Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

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

POLICY STATEMENT

This policy describes how the Fred Hutchinson Cancer Center (Fred Hutch) Institutional Review Office (IRO) creates and maintains written policies and supporting documents.

The IRO uses written policies and supporting documents to help the Fred Hutch Institutional Review Board (IRB) carry out its activities. The creation, processing, distribution, revision, format, file naming, and version control of these documents are standardized.

DEFINITIONS

Major change: Any substantive change(s) to either a policy or supporting document that results in a change to work processes, scope, or responsibilities.

Minor change: Any administrative change(s) to either a policy or supporting document that does not result in changes to work processes, scope, or responsibilities.

Document(s): Refers to policies and/or supporting documents.

Supporting document(s): Any document(s) that are referenced in the policy. This includes but is not limited to forms, worksheets, charts, job descriptions, etc.

PRINCIPLES/OVERVIEW

Written policies ensure a consistent level of quality and accountability in IRO and IRB activities. Proper change control of policies and supporting documents ensures that changes are implemented in a controlled manner and have been approved by an authorized individual.

INDIVIDUALS AFFECTED BY THIS POLICY

This policy applies to IRO staff and IRB members.

PROCEDURES

1. Dissemination of New Information

a. IRO staff are notified during staff meetings or at other appropriate venues when new information that might affect the protection of human subjects at Fred Hutch is available (including laws, regulations, policies, procedures, or emerging ethical/scientific issues).

b. IRO staff are assigned to review OHRP, FDA, NIH, and other information sources for new information affecting human subjects protection, and to report regularly to other IRO staff.

c. Relevant information is shared as appropriate among the IRO, IRB, Clinical Research Support, Office of the General Counsel, Compliance, and other offices or groups.

2. Creation of Policies and Supporting Documents

The IRO Director or Assistant Director determines when a new IRB policy or supporting document is needed. A request for a new document is made via *HRP-923 - STAFF FORM - Change Request*.

The IRO Quality Assurance (QA) Manager assigns a document number and title, and a draft is created using *HRP-597 - TEMPLATE - Policy*. The new document starts at version 1.00. The IRO Director and/or Assistant Director reviews the proposed policy or supporting document and determines whether additional reviews are needed as noted below:

a. IRB Committees (or designated subcommittees). A policy or supporting document generally requires review by the IRB Committees whenever a new or revised document affects IRB review procedures.

b. Office of the General Counsel.

c. Other individuals or groups within or outside of Fred Hutch that the IRB, IRO Director, or designee determines are necessary, such as Compliance, Clinical Research Support, University of Washington Human Subjects Division, etc.

Prior to approval of the change order, the Assistant Director and IRO QA Manager review the policy or supporting document to assess if changes are required to Hutch IRB, worksheets, checklists, or operational processes.

The Assistant Director reviews the documents and signs *HRP-923 - STAFF FORM - Change Request* to approve the policy and/or supporting documents. If the change order includes a policy, *HRP-923 - STAFF FORM - Change Request* is also routed to the IRO Director for review and approval of the policy. Documents are effective as of the "Effective Date" on *HRP-923 - STAFF FORM - Change Request*.

3. Revision of Approved Policies and Supporting Documents

a. *HRP-923 - STAFF FORM - Change Request* is completed when a revision to a policy or supporting document is needed.

b. Revisions are made on the most current version of the document. All changes to the document are tracked to capture any information that was updated.

c. Documents are version controlled. Any time a document is updated, the document will be versioned.

- Major changes: A major change would increase the version number by 1.00. For example, version 1.00 would become version 2.00.
- Minor changes: A minor change would increase the version number by 0.01. For example, version 1.00 would become version 1.01.

d. Reviews and approvals of revisions are conducted as described above for new policies and supporting documents.

e. When the necessary reviews are completed and the document is ready for finalization, the effective date and version in the footer are updated. For policies, the version history table will be updated as well. A final, clean, copy of the document is prepared.

f. Older, superseded versions of all policies and supporting documents are maintained electronically in SharePoint and, for document changes prior to March 28, 2023, in hard copy format in IR File 5215.

- Superseded versions of documents are made available by request to the IRO QA Manager.

4. Processing and Distribution of Approved Policies and Supporting Documents

Completed change orders are maintained in J:\IRO\Change Requests. A copy of the completed *HRP-923 - STAFF FORM - Change Request* and a clean and redlined copy of the document(s) are included.

For revisions prior to March 28, 2023: Hard copies of change orders are stored in IR file 5215. Original signed copies of revised policies can also be found in IR File 5215 along with the change order under which the version was implemented. (Policies after March 28, 2023 are no longer signed.)

The IRO QA Manager posts new and revised policies and supporting documents to SharePoint, the IRO website, and/or the Hutch IRB Library per *HRP-100 - Document Matrix*.

Investigators and research staff will have access to all IRB policies and applicable supporting documents on the IRO website. On-site staff will access the IRO website through CenterNet. External personnel (non-Fred Hutch personnel) will access the IRO website through ExtraNet.

The IRO QA Manager notifies IRO staff of any new or revised documents. Training for IRO staff for new or revised documents is completed per *HRP-062 - POLICY -Training* and *HRP-920 - PROCEDURE - Change Control and Training*. Training is assigned by job title per *HRP-100 - Document Matrix*, and is required for new IRO staff, when new documents are released, and when major revisions are made to documents. Training of IRO staff is completed prior to the effective date of the document. If training is completed after the effective date, an explanation must be noted on *HRP-924 - STAFF FORM - Training Documentation*. Training documentation is maintained by the IRO QA Manager.

When a new or revised policy is made available, the IRO staff will notify key individuals affected by the policy. A newsletter or targeted email to all principal investigators will be sent in the event of significant changes to a policy and/or process.

Individuals requesting a copy of an IRO policy will be referred to the IRO website or provided with a PDF document.

Word documents (*.doc or .docx) are maintained for internal use and can be accessed only by authorized personnel.

5. Retiring Policies and Supporting Documents

a. The IRO Director or Assistant Director determines if an existing document is no longer needed, and the document is flagged to be retired. *HRP-923 - STAFF FORM - Change Request* is completed.

b. The IRO QA Manager retires the document in SharePoint. The retired document is removed from all other locations where it is stored, including the IRO website and Hutch IRB Library.

c. SharePoint maintains all retired documents and their version history. Access to view retired documents is restricted to the SharePoint site owners user group. Retired documents will be made available by request.

6. Periodic Review of Approved Policies and Supporting Documents

a. All documents are routinely reviewed to ensure continued validity. All IRB policies and supporting documents are reviewed at least biennially by the IRO Director, Assistant Director, or designee.

b. The last periodic review date and next periodic review due date for all documents are tracked on *HRP-100 - Document Matrix*. The QA Manager is responsible for managing the periodic review process including tracking these dates and assigning reviews to the IRO Director, Assistant Director, or designee.

- The last periodic review date is considered the date of last periodic review or when the document was last revised, whichever occurs later.
- The next periodic review due date is two years after the last periodic review date.

c. Completion of periodic review is documented on the *HRP-925 - STAFF FORM - Biennial Policy and Supporting Document Review*. The document reviewer will indicate the status of the document as either “Approved” or “Needs Revision.” Approved documents require no further action. Documents identified as requiring revision are revised in accordance with this policy and prioritized according to impact of the change.

d. The *Human Research Protection Program* policy is also reviewed by the IRO on a biennial basis to ensure accuracy. Any suggested updates are presented to the Compliance Office which maintains the policy.

7. Annual Document Review by Other Departments

An annual IRB Operations Report for the preceding year, which includes copies of the current versions of all the IRB policies, is provided to the Institutional Official for review.

SUPPORTING DOCUMENTS

Human Research Protection Program

HRP-072 - POLICY - Training

HRP-100 - Document Matrix

HRP-597 - TEMPLATE - Policy

HRP-920 - PROCEDURE - Change Control and Training

HRP-923 - STAFF FORM - Change Request

HRP-924 - STAFF FORM - Training Documentation

HRP-925 - STAFF FORM - Biennial Policy and Supporting Document Review

REFERENCES

None

VERSION HISTORY

Version	Effective Date
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