

<b>Title:</b>	IRB Authorization Agreement
<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>	2.24

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## POLICY STATEMENT

It is the policy of Fred Hutchinson Cancer Research Center (FHRC) IRB to provide a review mechanism for research activity not covered under the *IRB Policy 2.3 Cooperative Review Agreements* (i.e. for performance sites other than the University of Washington, Children Hospital and Regional Medical Center, etc.) This review mechanism called an IRB Authorization Agreement can only be used when one performance site, either FHRC IRB or the performance site's IRB, elects to be the IRB of

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## 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.

**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.

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## REFERENCES

45 CFR 46.114  
21 CFR 56.114  
FDA Information Sheets: Non-Local IRB Review

## OHRP Guidance on Engagement in Research

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### PRINCIPLES/OVERVIEW

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It is the responsibility of the FHCRC IRB to engage in research with a performance site with whom it does not have a cooperative review agreement to confirm that the site has an approved Federalwide Assurance (FWA) with the Office of Human Research Protections (OHRP). It is also the responsibility of the FHCRC IRB to review and confirm that all appropriate documents are submitted before the performance site can engage in research with FHCRC to ensure the welfare and protection of its research participants.

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### INDIVIDUALS AFFECTED BY THIS POLICY

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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.

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### PROCEDURES

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1. Determining which Institution will be the IRB of Record
  - When a FHCRC principal investigator (PI) confirms that the performance site has an approved Federalwide Assurance (FWA) with OHRP and determines that the IRB Authorization Agreement is appropriate to use, the PI contacts the IRO Director (or designee) to determine which institution will be the IRB of record. In most cases where this process is used, the institution where research participants will be recruited, enrolled and receiving the research intervention, will be the IRB of record.
  - In addition, 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.
  - After confirming with the PI, the type of research activity involving the performance site, the IRO Director (or designee) will contact the performance site's IRB office to confirm which institution will be the IRB of Record. Once both IRB offices agree to which office will be the IRB of record, the PI will follow the submission instruction depending on whether FHCRC is Institution A or B.
2. When FHCRC is the IRB of Record (known as "Institution A")
  - New study
    - i. If the FHCRC PI does not have a currently approved IRB file, he/she must submit an *Application for Review Form with the IRB Protocol Disposition Form* along with the *IRB Authorization Form*. The *Application for Review Form* must describe the activity taking place at FHCRC as well as describing the engagement with the performance site. The FHCRC PI submits a completed *IRB Authorization Form*. The *IRB Authorization Form* should include the signature of the performance site's Institutional Official (IO).
    - ii. Minimal Risk Activity: When the *Application for Review* involves a minimal risk activity, the *Application for Review*, *IRB Protocol Disposition Form*, *Expedited Review Checklist for Minimal Risk Activities*, and the *IRB Authorization Agreement* are forwarded to the IRB Chair (or designee) for review and approval along with the *IRB Chair Determination Type Checklist*. If the IRB Chair (or designee) agrees that the activity meets the minimal risk category determined by the PI, the IRB Chair (or designee) signs the *Protocol Disposition Form*. Once the *IRB Protocol Disposition Form* is signed by the IRB Chair (or designee), the IRB

Authorization is signed the IRO Director (or designee). The *Application for Review Form* and the *IRB Authorization Agreement* are final processed by the IRB Administrative Assistant (or IRO Specialist) according to the *IRB Staff Screener: New IRB Authorization Agreement*.

The approved IRB Authorization Agreement is forwarded to the PI with a memo stating that the research activity with the performance site can not begin until FHCRC adds the performance site to its FWA.

All *Application for Review Forms* and *IRB Authorization Agreements* which were reviewed under expedited review are reported on the next available committee agenda under the section, "New IRB Authorization Agreement That Have Undergone Expedited Review". IRB members are given an opportunity to request full IRB review or to review additional documents of any items that underwent expedited review.

- iii. More than Minimal Risk Activity: When the *Application for Review* involves an activity that is more than minimal risk, the new application is placed on the next agenda for full IRB review. The submission must also include the completed *IRB Authorization Agreement*.

For IRB deliberation and the possible actions taken by the full IRB meeting, please see *IRB Policy 1.6 Meeting and Meeting Records*. Once the *Application for Review Form* is signed by the IRB Chair (or designee), the IRB Authorization is signed the IRO Director (or designee). The *Application for Review Form* and the *IRB Authorization Agreement* are final processed by the IRB Administrative Assistant (or IRO Specialist) according to the *IRB Staff Screener: New IRB Authorization Agreement*.

The approved IRB Authorization Agreement is forwarded to the PI with a memo stating that the research activity with the performance site can not begin until FHCRC adds the performance site to its FWA.

- On-going study
  - ii. If the activity with the performance site is not yet described in the currently approved IRB file, the PI must submit a *Protocol Modification Form*, describing the new activity with the performance site. Any documents e.g., consent form, protocol should be modified as appropriate.
  - iii. The FHCRC PI submits a completed IRB Authorization Form. The *IRB Authorization Form* should include the signature of the performance site's Institutional Official (IO).
  - iv. The complete packet which includes the *Protocol Modification Form* (if appropriate), *IRB Authorization Form*, the *IRB Chair Determination Type Checklist*, are then forwarded to the IRB Chair (or designee) for review and approval.
  - v. Once the *Protocol Modification Form* is signed by the IRB Chair (or designee), the IRB Authorization is signed by the IRO Director (or designee). The IRB Administrative Assistant (or IRO Specialist) will process the *Protocol Modification Form* and the *IRB Authorization Agreement* according to the *IRB Staff Screener: New IRB Authorization Agreement*.

The approved IRB Authorization Agreement is forwarded to the PI with a memo stating that the research activity with the performance site can not begin until FHCRC adds the performance site to its FWA.

- vi. All IRB Authorization Agreements which were reviewed under expedited review are reported on the next available committee agenda under the section, “New IRB Authorization Agreement That Have Undergone Expedited Review”. IRB members are given an opportunity to request full IRB review or to review additional documents of any items that underwent expedited review.
3. When the Performance Site is the IRB of Record (FHCRC is known as “Institution B”)
    - New Study
      - i. The FHCRC PI submits a completed *IRB Protocol Disposition Form* and *IRB Authorization Form* along with the performance site’s approved IRB documents which must include a statement describing its role with FHCRC. The *IRB Authorization Form* should include the signature of the performance site’s Institutional Official (IO).

Once the *IRB Protocol Disposition Form* is signed by the IRB Chair (or designee), the IRB Authorization Agreement is signed the IRO Director (or designee). The *Application for Review Form* and the *IRB Authorization Agreement* are final processed by the IRB Administrative Assistant (or IRO Specialist) according to the *IRB Staff Screener: New IRB Authorization Agreement*.

The approved IRB Authorization Agreement is forwarded to the PI with a memo stating that the research activity with the performance site can not begin until the performance site adds FHCRC to its FWA.

All *Application for Review Forms* and *IRB Authorization Agreements* which were reviewed under expedited review are reported on the next available committee agenda under the section, “New IRB Authorization Agreement That Have Undergone Expedited Review”. IRB members are given an opportunity to request full IRB review or to review additional documents of any items that underwent expedited review.

- iii. More than Minimal Risk Activity: When the *research activity* is more than minimal risk, the IRB Authorization Agreement is placed on the next agenda for full IRB review. The submission must also include the completed *IRB Authorization Agreement* with the performance site’s IO’s signature and the performance site’s complete IRB approval documents. The performance site’s approval documents must include a statement describing its role with FHCRC.

For IRB deliberation and the possible actions taken by the full IRB meeting, please see *IRB Policy 1.6 Meeting and Meeting Records*. Once the *Application for Review Form* approved by the full IRB Committee, the *Protocol Disposition Form* is signed by the IRB Chair (or designee), and the IRB Authorization Agreement is signed the IRO Director (or designee). The *Application for Review Form* and the *IRB Authorization Agreement* are final processed by the IRB Administrative Assistant (or IRO Specialist) according to the *IRB Staff Screener: New IRB Authorization Agreement*.

The approved IRB Authorization Agreement is forwarded to the PI with a memo stating that the research activity with the performance can not begin until the performance site adds FHCRC to its FWA.

- On-going study
  - i. If the activity with the performance site is not yet described in the currently approved IRB file, the PI must submit a *Protocol Modification Form*, describing

the new activity with the performance site. Any documents e.g., consent form, protocol should be modified as appropriate.

- ii. The FHCRC PI submits a completed *IRB Authorization Form* along with the performance site's approved IRB documents. The performance site's IRB documents must also include a statement describing its role with FHCRC. The *IRB Authorization Form* should include the signature of the performance site's Institutional Official (IO).
- iii. The complete packet which include the *Protocol Modification Form* (if appropriate), *IRB Authorization Form*, the performance site's approved IRB documents along with the *IRB Chair Determination Type Checklist*, are then forwarded to the IRB Chair (or designee) for review and approval. Once the *Protocol Modification Form* is signed by the IRB Chair (or designee), the IRB Authorization is signed by the IRO Director (or designee). The *Protocol Modification Form* and the *IRB Authorization Agreement* are final processed by the IRB Administrative Assistant (or IRO Specialist) according to the *IRB Staff Screener: New IRB Authorization Agreement*.
- iv. The approved IRB Authorization Agreement is forwarded to the FHCRC PI with a memo stating that the research activity with the performance site can not begin until the performance site adds FHCRC to its FWA.
- v. All IRB Authorization Agreements which were reviewed under expedited review are reported on the next available committee agenda under the section, "New IRB Authorization Agreement That Have Undergone Expedited Review". IRB members are given an opportunity to request full IRB review or to review additional documents of any items that underwent expedited review.

### 3. Approval Period and Continuing Review Report (CRR) Requirements

- When FHCRC is Institution B (relying on the performance site's IRB for review), an IRB Authorization Agreement is given a three (3) year approval period. However, the FHCRC IRO is responsible for sending out Continuation Review notices annually (of more often if appropriate) to the offsite institutions to assure that IRB continuation review has been conducted in compliance with relevant regulations.
- It is the responsibility of the FHCRC PI to contact the appropriate institution's review office to become familiar with the necessary continuing review procedure.
- At a minimum, once a year, the FHCRC PI is responsible to forward to the IRO the following documents:
  - i. First page of the FHCRC CRR;
  - ii. IRB of Record's Progress Report Form or Application for IRB Review (this document must be signed by either the IRB Chair or the Institutional Official authorized to sign, which shows current dates of approval);
  - iii. Approved version of protocol/activity plan;
  - iv. Approved version of all consent form(s);
  - v. Approved version of all other materials (i.e. approach letters, questionnaires, etc.).
  - vi. All IRB Authorization Agreement renewals are to be filed with the IRO after 30 days of the study's expiration. If not, the file will be closed and any *Certifications of Approval* (i.e. *Assurance Identification/IRB Certification/Declaration of Exemption form*, etc.) will not be signed unless the Institutional Review (IR) files

are re-activated with a continuation review renewal and show current approval periods.

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## **SUPPORTING DOCUMENTS**

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IRB Policy 1.2 Federal Wide Assurance

IRB Policy 2.1 New Application

IRB Policy 2.2 Continuing Review

IRB Policy 2.5 Modification to Ongoing Activities

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