Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Closure and Re-Open
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) closes research studies and when and how closed research studies are re-opened.

DEFINITIONS

See *HRP-001 – Glossary of Terms and Acronyms* for full definitions of the following:

Closure: A study is closed when accrual of research participants is complete and all research activities have ceased. This means no interaction/intervention is planned for the purpose of research with research participants and no long-term follow-up. Data collection and analysis are complete; identifiable data has been destroyed or archived according to institutional policy; and all remaining biospecimens have been either destroyed or transferred to another IRB file, to the sponsor, or to a designated third party as required by protocol or contract.

Status Report

PRINCIPLES/OVERVIEW

It is the responsibility of the principal investigator (PI) to notify the IRO when a research study is permanently closed. The Institutional Review Board (IRB) has the authority to close a study if the IRB does not re-approve the study before its expiration date.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to the 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. Criteria for closure

An IRB file may not be closed by the PI unless **all** of the following criteria are met:

Topic	Closure Criteria
Enrollment or accrual	Study is permanently closed to enrollment or to the accrual of new data/specimen subjects (or the study never opened to enrollment/accrual)
Interventions and procedures	All participants have completed all study-related interventions and procedures

Data collection	The collection of private identifiable information is complete
Data analysis	The analysis of private identifiable information is complete
Specimens	All biospecimens have been used, destroyed, or transferred

The Office of General Counsel generally recommends the IRB file also be kept open until manuscripts are published, because questions during the publication process could necessitate additional data or specimen analysis.

If any of the above closure criteria cannot be met, you should maintain IRB coverage of the research.

2. Closing a Full or a Minimal Risk Study (not eligible for Status Reports)

The PI must submit a Continuing Review in Hutch IRB, indicating a request for closure, and attach *HRP-253 - FORM - Continuing Review Supplement*. The Designated Reviewer will approve the submission once they determine the closure is final. IRB staff will then send a closure letter through Hutch IRB, which notifies the PI, Primary Contact, and PI Proxies. For legacy studies approved prior to Hutch IRB, all relevant files will also be sent to storage. For more detailed information regarding storage, see *HRP-072 - POLICY - Maintenance and Retention of IRB Documents*.

IRB staff will follow *HRP-367 - WORKSHEET - Closures.*

A study is not closed if the status on *HRP-253 - FORM - Continuing Review Supplement* indicates that the study is closed to enrollment with continued data collection or intervention of previously enrolled research participants, or if biospecimens remain under the file. This study must remain open and continue to undergo IRB review.

3. Closing a Full or Minimal Risk Study (eligible for Status Reports)

For studies that qualify for the status report process per *HRP-133 - POLICY - Status Reports for IRB Files*, the PI must submit a Continuing Review in Hutch IRB, indicating a request for closure. *HRP-253 - FORM - Continuing Review Supplement* is not required for studies that are eligible for status reports. The PI must confirm that the study meets all the closing criteria in Hutch IRB. Once IRB staff determine the closure criteria are met, the submission may be administratively approved by IRB staff. IRB staff will then send a closure letter through Hutch IRB, which notifies the PI, Primary Contact, and PI Proxies. For legacy studies approved prior to Hutch IRB, all relevant files will also be sent to storage. For more detailed information regarding storage, see *HRP-072 - POLICY - Maintenance and Retention of IRB Documents*.

IRB staff will follow *HRP-367 - WORKSHEET - Closures.*

4. Closure due to Lapse in Approval

If a Continuing Review has not been submitted in Hutch IRB and approved by the IRB before the study expiration date, IRB approval will lapse. The PI, Primary Contact, and PI Proxies will receive an automated email from Hutch IRB as notification that the IRB approval has expired and the treatment/intervention with previously enrolled participants/patients must stop. If the PI wishes to continue to treat previously enrolled participants/patients, he/she needs to contact the IRB immediately to provide rationale for the continuation of this treatment/intervention.

The IRB must address on a case-by-case basis those rare instances where “failure to enroll” would seriously jeopardize the safety or well-being of an individual prospective participant.

If the PI has not submitted a Continuing Review or Closure within 6 months of the expiration date, IRB staff will administratively close the study. However, before a study is administratively closed, the IRB staff, including the IRB Operations Manager, diligently makes every effort to contact the study's PI to inform him/her that the study will be closed. IRB Staff will run the Close Study (Admin) activity in Hutch IRB. Once a study is Closed in Hutch IRB, this action cannot be undone. The PI must submit a New Study in Hutch IRB if he/she wishes to resume research activities. If the study is administratively closed, the PI will be notified immediately. The IRB Operations Manager or IRB Analyst will call or email the PI regarding the closure. The PI is sent *HRP-511b - TEMPLATE LETTER - Closure Due to Lapse in Approval*.

5. Closure Initiated by the IRB

The IRB may suspend or terminate a study based on review of unanticipated problems involving risks, study participant complaints/concerns requiring evaluation, or serious or continued noncompliance with federal regulations or IRB policies. For more detailed information regarding these incidences, please see *HRP-131 - POLICY - Unanticipated Problems Involving Risks to Subjects or Others* and *HRP-117 - POLICY - Requirements for Reporting to Institutional and External Officials*.

6. Exempt Study Closure

The PI may initiate closure of an Exempt file by submitting a Continuing Review in Hutch IRB, indicating a request for closure. *HRP-253 - FORM - Continuing Review Supplement* is not required for studies that are Exempt. The PI must confirm that the study meets all the closing criteria in Hutch IRB. Once IRB staff determine the closure criteria are met, the submission may be administratively approved by IRB staff. IRB staff will then send a closure letter through Hutch IRB, which notifies the PI, Primary Contact, and PI Proxies. For legacy studies approved prior to Hutch IRB, all relevant files will also be sent to storage. For more detailed information regarding storage, see *HRP-072 - POLICY - Maintenance and Retention of IRB Documents*.

IRO staff will follow the process described in *HRP-367 - WORKSHEET - Closures.*

7. External IRB File

When a Fred Hutch PI is relying on an external IRB, the Fred Hutch PI must follow the closing procedures that are required by the external IRB. Additionally, the PI must alert the Fred Hutch IRO of the closure by the External IRB in Hutch IRB. The study team will run the Add Comment activity in Hutch IRB and attach closure documentation from the external IRB to the activity, alerting the assigned IRB Coordinator. *HRP-253 - FORM - Continuing Review Supplement* is not required for external IRB studies.

PIs have a 30-day grace period after the expiration date notify the IRO of the study's continuing review or closure. If after six months, documentation of IRB approval is not provided to renew the external IRB file, the IRO staff will follow the process described in *HRP-887 - WORKSHEET – Closures - External* to administratively close the study record.

8. Closing Sites in a Multi-Site Trial

Refer to *HRP-130 - POLICY - IRB Reliance Agreements* for terminating a reliance agreement.

a. When Fred Hutch is relying on an external IRB, refer to Section 6, External IRB File.

b. When Fred Hutch is the IRB of Record for a Participating Site outside the cancer consortium, the participating site must provide *HRP-898 - FORM - Closure - Participating Site* to request closure. The Fred Hutch study team submits this form using the Comment activity on the site workspace.

c. Once IRB staff determine the closure criteria are met for the site, staff may administratively close the site. A closure letter will be sent to the PI, Primary Contact, PI Proxies, and Site PI.

9. Sponsor Request to Access Patients' Records of a Closed IRB File

If a sponsor requests to review patients' medical records associated with a closed study, the IRB file does not need to be re-opened. However, a memo documenting this request must be added to the IRB file. Staff will draft a memo stating who requested the records and when and what will be reviewed. For studies in Hutch IRB, staff will attach the memo to a Private Comment on the study record. For legacy studies that were closed prior to the launch of Hutch IRB, staff will retrieve the applicable IRB file(s) from storage and include the memo in the file.

However, if the sponsor or PI is requesting to review patients' medical records to collect NEW data/information, the closed study must be re-opened by creating a new initial study in Hutch IRB.

10. Reopening a Closed Study

Once a study is closed in Hutch IRB, the record cannot be re-opened. If further activity needs to occur on the study, the investigator must create a new study record in Hutch IRB. Refer to *HRP-121 - POLICY - New Application* for the procedures for submitting a new study. A cover letter explaining the

reason for study reactivation is to accompany this type of reactivation request. The documents are forwarded to a Designated Reviewer, or to the appropriate IRB committee.

SUPPORTING DOCUMENTS

HRP-001 - Glossary of Terms and Acronyms
HRP-072 - POLICY - Maintenance and Retention of IRB Documents
HRP-117 - POLICY - Requirements for Reporting to Institutional and External Officials
HRP-121 - POLICY - New Application
HRP-130 - POLICY - IRB Reliance Agreements
HRP-131 - POLICY - Unanticipated Problems Involving Risks to Subjects or Others
HRP-133 - POLICY - Status Reports for IRB Files
HRP-253 - FORM - Continuing Review Supplement
HRP-367 - WORKSHEET - Closures
HRP-511b - TEMPLATE LETTER - Closure Due to Lapse in Approval
HRP-887 - WORKSHEET - Closures - External
HRP-898 - FORM - Closure - Participating Site

REFERENCES

OHRP Guidance on IRB Continuing Review of Research
FDA Guidance: IRB Continuing Review after Clinical Investigation Approval

VERSION HISTORY

Version	Effective Date
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