Fred Hutch Cancer Center

Institutional Review Board

# Policy/Procedure

| | |
|---|---|
| **Title:** | Funding Source Document (FSD) Review |
| **Version:** | 1.00 |
| **Effective Date:** | February 3, 2025 |
| **Responsible Office:** | Institutional Review Office (IRO) |
| **Responsible Official / Approved By:** | Meghan Scott, IRO Director |

## POLICY STATEMENT

The Fred Hutchinson Cancer Center (Fred Hutch) Institutional Review Board (IRB) is responsible for reviewing the funding source with the research activity it supports. This funding source review ensures that there are adequate resources to conduct the research activity and in the case of external funding, that the activity described in the funding proposal matches the activity proposed in the application form. The Institutional Review Office (IRO) is also responsible for issuing when appropriate, any assurance, certification, or declaration forms indicating that the protection of research participants regulations have been met.

## DEFINITIONS

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

***Funding Source Document (FSD)***

***Human Subject***

***Industry Contract***

## PRINCIPLES/OVERVIEW

The Institutional Review Board (IRB) is responsible for reviewing all funding related to a research study to ensure there are adequate resources to conduct the research activity and in the case of external funding, that the activity described in the funding proposal matches the activity proposed in the application form.

## 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. Funding source document (FSD) review

One of the responsibilities of the IRB under the Pre-2018 Requirements of the Common Rule is to review federal grant applications and the human subjects research activity to be supported by them. Fred Hutch extends this requirement to all types and sources of external funding, including research approved under the 2018 Requirements of the Common Rule (e.g., non-federal grants, industry contracts, private foundation funding, restricted gifts, and other funds).

All parts of the FSD that might directly or indirectly affect the conduct of human research must be reviewed - including but not limited to sections on specific aims, methods, human subjects, budget, personnel, and facilities.

To add a new funding source to an existing FHIRB file, the PI creates and submits a Modification submission in Hutch IRB. The FSD and *HRP-252 - FORM - Modification Supplement* must be attached to the submission to provide supporting information. See *HRP-119 - POLICY - Modification to Ongoing Activities*. Interim or bridge funding tied to an existing grant does not require approval by the IRB.

If a new funding source is being added at the same time as other modifications to the study, only one Modification needs to be submitted in Hutch IRB. The addition of funding should be described along with any other changes. *HRP-252 - FORM - Modification Supplement* must clearly mention the addition of funding.

If NIH funding is removed at any point during the study and the study had been granted a Certificate of Confidentiality under NIH policy, the investigator is strongly encouraged to obtain a continuity of protections from the NIH to remain covered by the Certificate of Confidentiality. If a continuity of protections is not obtained, consent form revisions to remove the language regarding the Certificate of Confidentiality may be required, depending on the language.

At the time of Continuing Review, study teams are expected to review the study SmartForm in Hutch IRB to confirm the accuracy of the funding information listed on the Funding Sources page. If any updates are needed, a combined Modification and Continuing Review should be created in order to submit continuing review data and revise the study SmartForms at the same time.

**2. Submission requirements for different types of funding sources:**

a. Federal Grants and other sponsored funding: A full copy of the most recent competing application must be attached to the Funding Sources page in Hutch IRB. A “full copy” includes everything except the appendices. A “full copy” means the face page, personnel, budget, facilities pages, and scientific and human subjects sections; just the ”specific aims” section is not sufficient, nor is a progress report from a non-competing continuation. Individual salaries may be redacted, but the overall budget information must be provided. For program project grants, relevant project(s) from the most recent competing application may be submitted in lieu of the entire grant.

   Grants may be submitted for IRB review at anytime during the grant application and funding cycle, the grant does not need to be awarded prior to submission to the IRB. If the grant scope of work changes between time of review by the IRB and notice of grant award, the PI must create a Modification in Hutch IRB to update the Funding Sources page in the Smart Form. The awarded grant with an updated scope of work must be attached to the submission for IRB review, along with *HRP-252 - FORM - Modification Supplement*.

   When a grant completes a competing renewal cycle, it is considered a “new” funding source. The competing grant application must be submitted to the IRB as if it were a new grant.

b. Industry Contracts or other “agreements”: A copy of the contract or agreement, including a scope of work and budget, must be attached to the Funding Sources page in Hutch IRB. If the new funding source involves an industry-sponsored agreement, it must be completed and attached to the Funding Sources page in Hutch IRB.

   Unsigned contracts may be submitted for review. When the final contract is signed, a copy of the finalized contract must be submitted to the IRB for review through Hutch IRB. The final contract and the currently proposed consent document(s) are reviewed by Office of the General Counsel prior to release of IRB approval documents.

c. Non-Sponsored (Internal) Funding (e.g., royalty account, divisional funds, PI discretionary funds, etc.): No funding source document is required; however, the funding source must still be added to the Funding Sources page in Hutch IRB.

d. Interim or bridge funding tied to a specific grant: For interim non-sponsored funding tied to a specific grant that has already been approved by the IRB, no additional review is required by the IRB.

   If the interim funding is for a scope of work beyond that of the original grant, or if the grant was not approved under a particular FHIRB file(s), then the interim funding must be submitted as a new non-sponsored funding source as outlined above.

e. Exceptions:

- The Core grant does not need to be submitted in Hutch IRB for each study it funds because it undergoes a comprehensive separate review.
- No-Cost Extensions (NCE) for a grant where none of the activity involving human subjects has changed. The research team must submit a Modification in Hutch IRB to update any details on the Funding Sources SmartForm page, including the grant end date. However, no cost extensions are considered administrative modifications and may be administratively "approved" in Hutch IRB by IRO staff.
- National Clinical Trials Network (NCTN) studies funded through the LAPS grant do not require individual FSDs because the FSD is reviewed with the "master" NCTN regulatory file.
- External IRB files, where another IRB serves as the IRB of record must list all current funding on the Funding Sources page of the SmartForm. A funding source document (FSD) only needs to be attached in some instances:
  - For federal grants and sponsored funding, a copy of the FSD does not need to be attached when the external IRB will review the FSD. Approval of the funding source should be listed in the external IRB's approval documentation. If the external IRB does not review the FSD (e.g., when not regulatorily required), the FSD should be attached to the Funding Sources page in Hutch IRB so the IRO can perform an administrative review.
  - For industry-sponsored contracts or other agreements, the final contract must be attached in Hutch IRB if Fred Hutch is a signatory on the contract. The final contract and the currently proposed consent document(s) are reviewed by Office of the General Counsel prior to release of IRB approval documents. If Fred Hutch is not a signatory on the contract, a copy of the contract is not required.

**3. Certification of Approval**

If a funding proposal is awarded, the PI may request an IRB certification, and the IRO staff will prepare the federal *IRB Assurance Identification/IRB Certification/Declaration of Exemption Form* (formerly known as the Optional 310 Form). A certification will only be prepared once the sponsored funding source has been approved by the IRB as part of an approved IRB file.[1]

**4. IRO Confirmation of Limited Activity**

a. *HRP-269 - FORM - IRO Confirmation of Limited Activity* allows the PI to request release of funds prior to IRB or IACUC review. The activities may not involve the use of human subjects or live vertebrate animals. Only activities that are clearly severable and independent from activities that involve human subjects or live vertebrate animals may be conducted under the award until the project has received approvals, and approvals have been submitted and accepted by the agency as appropriate.

b. The IRO staff follows the instructions in *HRP-369 - WORKSHEET - IRO Confirmation of Limited Activity*.

## SUPPORTING DOCUMENTS

HRP-001 - Glossary of Terms and Acronyms

HRP-119 - POLICY - Modification to On-Going Activities

HRP-252 - FORM - Modification Supplement

HRP-269 - FORM - IRO Confirmation of Limited Activity

HRP-369 - WORKSHEET - IRO Confirmation of Limited Activity

IRB Assurance Identification IRB Certification Declaration of Exemption Form

## REFERENCES

45 CFR 46.103

[1] HHS: 45 CFR 46.103(d)

45 CFR 46.118

45 CFR 46.119

NIH Policy for Issuing Certificates of Confidentiality https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

OHRP Guidance: IRB Review of Applications for HHS Support

## VERSION HISTORY

| Version | Effective Date |
|---|---|
| - | - |