

Title:	Control and Distribution of Policies
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	<i>Karen Hansen 8/26/09</i>
	Signature/date
Effective Date:	
Policy:	1.1

PURPOSE

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

POLICY STATEMENT

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

DEFINITIONS

None.

REFERENCES

None.

PRINCIPLES/OVERVIEW

Written policies ensure a consistent level of quality and accountability in IRB activities. Proper change control and distribution of policies, in turn, ensure a consistent level of knowledge and training among the individuals affected by IRO policies.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to Institutional Review Office (IRO) staff, IRB members, employees of FHCRC and investigators from other institutions who submit research studies to the FHCRC IRB for review and approval.

PROCEDURES

Dissemination of New Information or changes to policies

- a. When new information that might affect the protection of human subjects at FHCRC (including laws, regulations, policies, procedures, or emerging ethical/scientific issues) is

learned by the IRO Director, Assistant Director, or staff members, the IRO staff is informed in a staff meeting or other appropriate venue.

- b. IRO Staff is assigned to review OHRP, NIH, and other information sources for new information affecting human subjects protection, and to report regularly to IRO staff.
- c. Relevant information is shared as appropriate among the IRO, IRB, Research Trials Office, General Counsel's Office, and other offices or groups.

Creation of Policies

The IRO Director or Assistant Director will determine when a new IRB policy is needed and notify the IRO SOP Administrator via the *Change Request Form*.

The IRO SOP Administrator uses the *Policy Template*. The IRO SOP Administrator assigns a number and title to the new policy. The IRO Director and Assistant Director review the proposed policy. The IRO Director or Assistant Director determines whether the additional reviews are needed as noted below:

- a. The IRB Committees. If a policy requires IRB review due to changes to their review process, all three IRB committees must approve the policy. Approvals are documented in the IRB meeting minutes.
- b. The Office of the General Counsel.
- c. Other individuals or groups that IRB, IRO Director or designee determines are necessary.

After all additional review are completed, and prior to the policy approval the Assistant Director and IRO SOP Administrator will review the policy to assess if changes are required to the IRO database (PIRO), staff forms or operational processes.

After all reviews are complete, the policy is approved when signed by the IRO Director. The policy takes effect on the "Effective Date" noted on page 1 of the policy.

Revision of Approved Policies

- a. The IRO SOP Administrator will receive an IRO *Change Request Form* to notify them of a requested revision to a policy.
- b. The IRO SOP Administrator will draft the revision to the policy when any part of the policy changes, to ensure compliance with the policy.
- c. Reviews and approvals of revisions are conducted as described above.
- d. After a policy is approved, the "old" version of the policy is stored in the "Archived" folder on the shared network drive by the IRO SOP Administrator. The version date of the old document is added to the file name (e.g. *Approval Dates Guidelines*)

Processing and Distribution of Approved Policies

When necessary approvals have been received and the policy is ready for signature, the revision history is updated.

The document is printed and forwarded to the IRO Director for signature and final approval.

New policies or revised policies: The SOP Administrator obtains the IRO Director's signature and date on the printed document. All signed policies are stored in file IR# 5215

The IRO Assistant Director or the SOP Administrator will add all new or revised policies and supporting documents to PIRO.

A PDF version of the document is posted to the IRO website. Investigators and research staff will have access to all IRB SOP from the IRO website. All IRB Policies will also be available to all IRB Members on eReview.

IRO Staff will be notified and trained on new or revised policies by the IRO SOP Administrator or Assistant Director. These will take place either via:

- a. Scheduled Training
- b. Staff Meetings
- c. Email

IRO staff will notify key individuals affected by the policy that a new or revised policy is available. Individuals requesting a copy of an IRO policy will be

- referred to the IRO website, or
- provided with a PDF document (*.pdf) or a printed paper copy

Word documents (*.doc) are maintained for internal editing processes use only and will be accessed only by IRO SOP Administrator or Assistant Director.

Periodic Review of Approved Policies and Supporting Documents

All IRB policies are reviewed by the Office of the Director and the IRBs once each calendar year.

- a. Policies identified as requiring revision will be revised in accordance with this policy.
- b. IRB policy development and changes are made with guidance and oversight of FHCRC General Counsel as outlined in step 1(b).
- c. The IRO Director and other individuals or groups may review approved policies more frequently, if needed.
- d. All IRO Supporting Documents are reviewed by the IRO Director once each calendar year.
 - Documents identified as requiring revision will be revised in accordance with this policy.
- e. The IRO will maintain the Office of Director (OD) Policy on Human Subject Research Protection Program. The OD Policy will be reviewed annually by the IRO Director and Vice President, General Counsel.
- f. The IRO Director, or Assistant Director and other individuals or groups may review approved supporting documents more frequently, if needed.

Format of Policies

Each policy contains a header with the following information:

- a. Title: Title of policy.
- b. Policy ID: Unique number assigned to the policy. It is a sequential numeric designation. Example: 1.1.
- c. Responsible Center Official: The individual or designee authorized to approve policies for the identified Responsible Office.
- d. Signature/date: The policy is approved when the Responsible Center Official signs and dates the policy.
- e. Responsible Office: The institution, division, or other administrative body that is responsible for the document.

- f. Effective date: The date when the policy becomes effective. This date may differ from the approval signature date.

Each policy may include the following section headings when applicable:

- a. Purpose: Defines the intent of the policy.
- b. Policy Statement: Summarizes the content of the policy.
- c. Definitions: Defines any terms that may be unfamiliar.
- d. References: Lists written material (other than supporting documents) referred to in the policy, such as regulations or guidance's.
- e. Individuals Affected by this Policy: Lists the individuals or groups responsible for, or affected by, the procedures outlined in the policy.
- f. 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) 45CFR46 regulation will only be cited unless the Food and Drug Administration (FDA) 21CFR56 regulation differs substantially.
- g. Supporting Documents: Additional documents used by individuals to complete processes outlined in a specific policy.

Each policy and supporting document will contains footer with the following information:

- Document file name/Version/effective date: The file name of the document the version and the date when the policy became effective

Electronic File Naming for Policies and Supporting Documents

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

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

Approved Polices and Supporting Documents are stored in the Policy tab in PIRO (database).

The generic appendix filename is Institution Title####, where #### is the 3-letter file extension. Institution refers to the institution, division, or other administrative body that is responsible for the document, abbreviated as follows:

- BaS Basic Sciences
- BOT Board of Trustees
- BPF Biologics Production Facility
- Seattle Children's
- CITI Collaborative Institutional Training Initiative
- EH&S Environmental Health & Safety
- ERC External Relations and Communications
- FHCRC Fred Hutchinson Cancer Research Center
- HB Human Biology
- HVTN HIV Vaccine Trials Network
- IRB Institutional Review Board
- IRO Institutional Review Office
- OD Office of the Director
- OGC Office of the General Counsel
- OSR Office of Sponsored Research
- PHS Public Health Sciences
- PSOC Puget Sound Oncology Consortium
- RTO Research Trials Office
- SCCA Seattle Cancer Care Alliance
- UW University of Washington

Version Control for Policies and Supporting Documents

- Minor administrative changes (correcting typos, grammatical corrections and etc.) not requiring review would increase the version number by 0.01 at a time. For example, version 1.0 would become version 1.01.
- For substantive changes to either a policy or supporting document rounds the version number to the next unit. For example, version 1.0 would become version 2.0.

SUPPORTING DOCUMENTS

Glossary of Terms and Acronyms

Policy Template

Change Request Form