roster is updated electronically within 10 working days of the IRB Membership's effective date. The current OHRP rosters are located in IRB file 5710B.

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 Committee Roster. The IRB Committee Roster will include each member's chief anticipated contributions to the meeting. It will also specify the alternate members, including their scientific status, who can substitute for a member. See *IRB Committee Roster Template*. For the list of information required on the roster, please see *IRB 1.3 Policy Committee Structure*.

When updating the IRB roster, the IRO staff follows the instructions in the *Screener: FWA Update*.

A new IRB member (or Alternate as needed) cannot vote until the updated roster is effective. Once the updated roster is posted to OHRP, the OHRP website is checked by the IRO staff to verify that OHRP has received and approved the updated roster.

3. Registered IRBs Performance Sites Added/Deleted

When **FHCRC is the IRB of Record** and enters into an IRB Authorization Agreement and another collaborating performance site relies on FHCRC's IRB, the collaborating performance site must update their FWA listing FHCRC as an IRB including all three IRB committees on their FWA. This update can be confirmed with OHRP at the following website: <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>

When the **Collaborating Performance Site is the IRB of Record** and FHCRC enter into an IRB Authorization Agreement, the IRB SOP Administrator must add the collaborating performance site's IRB registration to the FHCRC FWA. The FHCRC FWA can be updated electronically at <http://ohrp.cit.nih.gov/efile/>.

OHRP must first receive notification of and approve the addition of the performance site before the activity can begin.

The IRB AAll follows the instructions in the *Screener: FWA Update*.

4. Renewing FHCRC FWA00001920

Six months before the FHCRC FWA expires, the IRO staff gathers all the cooperative agreements (see IR 5710), FHCRC FWA and the Authorization Agreements that describe FHCRC as the IRB of record. The IRO staff meets with the IRO Director/Assistant Director to start the renewal process.

To renew the cooperative agreements, the IRO staff follows the instructions found in the *Screener: Cooperative Agreement Renewal*.

To renew the FWA, follow the instructions found in the *Screener: FWA Renewal*.

5. Verifying Performance Sites Have an FWA

The IRO staff screening a new IRB authorization agreement or IRB Certification verifies on the OHRPs website that the performance site has an approved FWA at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR> by following either the *Screener: New IRB Authorization Agreement* or *Screener: Assurance Identification/Declaration of Exemption/Multi-Center IRB Documentation*.

6. Monitoring Expiration Dates of Performance Sites' FWAs and IRB Registrations

The IRO staff is responsible for ensuring that all performance sites with whom FHCRC is engaged in research have current FWAs and IRB registrations on file with OHRP.

The IRO staff monitors the FWAs and IRB registrations for each Committee:

- The IRO staff runs monthly queries of FWAs and registration numbers for their expiration dates (select in PIRO query IRB registration expiration dates and FWA expiration dates queries).
- The IRO staff also reviews weekly tickler list for all FWAs and IRB registrations.
- The IRO staff monitors the expiration dates of all FWAs and IRB registrations associated with FHCRC's FWA whenever the FWA is being updated per the *Screener: Committee Roster Update (IR5710)*.

Information regarding monitoring expiration dates of performance sites' FWAs and IRB registrations is found in *IRB 2.14 Policy Multi-Center Study Coordination – IRB Review and Oversight*.

The IRO staff checks OHRPs website at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR> to confirm whether the performance site has updated its FWA and IRB registration. The IRO staff notifies the IRO Assistant Director if the performance site has not updated its FWA or IRB registration 30 days before the expiration date.

SUPPORTING DOCUMENTS

IRB Policy 1.3 Committee Structure
IRB Policy 2.14 Multi-Center Study Coordination – IRB Review and Oversight
IRB Policy 2.24 IRB Authorization Agreement
FHCRC Federal Wide Assurance
IRB Membership Roster Template
Screener: Committee Roster Update (IR 5710B)
Screener: FWA Renewal
Screener: FWA Update
Sample Assurance Email

Screener: Cooperative Agreement Renewal
 Assurance Identification/Declaration of Exemption/Multi-Center IRB Documentation
 Screener: New IRB Authorization Agreement