



Title:	Federalwide Assurance
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Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Meghan Scott, IRO Director
	
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	<i>Signature/date</i>

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7.00	01-21-2019
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POLICY STATEMENT

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

DEFINITIONS

See *IRB Glossary of Terms and Acronyms* (050) for full definitions of the following:

Federalwide Assurance (FWA)

Individual Investigator

Individual Investigator Agreement

IRB Authorization Agreement

Performance Site

PRINCIPLES/OVERVIEW

The purpose of this policy is to describe the FWA of Fred Hutch and its Institutional Review Boards (IRB) and when the FWA may be extended to Individual Investigators. This policy also describes the responsibilities of the Fred Hutch Institutional Review Office (IRO) to maintain and update the Fred Hutch FWA; as well as procedures for ensuring all Performance Sites relying on Fred Hutch IRB, or being relied upon by the Fred Hutch for IRB review, have an approved FWA with current approval dates on file with the OHRP.¹

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to IRO staff, IRB members, employees of Fred Hutch, and investigators from other institutions who submit research studies to the Fred Hutch IRB for review and approval.

PROCEDURES

1. Federalwide Assurance (FWA)

Fred Hutch has an approved FWA on file with the Office for Human Research Protections (OHRP) under assurance number 00001920. IRB registration numbers are 00000021 for IRB Committee A, 00000022 for IRB Committee B, 00005619 for IRB Committee C, and 00009831 for IRB Committee D.

The FWA is maintained in IR file 5710B. The OHRP's website at <http://ohrp.cit.nih.gov/search/> 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. Renewing Fred Hutch's Federalwide Assurance

Six months before the Fred Hutch FWA expires, the IRO staff gathers the Fred Hutch FWA and all Cooperative Review Agreements (see IR 5710B) that describe Fred Hutch 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* (0126).

To renew the FWA, the IRO staff follows the instructions found in the *Screener: FWA Renewal* (0257).

3. Verifying Outside Performance Sites Have an FWA

When Fred Hutch enters into an *IRB Authorization Agreement* (043) or Cooperative Review Agreement with another Performance Site, the IRO staff verifies via the OHRP's website that the Performance Site entering into the agreement with Fred Hutch has an approved FWA at

¹ HHS: 45 CFR 46.103

<http://ohrp.cit.nih.gov/search/>. When Fred Hutch is relying on the other Performance Site's IRB, staff will also verify the IRB being relied upon has a current IRB registration. Staff will follow one of the following:

- *Screener: New or Updated IRB Reliance Agreement When Fred Hutch is the IRB of Record (0293)*
- *Screener: External IRB Cover Sheet – New Application (0292)*

4. Monitoring FWA and IRB Registration Expiration Dates

- a. Performance Sites relying on Fred Hutch IRB: The IRO staff verifies each year that all Performance Sites that have entered into an *IRB Authorization Agreement (043)* or Cooperative Review Agreement, and that are relying on the Fred Hutch IRB, maintain their FWA and IRB registration, as appropriate, with OHRP. IRO staff follows the *Screener: Continuing Review Report (0124)* and notifies the IRO Director if any Performance Site's FWA or IRB registration has expired.
- b. Relying on another IRB: When Fred Hutch enters into an *IRB Authorization Agreement (043)* or Cooperative Review Agreement with another organization that will serve as the IRB or record for a Fred Hutch investigator, the IRO staff verifies each year that the organization's FWA and IRB registration are maintained, as appropriate, with OHRP. Staff follows the *Screener: External IRB Coversheet – CRR or Other (0127)* and notifies the IRO Director if the IRB of record's FWA or IRB registration has expired.

5. Extending the Fred Hutch Federalwide Assurance to Cover Individual Investigators

Fred Hutch may extend its Federalwide Assurance to cover individual investigators who are engaged in the research, but are employees or agents of a Performance Site that does not hold a Federalwide Assurance. Individual Investigators must sign an *Individual Investigator Agreement (052)*. The Fred Hutch PI assumes responsibility for directing and appropriately supervising the Individual Investigator's activities.

For new *Individual Investigator Agreements (052)* IRO staff follow the *Screener: New Individual Investigator Agreement (0136)* to verify the Individual Investigator's human subject's protection training, curriculum vitae (CV), medical license and Good Clinical Practice (GCP) training are completed as appropriate, and confirm there is a letter of support from the Individual Investigator's institution to conduct research that the non-assured facility. *Individual Investigator Agreements (052)* are signed by the Individual Investigator and, after the Individual Investigator's performance site is approved by the IRB, by the IRO Director or designee.

SUPPORTING DOCUMENTS

Individual Investigator Agreement (052)
IRB Authorization Agreement – Fred Hutch as Institution A (043)
IRB Authorization Agreement – Fred Hutch as Institution B (043)
IRB Glossary of Terms and Acronyms (050)
Screener: Continuing Review Report (0124)
Screener: Cooperative Agreement Renewal (0126)
Screener: External IRB Cover Sheet – CRR or Other (0127)
Screener: External IRB Cover Sheet – New Application (0292)
Screener: FWA Renewal (0257)
Screener: New Individual Investigator Agreement (0136)
Screener: New or Updated IRB Reliance Agreement When Fred Hutch is the IRB of Record (0293)

REFERENCES

45 CFR 46.103

FDA Information Sheet, FAQs

OHRP Compliance Activities: Common Findings and Guidance #72

OHRP Assurance FAQs

OHRP Guidance: Engagement of Institutions in Research

OHRP Guidance: Extension of an FWA to Cover Collaborating Individual Investigators