Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Maintenance and Retention of IRB Documents
Policy:	2.17
Version:	5.00
Effective Date:	March 28, 2023
Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

Version History	Effective Date
4.00	01-21-2019
3.03	07-03-2017
3.02	06-15-2015
3.01	12-07-2009
3.00	08-01-2007
2.00	03-22-2007
1.00	11-03-2006

PURPOSE

This policy describes how the Fred Hutchinson Cancer Center (Fred Hutch) Institutional Review Office (IRO) maintains and retains Institutional Review Board (IRB) documents.

POLICY STATEMENT

The Fred Hutch IRO maintains IRB documents in accordance with federal, state, and local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) and regulations, as well as institutional policies, to ensure that they are stored safely and in a manner to maintain their confidentiality.

DEFINITIONS

None.

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. **IRB documents that are maintained by the IRO:**
    a. IRB records and materials relating to a specific research activity (study file). These may include:

- All submitted materials
- IRB application forms and supplement
- scientific review evaluations, if any, that accompany the application
- protocol, if applicable
- investigator brochure(s), if applicable
- informed consent documents
- DHHS-approved sample consent documents and protocol when they exist
- any determinations required by the regulations, including exempt determinations along with justification for those determinations
- the frequency for the next continuing review
- Records of continuing review activities, including the rationale for requiring continuing review of research that otherwise would not require continuing review when applicable under the 2018 Rule.
- recruitment material
- funding source document(s)
- modifications made to the study
- reports of unanticipated problems involving risk to subjects or others
- reports of noncompliance
- continuing review reports or other progress reports submitted by the investigator
- data and safety monitoring reports, if applicable
- significant new findings and statements about them provided to subjects.
- correspondence between the IRB and investigator related to the protocol.
- documents that were reviewed, but not approved
- external review committee documentation
- For initial and continuing review by the expedited procedure:
  - the specific permissible category
  - description of action taken by the reviewer
  - determinations required by the regulations along with protocol-specific findings justifying those determinations
  - The rationale for a determination that research that otherwise meets a category for expedited review is greater than Minimal Risk.

b. All documents related to an IRB meeting. These may include:
   - meeting minutes
   - agenda (full and expedited)
   - continuing education materials

c. Copies of all correspondence between the IRB and the investigators.

d. Reports of any injuries to research participants

e. Any correspondences or communication with research participants (see *IRB Policy 2.10 Research Participant Inquiries* [034])

f. Current and all previous copies of IRB member rosters

g. A statement of significant new findings provided to research participants

h. Current and previous versions of written procedures for the IRB, including:

- Checklists
- Forms
- SOPs
- Template letters
- Template minutes
- Worksheet

i. Documentation specifying the responsibilities that Fred Hutch and the IRO will undertake to ensure compliance with the requirements of the Common Rule, including documentation of reliance agreements.[1]

j. IRB member files, including current and previous copies of the following:

- Curriculum vitae/resume
- Appointment letters
- IRB Member training and orientation
- *HRP-283 - FORM - IRB Member Annual Certification*
- *HRP-563 - TEMPLATE LETTER - IRB Member Evaluation Feedback*

2. The Method of Maintaining IRB Documents

a. IRB Committee meeting

- All documents related to an IRB meeting are maintained in the following ways:
  - For IRB meeting held after the launch of Hutch IRB on March 29, 2023, IRB meeting documents are stored in the Hutch IRB electronic system.
  - For IRB meetings held prior to the launch of Hutch IRB (before March 29, 2023), IRB meeting documents are maintained as follows:
    - Hard copies are maintained in the Minutes - Agenda binder located in the IRO file room. Documents are filed according to the meeting date.
    - Electronic versions of the documents are maintained in the shared network drive. After each meeting, each document (full agenda, expedited agenda, minutes, result letters) are converted into PDF documents. This ensures the integrity of the documents.
    - Some files were microfiched. If a file was microfiched, the hard copy is destroyed. A copy of the microfiche file document is retained in the IRO and the original microfiche file document is stored in a safety deposit box arranged for by the Institutional Review Office Director.
- IRB records are clearly documented to indicate the decision reached by the IRB Committees.

b. IRB study file

- Stored in the Hutch IRB electronic system
- Study-specific information prior to the launch of Hutch IRB on March 29, 2023, are maintained as follows:
  - Hard copies are located in the IRO file room. Documents are filed according to a unique identification number associated with the research activity.
  - Electronic copies of the documents are maintained in the shared network drive.
- Each approved research activity is assigned a unique identification number. The identification number remains associated with the research activity throughout the life of the research activity.

[1] HHS: 45 CFR 46.115(a); FDA: 21 CFR 56.115(a)

- For studies that were approved at the launch of Hutch IRB and migrated to the new system, the unique identification number was maintained. For example, if the IR File # in the legacy system was IR# 8000, the study number in Hutch IRB was created as FHIRB00008000.

c. Correspondence NOT related to a specific study
   - Keep in a file related to that person or topic

d. IRB member rosters
   - File in IRB member roster binder

e. IRB membership records (e.g., curricula vita and resumes)
   - File in IRB member files

f. Policies and procedures:
   - File current policies and procedures in the IRB Library in the electronic system.
   - File replaced policies and procedures in the policies and procedures history file.

3. How long IRB documents are maintained

At Fred Hutch, the IRO maintains all IRB documents related to the IRB activity indefinitely. This includes IRB records related to research which was cancelled or stopped prior to participant enrollment.[2]

4. How long PIs retain research related documents

PIs should retain research related documents in accordance with the Fred Hutch *Records Retention and Destruction Policy*.

5. Access to and copying of IRB documents

Officials of federal agencies or departments or authorized Fred Hutch staff (e.g., PIs of their own IRB-approved studies) may forward their request to review IRB documents to the IRO Director or Assistant Director. Requests should be made at reasonable times and in a reasonable manner.

IRB documents will be copied by IRO staff assigned by the IRO Director or Assistant Director. Requests to copy research records for a study sponsored by a commercial sponsor must be forwarded to the Fred Hutch Office of the General Counsel in keeping with the proprietary nature of the documents.

6. Storage of IRB documents

All IRB records created prior to the launch of Hutch IRB (before March 29, 2023) that are closed or no longer valid are sent to the Fred Hutch long-term storage facility. *HRP-922 - PROCEDURE - Storage of Closed Files* outlines the following procedures:

- how IRB staff records the documents being sent to storage;
- how to store documents in a manner to maintain their confidentiality and safety; and
- the process to access these documents.

SUPPORTING DOCUMENTS

IRB Policy 2.10 Research Participant Inquiries (034)
HRP-283 - FORM - IRB Member Annual Certification
HRP-563 - TEMPLATE LETTER - IRB Member Evaluation Feedback
HRP-922 - PROCEDURE - Storage of Closed Files

[2] HHS: 45 CFR 46.115(b); FDA: 21 CFR 56.115(b)

REFERENCES

45 CFR 46.115

21 CFR 56.115

OHRP Compliance Activities: Common Findings and Guidance #20, #26, #28, #57, #69

FDA Information Sheets: Frequently Asked Questions: IRB Records