FRED HUTCH
Institutional Review Board

Policy/Procedure

Title:	Funding Source Document (FSD) Review
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Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director for Karen Hansen 1/11/2019 *Signature/date*

Version History	Effective Date
9.00	11-20-2017
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7.01	05-15-2014
7.00	10-01-2011
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POLICY STATEMENT

The Fred Hutchinson Cancer Research 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 *IRB Glossary of Terms and Acronyms* (050) for full definitions of the following:

***Attachment B**:* The internal routing and approval form submitted along with a funding proposal for an activity to be performed at Fred Hutch funded by Center funds, discretionary funds, royalties, or other non-sponsored funding source.

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. Attachment B Procedures

The IRO provides periodic training and decision support tools to investigators and their teams regarding Attachment B and associated requirements for completing their grant and funding applications.

2. 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 IR file, the PI submits a *Research Modification Form* (062) with a *Funding Source Supplement Form* (049). See *IRB Policy 2.5 Modifications to On-Going Activities* (025). Interim or bridge funding tied to an existing grant does not require approval by the IRB.

If adding a funding source is in addition to other modifications, a separate *Research Modification Form* (062) is not required. However, the *Research Modification Form* (062) must clearly mention the FSD addition.

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 must either (a) obtain a continuity of

protections from the NIH to remain covered by the Certificate of Confidentiality or (b) modify the consent form to remove the Certificate of Confidentiality language.

At the time of Continuing Review, a *Funding Source Supplement* (049) is submitted to disclose all active funding associated with the ongoing research.

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 submitted along with the *Funding Source Supplement* (049). 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 blacked out, 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 awarded grant with an updated scope of work must be submitted to the IRB as an updated funding source along with a *Research Modification Form* (062).

   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 submitted along with the *Funding Source Supplement* (049). If the new funding source involves an industry-sponsored agreement, it must be completed and submitted to the IRB along with the *Application for Review* (0324, 0325, or 0326) or *Research Modification Form* (062) (to an existing IR File).

   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. 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, only a *Funding Source Supplement* (049) must be submitted for internal funding.

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, only the Attachment B form needs to be submitted to the Finance Department. Finance routes the Attachment B form to the IRO (and any other necessary departments) for review. The grant associated with the interim funding must be identified on the Attachment B. IRO staff will conduct an administrative review to confirm the grant has already been approved by the IRB and will update the IRB records to indicate the grant scope of work has been extended through interim funding.

   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 IRB file(s), then the interim funding must be submitted as a new non-sponsored funding source as outlined above.

e. Exceptions:

   - Copies of the Core grant are not required 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 is responsible for notifying the IRO at IRO@fredhutch.org of the grant's NCE. Upon notification, the relevant IRB funding source dates can be administratively updated in the IRO database maintained by the 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 registered IRB serves as the IRB of record do not need FSD review by the Fred Hutch IRB, because the IRB of record reviews the FSD.

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) or a *Certification Letter* (0228). 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. The *IRO Confirmation of Limited Activity Form* (0276) 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 the *Screener: IRO Confirmation of Limited Activity* (0260).

SUPPORTING DOCUMENTS

IRB Policy 2.5 Modification to On-Going Activities (025)
Application for Review Human Specimens or Data Research (0326)
Application for Review Interventional Research (0324)
Application for Review Observational Research (0325)
Finance Attachment B
Funding Source Supplement (049)
IRB Assurance Identification IRB Certification Declaration of Exemption Form
IRB Glossary of Terms and Acronyms (050)
IRO Confirmation of Limited Activity (0276)
Certification Letter (0228)
Research Modification Form (062)
Screener: IRO Confirmation of Limited Activity (0260)

REFERENCES

45 CFR 46.103
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

[1] HHS: 45 CFR 46.103(d)