



<b>Title:</b>	IRB Reliance Agreements
<b>Policy:</b>	2.24
<b>Version:</b>	4.00
<b>Effective Date:</b>	February 24, 2020
<b>Responsible Office:</b>	Institutional Review Office (IRO)
<b>Responsible Official:</b>	Meghan Scott, IRO Director
	 <span style="float: right;">2/21/2020</span>
	<i>Signature/date</i>

Version History	Effective Date
3.01	01-21-2019
3.00	07-03-2017
2.03	06-15-2015
2.02	05-15-2014
2.01	01-31-2012
2.00	05-01-2010
1.01	12-07-2009
1.00	01-14-2008

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**POLICY STATEMENT**

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The Fred Hutchinson Cancer Research Center (Fred Hutch) will serve as the Institutional Review Board (IRB) of record for Fred Hutch investigators and investigators at other sites with which Fred Hutch has reliance agreements. When single IRB (sIRB) review is called for, Fred Hutch will serve as the single IRB of record for multi-site studies in which a Fred Hutch investigator is involved. Fred Hutch will also rely on review by other sIRBs of multi-site studies involving Fred Hutch investigators. In each situation, the reliance arrangement for IRB review will be agreed upon and documented by the Fred Hutch Institutional Review Office (IRO) and the corresponding organization’s IRB office prior to IRB review of the participating site.<sup>1</sup>

Fred Hutch will comply with the requirements set forth in 45 CFR 46, Section 114 and 21 CFR 56, Section 114 regarding cooperative research projects, and with the *NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research*.

This policy only applies to research conducted in the United States.

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<sup>1</sup> HHS: 45 CFR 46.103(e)

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## DEFINITIONS

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### **Authorized Institutional Official**

### **Delayed Onset Research**

### **Engaged in Research**

### **Federalwide Assurance (FWA)**

### **IRB of Record**

### **IRB Reliance Agreement**

An IRB reliance agreement may one of the following:

- a. **Individual Investigator Agreement** – Used for investigators collaborating on research overseen by the Fred Hutch IRB and who are not performing the research under a participating site that has an Federalwide Assurance. An individual investigator can agree to abide by the Fred Hutch IRB review requirements and terms of the Fred Hutch Federalwide Assurance using the *Individual Investigator Agreement* (052). See *IRB Policy 1.2 Federalwide Assurance* (016).
- b. **IRB Authorization Agreement** – Used when the Fred Hutch IRB serves at the IRB of record for participating sites with a Federalwide Assurance engaged in the research, or when a Fred Hutch investigator relies on another institution’s IRB as the IRB of record.
- c. **Cooperative Review Agreement** – Used for certain institutions in the state of Washington who are engaged in frequent research collaborations with Fred Hutch investigators and wish to avoid duplicate IRB review.
- d. **IRB Services Contract** – Used to establish the reliance arrangement between Fred Hutch and an independent IRB where the independent IRB will serve as the IRB of record for certain established research projects. May also be called a master services agreement.

### **Local Research Context**

### **Multi-Site Study**

### **Participating Site**

### **Single IRB (sIRB)**

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## PRINCIPLES/OVERVIEW

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When a Fred Hutch investigator is engaged in a multi-site research study, Fred Hutch IRB will either:<sup>2</sup>

- 1) serve as the IRB of record for the Fred Hutch investigator and any other investigators from institutions with which Fred Hutch IRB has a reliance agreement, including in cases where Fred Hutch IRB will serve as the sIRB and perform the IRB review for all participating sites, or
- 2) rely on another IRB as the IRB of record, including in cases where that IRB will serve as the sIRB, when the Fred Hutch investigator is engaged as a participating site. The Fred Hutch investigator agrees to comply with the determinations and requirements of the reviewing IRB.

IRB reliance requests and agreements must be pre-approved by the IRO Director, or designee.

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<sup>2</sup> Single IRB review required by National Institutes of Health (NIH) for all NIH-funded research effective January 25, 2018. See <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html> for guidance.

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## INDIVIDUALS AFFECTED BY THIS POLICY

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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.

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## PROCEDURES

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### 1. Grant Application Requirements for Multi-site Studies (NIH Funding Only)

- a. Effective January 25, 2018, new or competing continuation grant or contract applications/proposals submitted to the NIH are expected to include a plan describing the use of an sIRB that will be selected to serve as the IRB of record for all study sites. The plan should include a statement confirming that participating sites will adhere to the NIH sIRB policy and describe how communications between sites and the sIRB will be handled. If, in delayed-onset research, an sIRB has not yet been identified, applications/proposals should include a statement that awardees will follow the NIH sIRB policy and communicate plans to use a registered IRB of record to the funding NIH Institute/Center prior to initiating a multi-site study.
- b. The reliance arrangement should be known at the time of funding application. The IRO will provide the lead Principal Investigator (PI) with written statement(s) of support describing whether the Fred Hutch IRB will rely upon an sIRB or be the sIRB of record for a multi-site trial. Signed reliance agreement(s) do not have to be in place at the time funds are requested, but do need to be completed prior to sIRB review of the research.

### 2. General Fred Hutch Institutional Requirements for Multi-site Studies

- a. The participating site must have an approved FWA with OHRP. In addition, when Fred Hutch relies on an sIRB, the sIRB's registration must be current with OHRP.
- b. A Fred Hutch PI who coordinates a multi-site study is responsible for the oversight and management of IRB approval for each participating site and individual investigator engaged in research they oversee. When Fred Hutch IRB is the sIRB, each site PI will provide sufficient information about the participating site(s), including the local research context, so the Fred Hutch IRB can evaluate if the site's investigator is qualified, and the site adequate, to conduct the research activities. Refer to *IRB Policy 2.14 Multi-Center Study Coordination – IRB Review and Oversight (027)* for site submission requirements.
- c. The Fred Hutch PI or study team informs the IRO Director (or designee) of a multi-site study(ies) in which the PI plans to participate. The PI identifies the sIRB for the multi-site study in consultation with the IRO Director (or designee) and the participating sites' investigators and IRB offices.
- d. The IRO Director (or designee) contacts the IRB office(s) at the other site(s), or at the independent IRB (if applicable), to discuss the following:
  - Accreditation status
  - Type of reliance agreement to be used and scope of reliance (e.g. project-specific or for multiple projects)
  - Who will serve as the IRB of record

Refer to  *Screener: External IRB Contact (0396)* for information to be gathered.

- e. If there are any questions about the proposed reliance agreement, the IRO Director will consult the Office of General Counsel.
- f. A reliance agreement must be in place before a participating site submits their site application to the Fred Hutch IRB.

- g. A reliance agreement must be in place before a Fred Hutch investigator may submit research for review to another IRB.

### 3. Fred Hutch Serves as the sIRB

Refer to workflow diagram *IRB Reliance Agreements: Fred Hutch Serves as the Single IRB for Participating Sites* (0393) for detailed steps and tasks.

If it is agreed that the Fred Hutch IRB will be the IRB of record and that the participating site(s) will rely on Fred Hutch:

- a. The IRB Reliance Coordinator will prepare the appropriate reliance agreement outlining responsibilities of the Fred Hutch IRB and the participating site. Refer to the *IRB Authorization Agreement* (043) template (Fred Hutch as Institution A). The IRB Reliance Coordinator will send drafts to the participating site(s) relying on the Fred Hutch IRB.
- b. Once the reliance agreement is signed by both the IRO Director (or designee) and the participating site's institutional official, and the study protocol and model consent form have been reviewed and approved by the Fred Hutch IRB, the participating site's application will be sent to the Fred Hutch IRB for review. Refer to *IRB Policy 2.14 Multi-Center Study Coordination – IRB Review and Oversight* (027) for documents required to be submitted in the application.
- c. The PI will provide the IRB with an appropriate level of information regarding the site and the local investigator so the IRB can evaluate the qualifications of the investigator and the adequacy of the site before approving research to be conducted at the site. Information about the site is provided on the *Participating Site Application* (0395) and associated attachments. The IRB, or the IRO Director (or designee), can request additional information about the site as necessary.

### 4. Fred Hutch Relies on Another Institution or Organization's sIRB

#### Institutional IRBs

Refer to workflow diagram *IRB Reliance Agreements: Fred Hutch Relies on a Single IRB* (0392) for detailed steps and tasks.

When a Fred Hutch PI wants to rely on another institution's IRB:

- a. The IRO Director (or designee) ensures the institution's IRB is either AAHRPP accredited or has a robust HRPP with policies and procedures that show the IRB can provide sufficient review.
- b. The IRB Reliance Coordinator will assist the IRO Director when assessing the institution's IRB policies and procedures using the *AAHRPP IRB Evaluation Checklist*. If the evaluation shows that the policies and procedures do not meet the AAHRPP criteria, the IRO Director (or designee) requests updates or further information. The IRO Director will discuss with the site whether a plan to use a different IRB (including Fred Hutch IRB, if applicable) is appropriate.
- c. If needed, the IRB Reliance Coordinator will assist with drafting a reliance agreement outlining responsibilities of the Fred Hutch IRB and the institution's IRB. Refer to the *IRB Authorization Agreement* (043) template (Fred Hutch as Institution B).
- d. Once the reliance agreement is signed by both the IRO Director (or designee) and the site's institutional official, the Fred Hutch PI will prepare the sIRB application. The Fred Hutch PI must submit an *External IRB Cover Sheet – New Application* (0327) to the Fred Hutch IRO before sending their application to the sIRB. The IRO uses the information in the cover sheet to maintain a record of the external IRB application and to ensure any other Fred Hutch institutional requirements are met. Refer to *IRB Policy 2.14 Multi-Center Study Coordination – IRB Review and Oversight* (027) for documents required to be submitted in the application. After receiving endorsement from the IRO, the Fred Hutch PI may submit their application to the external IRB.

- e. The Fred Hutch investigator is responsible for submitting all IRB-approved documents to the Fred Hutch IRO throughout the life of the study.

### Independent IRBs

Refer to workflow diagram *IRB Reliance Agreements: Fred Hutch Relies on an Independent IRB (0394)* for detailed steps and tasks.

When a Fred Hutch PI wants to rely on an independent IRB:

- a. The IRO Director (or designee) will determine whether a reliance agreement exists and whether it is appropriate for the Fred Hutch PI to use the independent IRB in lieu of the Fred Hutch IRB.
  - i. If no reliance agreement exists and it is appropriate to rely on the independent IRB, the IRO Director (or designee) works with OGC to establish a reliance agreement with the independent IRB. OGC must approve the final IRB reliance agreement, as well as the final consent form for each project, if the research is industry sponsored.
- b. The IRO Director (or designee) provides written confirmation to the PI and study team when it is appropriate to use an independent IRB.
- c. Once the reliance agreement is signed by both the IRO Director (or designee) and the independent IRB's organizational official, the Fred Hutch PI will prepare the independent IRB application. The Fred Hutch PI must submit an *External IRB Cover Sheet – New Application (0327)* to the Fred Hutch IRO before sending their application to the independent IRB. The IRO uses the information in the cover sheet to maintain a record of the external IRB application and to ensure any other Fred Hutch institutional requirements are met. After receiving the *IRO Endorsement of External IRB Application (0338)* from the IRO, the Fred Hutch PI may submit their application to the external IRB.
- d. The Fred Hutch investigator is responsible for submitting all IRB-approved documents to the Fred Hutch IRO throughout the life of the study.

## **5. Cooperative Review Agreements**

Fred Hutch has grandfathered Cooperative Review Agreements with organizations within the state of Washington that were initially signed prior to June 15, 2015. The following organizations are involved in these agreements and copies are maintained in the IRO:

- University of Washington (UW)
- Seattle Cancer Care Alliance (SCCA)
- Seattle Children's Hospital (SCH)
- Kaiser Permanente (formerly Group Health Cooperative)
- Benaroya Research Institute at Virginia Mason (BRI at VM)
- Washington State Department of Health (WSDH)

These institutions may accept, for the purpose of meeting the IRB review requirements, the review of an IRB established under another assurance of compliance with the Department of Health and Human Services. Such acceptance will be in writing, approved and signed by this institutions' directors, approved and signed by correlative officials of each of the other cooperating institutions. Cooperative Review Agreements between Fred Hutch and the institutions described above cover a broad scope of research projects and sIRB reliance, but generally serve the same function as IRB authorization agreements for individual research projects.

## 6. Transferring a Study from Another IRB to Make Fred Hutch the IRB of Record

As applicable, the Fred Hutch PI will follow the instructions in the *IRB Transfer Agreement* (0367) and *Transfer of IRB Oversight Supplement* (0366) documents when arranging to transfer the IRB review to Fred Hutch IRB from another institution or organization's IRB.

## 7. Terminating Reliance Agreements

IRB reliance agreements are valid until terminated by either party.

To terminate an agreement, the Fred Hutch PI, or the participating site when Fred Hutch is the sIRB, submits a letter or email to the IRO that includes the effective end date and reason for the agreement termination. The Fred Hutch IRO or IRB, or the external IRB when Fred Hutch relies on one, may also terminate an agreement as arranged by those offices, as applicable.

### a. When Fred Hutch is relying on an external IRB

An *IRB Reliance Agreement Closure Letter* (0289) is forwarded to the performance site, and if there is no response 30 days after the letter was sent, the reliance agreement termination is finalized and the IR file is archived.

### b. When Fred Hutch is the IRB of Record

An *IRB Reliance Agreement Closure Letter* (0289) or *Individual Investigator Agreement Closure Letter* (0289) is forwarded to the performance site, as applicable. The reliance agreement file is closed and re-filed until the parent IR file is closed.

Refer to *IRB Policy 2.9 Closure and Re-Open* (08) for instructions on closing studies and sites.

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## SUPPORTING DOCUMENTS

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IRB Policy 1.2 Federalwide Assurance (016)  
IRB Policy 2.9 Closure and Re-Open (08)  
IRB Policy 2.14 Multi-Center Study Coordination – IRB Review and Oversight (027)  
External IRB Cover Sheet – New Application (0327)  
Individual Investigator Agreement (052)  
Individual Investigator Agreement Closure Letter (0289)  
IRB Authorization Agreement – Fred Hutch as Institution A (043)  
IRB Authorization Agreement – Fred Hutch as Institution B (043)  
IRB Reliance Agreement Closure Letter (0291)  
IRB Reliance Agreements: Fred Hutch Relies on a Single IRB Flow Chart (0392)  
IRB Reliance Agreements: Fred Hutch Relies on an Independent IRB Flow Chart (0394)  
IRB Reliance Agreements: Fred Hutch Serves as the Single IRB for Participating Sites Flow Chart (0393)  
IRB Transfer Agreement (0367)  
IRO Endorsement of External IRB Application (0338)  
Participating Site Application (0395)  
Screener: External IRB Contact (0396)  
Transfer of IRB Oversight Supplement (0366)  
AAHRPP IRB Evaluation Checklist

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## REFERENCES

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45 CFR 46.103  
45 CFR 46.114  
21 CFR 56.114  
FDA Information Sheets: Non-Local IRB Review

OHRP Guidance on Engagement in Research

FDA Guidance: IRB Responsibility for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether and IND/IDE is Needed

NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research