FRED HUTCH
Institutional Review Board

Policy/Procedure

Title:	Closure and Re-Open
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Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Meghan Scott, IRO Director  Digitally signed by Meghan Scott Date: 2022.02.28 10:59:33 -08'00'
	Signature/date

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3.04	05-15-2014
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3.00	05-01-2010
2.02	12-21-2009
2.01	01-14-2008
2.00	08-01-2007
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POLICY STATEMENT

This policy describes how the Fred Hutchinson Cancer Research Center (Fred Hutch) Institutional Review Office (IRO) closes research studies and when and how closed research studies are re-opened.

DEFINITIONS

See *IRB Glossary of Terms and Acronyms* (050) 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 by 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. Closing a Full or a Minimal Risk Study (<u>not</u> eligible for Status Reports)

The PI must submit a *Continuing Review Report* (CRR) (045). If the IRB Chair (or designee) determines that the closure is final, the file will be closed, processed, the database (PIRO) is updated, and all the relevant files are sent to storage. For more detailed information regarding storage, see *IRB Policy 2.17 Maintenance and Retention of IRB Documents* (023).

IRB staff will follow the *Screener: Closures* (0120). The closure date entered into PIRO is the IRB Chair's (or designee) signature date or the expiration date of the file, whichever comes first.

A study is not closed if the status on the CRR indicates that the study is closed to accrual 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.

2. Closing a Full or Minimal Risk Study (<u>eligible</u> for Status Reports)

For studies that qualify for the status report process per *IRB Policy 2.28 Status Reports for IRB Files* (0403), the PI responds to the Status Report Notification to close the study. The PI must confirm that the study meets the definition for Closure. Once IRB staff determine the closure criteria are met, the file will be closed, the database (PIRO) is updated, and all the relevant files are sent to storage. For more detailed information regarding storage, see *IRB Policy 2.17 Maintenance and Retention of IRB Documents* (023).

IRB staff will follow the *Screener: Closures* (0120). The closure date entered into PIRO is the date IRB staff confirm the criteria for Closure have been met or the expiration date of the file, whichever comes first.

3. Closure Initiated by the IRB

The IRB may close a study if IRB approval lapses or if the PI does not respond to the Status Report Notification before the end of the designated check-in period. However, before a study is closed by the IRB, 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 could be closed. If the IRB closes the study, the PI will be notified immediately and IRB staff will follow the *Screener: Closures* (0120). The IRB Operations Manager or IRB Analyst will call or email the PI regarding the closure. The IRB forwards a *Closure Letter* (086) 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.

The IRB may also 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 *IRB Policy 2.6 Unanticipated Problems Involving Risk to Subjects or Others* (0224) and *IRB Policy 2.8 IRB Requirements for Reporting to Institutional and External Officials* (021).

4. Exempt File Closure

The PI may initiate closure of an Exempt file with an email notification to IRO staff confirming that all closure criteria have been met. A *Research Modification Form* (062) requesting closure of the file may also be used to close an exempt file. IRO staff will follow the process described in the *Screener: Closures* (0120).

5. 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 submit an *External IRB Coversheet – Continuing Review or Other* (0321) requesting closure to the IRO. The date of closure should be provided in addition to closure documentation from the external IRB.

If the PI fails to timely submit a renewal or study closure within 30 days after the expiration date, the file is presumptively closed. If after six months, documentation of IRB approval is not provided to re-open the external IRB file, the IRO staff will follow the process described in the *Screener: Closures* (0120) to close and archive the file.

6. Closing Sites in a Multi-Site Trial

Refer to *IRB Policy 2.24 IRB Reliance Agreements* (0178) for terminating a reliance agreement.

a. When Fred Hutch is relying on an external IRB, refer to Section 5, External IRB File.

b. When Fred Hutch is the IRB of Record and the site has a separate Participating Site file, the participating site must submit a site-specific Continuing Review Report (045) and indicate the site is closing.

c. When Fred Hutch is the IRB of Record and the site is only listed on the Multi-Center Supplement (i.e. no Participating Site file), indicate that the site has closed on the Multi-Center Supplement at the time of Continuing Review for the protocol.

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

If a sponsor requests to review patients' medical records associated with a closed IRB file, the IRB file does not need to be re-activated. However, a memo documenting this request must be added to the IRB file. Staff will retrieve the applicable IRB file(s) from storage and place a memo stating who requested the records and when and what will be reviewed.

However, if the sponsor or PI is requesting to review patients' medical records to collect NEW data/information, the closed IRB file must be re-activated.

8. Reopening a Closed File

Within 6 months (or less) of the initial closure (**not Status Report eligible**): A *CRR* may be submitted for expedited or full review in order to reactivate the file. Refer to *IRB Policy 2.2 Continuing Review* (010) for completion of this type of report.

Within 6 months (or less) of the initial closure (**Status Report eligible**): A *Research Modification Form* (062) may be submitted for expedited or full review in order to reactivate the file. The modification should explain the reason for study reactivation.

More than 6 months from the initial closure: An appropriate new application must be submitted to the IRB. Refer to the *IRB Policy 2.1 New Application* (028) for the procedures for submitting a new application. A cover letter explaining the reason for study reactivation is to accompany this type of reactivation request. The documents are forwarded to the IRB Chairperson or designee for expedited review, or to the appropriate IRB committee.

9. IRB Reporting Requirement

All information, including closure date, is reported to the IRB on the next available agenda.

SUPPORTING DOCUMENTS

IRB Policy 2.1 New Application (028)
IRB Policy 2.2 Continuing Review (010)
IRB Policy 2.6 Unanticipated Problems Involving Risk to Subjects or Others (0224)
IRB Policy 2.8 IRB Requirements for Reporting to Institutional and External Officials (021)
IRB Policy 2.17 Maintenance and Retention of IRB Documents (023)
IRB Policy 2.24 IRB Reliance Agreements (0178)
IRB Policy 2.28 Status Reports for IRB Files (0403)
Closure Letters (086)
Continuing Review Report (045)
IRB Glossary of Terms and Acronyms (050)
Research Modification Form (062)
Screener: Closures (0120)

REFERENCES

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