

Title:	Closure and Re-Open
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	<i>Signature/date</i>
Effective Date:	January 14, 2008
Policy:	2.9

POLICY STATEMENT

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

DEFINITIONS

None

REFERENCES

OHRP Guidance on Continuing Review

PRINCIPLES/OVERVIEW

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

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

1. Closure by the PI

The PI must submit both a *Continuation Review Report* (CRR) and a manuscript or abstract, if appropriate to the IRO. If the IRB Chairperson 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 2.17 Policy Maintenance and Retention of IRB Document*.

IRB staff will follow the *Screener: Closure*. The closure date entered into PIRO is the IRB Chairperson's signature date or the expiration date of the file, whichever comes first.

The study is not closed if the status indicates on the CRR that the study is closed to accrual with continued data collection or intervention of previously enrolled subjects. The study must continue to undergo IRB review on a continuation basis.

2. Closure Initiated by the IRB

The Institutional Review Board (IRB) may close a study if the IRB approval expires. However, before a study is closed by the IRB, the IRB staff, including the IRO Assistant Director, diligently makes every effort to contact the PI/study that the study may be closed. If the IRB closes the study, the PI will be notified immediately and IRB staff will follow the *Screener: Closure*. The IRO Assistant Director or IRB analyst will call the PI regarding the closure. The IRB forwards a *Closure Letter* notifying that accrual is temporarily closed and the treatment/intervention with previously enrolled participants/patients must stop. If the principal investigator wishes to continue to treat previously enrolled participants/patients, he/she needs to contact the IRO 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 of IRB approved procedures. For more detailed information regarding these incidences, please see *IRB 2.6 Policy Unanticipated Problems Involving Risk to Participant and Others*, and *IRB 2.8 Policy IRB Requirements for Reporting to Institutional and Governmental Officials*.

3. Category 3 Closure

When the Scientific Review Committee (SRC) determines that a protocol is eligible for Category 3 (Standard Treatment status), a protocol modification form with final findings is sufficient. Minutes from the SRC documenting the determination should be attached.

4. Exempt and Cooperative Files

A protocol modification form closing the file is sufficient documentation. No final report is needed.

5. Sponsor Requested to Access Patients' Records of a Closed IRB File

If a sponsor has requested to review patients' medical records of a closed IRB file, for audit purposes, the IRB file does not need to be re-activated. However, a memo documenting this request must be added to the IRB file. Retrieve the applicable IRB file(s) from storage and place a memo stating whom, when and what will be reviewed.

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

6. Reopening a Closed File

Within 6 months (or less) of the initial closure: A CRR may be submitted for expedited or full review in order to reactivate the file. Refer to *IRB 2.2 Policy Continuation Review* for completion of this type of report.

More than 6 months of the initial closure: A new application must be submitted to the IRB. Refer to the *IRB 2.1 Policy New Application* 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 that most recently reviewed the activity prior to closure for full review.

7. 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

IRB Policy 2.2 Continuation Review

IRB Policy 2.6 Unanticipated Problems Involving Risk to Participant and Others

IRB Policy 2.8 IRB Requirements for Reporting to Institutional and Governmental Officials

RB Policy 2.17 Maintenance and Retention of IRB Documents

Screener: Closures

Closure Letter