




<b>Title:</b>	Control and Distribution of Policies and Supporting Documents
<b>Policy:</b>	1.1
<b>Version:</b>	7.00
<b>Effective Date:</b>	September 4, 2018
<b>Responsible Office:</b>	Institutional Review Office (IRO)
<b>Responsible Official:</b>	Karen Hansen, IRO Director
	 for Karen Hansen
	8/31/2018
	Signature/date

Version History	Effective Date
6.00	02-26-2018
5.02	08-01-2014
5.01	05-15-2014
5.00	09-01-2009

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### **POLICY STATEMENT**

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This policy describes how the Fred Hutchinson Cancer Research 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.

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### **DEFINITIONS**

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**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, screeners, charts, job descriptions, etc.

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## PRINCIPLES/OVERVIEW

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Written policies ensure a consistent level of quality and accountability in 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.

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## INDIVIDUALS AFFECTED BY THIS POLICY

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This policy applies to IRO staff and IRB members.

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## PROCEDURES

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### 1. Dissemination of New Information

- a. IRO staff will be notified during staff meetings or at other appropriate venues when new information that might affect the protection of human subjects at Fred Hutch becomes available (including laws, regulations, policies, procedures, or emerging ethical/scientific issues).
- b. IRO Staff are assigned to review OHRP, 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, and other offices or groups.

### 2. Creation of Policies and Supporting Documents

The IRO Director or Assistant Director will determine when a new IRB policy or supporting document is needed. A request for a new document is made via the *Change Request Form* (085).

The IRO Quality Assurance (QA) Manager assigns a document number and title, and a draft is created using the *Policy Template* (0106) or the *Form Template* (0234). The new document will start 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 that the IRB, IRO Director, or designee determines are necessary.

Prior to approval of the change order, the Assistant Director and IRO QA Manager will review the policy or supporting document to assess if changes are required to the IRO database (PIRO), staff forms, or operational processes.

For Policies: After all reviews are complete, policies are approved when signed by the IRO Director (or designee). The policy takes effect on the "Effective Date" noted on the first page of the policy. The Assistant Director will review and sign the *Change Request Form* (085) to approve the policy and/or supporting documents.

### 3. Revision of Approved Policies and Supporting Documents

- a. A *Change Request Form* (085) will be completed when a revision to a policy or supporting document is requested.
- b. Revisions are made on the most current version of the document. Any changes to the document are tracked in order 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 have been completed and the document is ready for finalization, the effective date and version in the footer are updated. For policies, the version history on the first page will be updated as well. A final, clean, copy of the document is prepared.
- f. Older versions of all policies and supporting documents are maintained electronically in Sharepoint and in hard copy format in IR File 5215.

#### 4. Processing and Distribution of Approved Policies and Supporting Documents

Hard copies of completed change orders, which includes a copy of the completed *Change Request Form (085)*, as well as a clean copy and a redlined copy of the document(s) are stored in IR file 5215.

For Policies: The original signed copy of the policy is kept in IR File 5215 and is filed with the change order under which the version was implemented. A copy of the signed policy is kept in the IRB policy binder and is also made available on the IRO website and eReview.

The IRO QA Manager will post new and revised policies and supporting documents to SharePoint, the IRO website, PIRO, and/or eReview per the *Document Matrix (0413)*.

Investigators and research staff will have access to all IRB policies and applicable forms from 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 will notify IRO staff of any new or revised documents. Training for IRO staff for new or revised documents is completed per *IRB Policy 2.20 Training (038)* and the *Change Control and Training Procedures (0398)*. Training is assigned by job title per the *Document Matrix (0413)*, and is required for new IRO staff, when new documents are released, and when major revisions are made to documents. Training of IRO staff will be completed prior to the effective date of the document. If training is completed after the effective date, an explanation must be noted on the *Training Documentation Form (0399)*. Training documentation will be 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 (\*.pdf),
- or provided with a printed paper copy

Word documents (\*.doc) are maintained for internal use only and will be accessed only by authorized personnel.

## 5. Retiring Policies and Supporting Documents

- a. The IRO Director or Assistant Director will determine if an existing IRB document is no longer needed and the document will be flagged to be retired. A *Change Request Form* (085) will be completed.
- b. The IRO QA Manager will retire the document in Sharepoint. The retired document will then be removed from all other locations where it is stored, including the IRO website, PIRO, and eReview.
- c. Sharepoint maintains all retired documents and their version history. Access to view retired documents is restricted to the SharePoint site owners user group.

## 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 the *Document Matrix* (0413). 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 *Biennial Policy and Supporting Document Review Form* (0405). The document reviewer will indicate the status of the document as either "Approved" or "Needs Revision". Approved documents require no further action. Documents that are identified as requiring revision will be revised in accordance with this policy.
- d. The *Office of the Director Policy on Human Research Protection Program* (0280) will be reviewed by the IRO on a biennial basis to ensure accuracy. This document is not maintained by the IRO so any suggested updates will be presented to the Office of the Director.

## 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 Office of the Director for review.

## 8. Format of Policies

Each policy contains a header with the following information:

- a. Title: Title of policy.
- b. Policy: Unique number assigned to the policy. It is a sequential numeric designation. Example: 1.1.
- c. Version: Version of the policy.
- d. Effective date: The date when the policy becomes effective. This date may differ from the approval signature date.
- e. Responsible Office: The institution, division, or other administrative body that is responsible for the document.
- f. Responsible Official: The individual or designee authorized to approve policies for the identified Responsible Office.

- g. Signature/date: The policy is approved when the Responsible Fred Hutch Official signs and dates the policy. This date may differ from the effective date of the policy.
- h. Version History: A table that lists all previous versions and effective dates of the policy.

Each policy may include the following section headings when applicable:

- a. Policy Statement: Defines the intent of the policy.
- b. Definitions: Defines any terms that may be unfamiliar.
- c. Individuals Affected by this Policy: Lists the individuals or groups responsible for, or affected by, the procedures outlined in the policy.
- d. Principles/Overview: Summarizes the content of the policy.
- e. Procedures: Describes activities performed to comply with the policy. When applicable, the procedures also identify who is responsible for carrying out a given step. If a regulation/guidance is referenced in this section, then the Office of Human Research Protections (OHRP) 45 CFR 46 regulation will only be cited unless the Food and Drug Administration (FDA) 21 CFR 56 regulation differs substantially.
- f. Supporting Documents: A list of documents referenced in the policy.
- g. References: Lists written material (other than supporting documents) referred to in the policy, such as regulations or guidance.

Each policy and supporting document includes a footer with the following information:

- Document file name / Version / Effective date / Page [x] of [y]

## 9. Document Naming Convention

All documents are assigned a unique document ID. Additionally, policies are assigned a unique policy number. These numbers are assigned using the next available document ID and/or policy number from the *Document Matrix* (0413).

The document title is based on the type of document and user. See the table below for the naming convention:

Type	Naming Convention	Document Title (Example)	Name on the actual document (Example)
IRB Policies	IRB Policy	<ul style="list-style-type: none"> <li>o IRB Policy 2.22 Database</li> <li>o IRB Policy 1.1 Control and Distribution of Policies</li> </ul>	<ul style="list-style-type: none"> <li>o Database</li> <li>o Control and Distribution of Policies</li> </ul>
Supporting Documents used by IRB Staff	IRB Staff	<ul style="list-style-type: none"> <li>o IRB Staff Modification Screener Form</li> <li>o IRB Staff AE Memo</li> </ul>	<ul style="list-style-type: none"> <li>o Modification Screener Form</li> <li>o AE Memo</li> </ul>
Supporting Documents used by PIs and coordinators	IRB Form	<ul style="list-style-type: none"> <li>o IRB Form Continuing Review Report</li> <li>o IRB Form Unanticipated Problem Reporting Form</li> </ul>	<ul style="list-style-type: none"> <li>o Continuing Review Report</li> <li>o Unanticipated Problem Reporting Form</li> </ul>
Supporting Documents used by IRB Chairs & Members	IRB Member	<ul style="list-style-type: none"> <li>o IRB Member Conflict of Interest Procedures</li> <li>o IRB Member Committee Member Service Description</li> </ul>	<ul style="list-style-type: none"> <li>o Conflict of Interest Procedures</li> <li>o Committee Member Service Description</li> </ul>

Document files are named using the following convention:

[Document ID][Group][Document Type][Policy # (if applicable)]\_[Abbreviated document title]

Example: 017IRBpolicy2\_11Informed Consent, 045IRBform\_CRR

Group refers to the institution, division, or other administrative body that is responsible for the document, abbreviated as follows:

- FHCRC Fred Hutch Fred Hutchinson Cancer Research Center
- IACUC Institutional Animal Care & Use Committee
- IRB Institutional Review Board
- IRO Institutional Review Office
- OD Office of the Director
- OGC Office of the General Counsel

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## **SUPPORTING DOCUMENTS**

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Office of the Director Policy on Human Research Protection Program (0280)

IRB Policy 2.20 Training (038)

Biennial Policy and Supporting Document Review Form (0405)

Change Control and Training Procedures (0398)

Change Request Form (085)

Document Matrix (0413)

Form Template (0234)

Policy Template (0106)

Training Documentation Form (0399)

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## **REFERENCES**

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None