Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Federalwide Assurance
Version:	1.00
Effective Date:	February 3, 2025
Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

POLICY STATEMENT

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

DEFINITIONS

See *HRP-001 - Glossary of Terms and Acronyms* for full definitions of the following:

Federalwide Assurance (FWA)

Individual Investigator

Individual Investigator Agreement (IIA)

IRB Authorization Agreement (IAA)

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.

[1] HHS: 45 CFR 46.103

The FWA is maintained in File 5710B in the IRB Operations Manager office. 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

To renew the FWA, the IRO staff follows the instructions found in *HRP-373 - WORKSHEET - FWA Renewal*.

3. Verifying Outside Performance Sites Have an FWA

When Fred Hutch enters into an IRB Authorization Agreement (*HRP-277a - FORM - IRB Authorization Agreement A* or *HRP-277b - FORM - IRB Authorization Agreement B)* 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 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:

- *HRP-897 - WORKSHEET - New or Updated IRB Agreement when Fred Hutch is the IRB of Record*
- *HRP-895 - WORKSHEET - External IRB*

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 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 *HRP-363 - WORKSHEET - Continuing Review* 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 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 *HRP-895 - WORKSHEET - External IRB* 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 *HRP-278 - FORM - Individual Investigator Agreement.* The Fred Hutch PI assumes responsibility for directing and appropriately supervising the Individual Investigator's activities.

Before an individual investigator is approved to do research, they must be approved as a Participating Site in Hutch IRB. The individual investigator will complete *HRP-893 - FORM - Participating Site Supplement* and any requested attachments to the Fred Hutch lead study team. The lead study team will facilitate the submission in Hutch IRB. A letter of support is required from the Individual Investigator's institution to confirm there is support to conduct research at the non-assured facility.

SUPPORTING DOCUMENTS

HRP-001 - Glossary of Terms and Acronyms
HRP-277a - FORM - IRB Authorization Agreement A
HRP-277b - FORM - IRB Authorization Agreement B
HRP-278 - FORM - Individual Investigator Agreement
HRP-363 - WORKSHEET - Continuing Review
HRP-373 - WORKSHEET - FWA Renewal
HRP-893 - FORM - Participating Site Supplement

HRP-895 - WORKSHEET - External IRB
HRP-897 - WORKSHEET - New or Updated IRB Agreement when Fred Hutch is the IRB of Record

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

VERSION HISTORY

Version	Effective Date
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