FRED HUTCH
Institutional Review Board

Policy/Procedure

Title:	Maintenance and Retention of IRB Documents
Policy:	2.17
Version:	4.00
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Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director for Karen Hansen 1/17/2019 *Signature/date*

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PURPOSE

This policy describes how the Fred Hutchinson Cancer Research 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. These may include:

- the new application form
- scientific review evaluations, if any, that accompany the application
- protocol, if applicable
- investigator brochure, if applicable
- informed consent documents
- DHHS-approved sample consent documents
- any determinations required by the regulations, including exempt determinations along with justification for those determinations
- the frequency for the next continuing review
- 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
- copies of all correspondence between the IRBs and the research investigators
- IRB screener forms
- 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

b. All documents related to an IRB meeting. These may include:

- meeting minutes
- agenda (full and expedited)
- meeting result letters
- continuing education materials

c. Reports of any injuries to research participants

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

e. A roster of IRB membership

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

g. Written procedures for the IRB

h. Miscellaneous correspondence

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]

2. The Method of Maintaining IRB Documents

a. IRB Committee meeting

- All documents related to an IRB meeting are maintained in 4 ways:
  - Hard copies are maintained in the Minutes - Agenda binder located in the IRO file room. Documents are filed according to the meeting date. IRB Staff follows the procedures outlined in the *Screener: Meeting Minutes/Agenda Binder Form* (0132). Documents such as signed confidentiality agreements are maintained only in the Minutes – Agenda binder.
  - eReview maintains the documents that are accessed by IRB members and staff for each Committee meeting. Documents are then archived and can be accessed by authorized IRO staff.
  - 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 research file

- 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.
- All of the IRB screeners used by IRB staff outline the procedures on how IRB files are maintained. These procedures ensure that documents are filed in such a manner that the review and approval history can be clearly recognized by any individual reviewing the 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]

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

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

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 that are closed or no longer valid are sent to the Fred Hutch long-term storage facility. The procedure document *Storage of Closed Files* (0265) 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)
Storage of Closed Files (0265)
Screener: Meeting Minutes / Agenda Binder (0132)

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