FRED HUTCH
Institutional Review Board

Policy/Procedure

Title:	Status Reports for IRB Files
Policy:	2.28
Version:	3.00
Effective Date:	February 24, 2020
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Meghan Scott, IRO Director  2/21/2020 *Signature/date*

Version History	Effective Date
2.00	12-30-2019
1.00	01-21-2019

POLICY STATEMENT

Continuing review of approved human research studies occurs depending on the degree of risk of the study. Where federal regulations allow, continuing review may not be required in certain circumstances. When continuing review of ongoing research is not required, Principal Investigators (PIs) of these eligible research studies provide the Institutional Review Office (IRO) with a brief annual status report.

DEFINITIONS

See *IRB Glossary of Terms and Acronyms* (050) for full definitions of the following:

2018 Requirements of the Common Rule

Continuing Review

Exempt

IRB of Record

Long-Term Follow-Up

Minimal Risk

Status Report

PRINCIPLES/OVERVIEW

The purpose of Status Report Requests is to maintain a centralized record of all active, non-exempt human subjects research involving Fred Hutch, and to ensure consistency between IRB records and each Principal Investigator's (PI) study records. It also provides an opportunity to remind the PIs of their obligations to submit any proposed research modifications and reportable events to the IRB according to established policies.

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. Eligibility for Utilizing Status Report Updates (in lieu of Continuing Review)

For research studies subject to only the 2018 requirements of the Common Rule, annual continuing review is not required in certain cases. **However**, if a study is subject to FDA regulations, continuing review must still be conducted.

There are three requirements for utilizing the status report process:

1. The research is not FDA-regulated; and
2. The research study was initially approved by the IRB on or after January 21, 2019; and
3. The research is eligible for expedited review, either because it was determined to be no more than minimal risk by the IRB or because the research study status is currently "closed to accrual, in long-term follow-up only" or "closed to accrual, in data analysis only."

Note: Even if these three requirements are met, the IRB retains the authority to require Continuing Review. If the IRB determines Continuing Review is required, it must document this decision with sufficient rationale.[1]

Exempt research, including research reviewed by the IRB in accordance with the limited IRB review described in 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8), is not required to follow the status report process.

2. Process for Sending Status Report Requests

IRO staff will initiate the Status Report Request email for each eligible study annually. IRO Staff will follow the *Continuing Review Report and Status Report Notification Procedures* (0107). The PI and IRO contact will be provided information as outlined in the *Status Report Request Email Template (Fred Hutch IRB)* (0427) or *Status Report Request Email Template (External IRBs)* (0443).

3. PI Responsibility

It is the responsibility of the PI, or the designated IRO contact, to respond to the Status Report Request email to confirm the current status of the study. It is also the responsibility of the PI to follow *IRB Policy 2.5 Modification to Ongoing Activities* (025) to obtain prospective approval for any changes in research, and *IRB Policy 1.11 Reporting Obligations for PIs* (032) to submit reportable events in an appropriate timeframe.

4. Requirements When Fred Hutch Is Relying on an External IRB

When a Fred Hutch PI is relying on an external IRB of Record, the approval period and level of review is that which the external IRB determines. It is the responsibility of the Fred Hutch PI to contact the external IRB's office to become familiar with the necessary review procedures.

If the external IRB has allowed the study to forego continuing review, the Fred Hutch IRO will annually send a Status Report Request to the PI and IRO contact to obtain confirmation that the study is ongoing. It is the responsibility of the Fred Hutch PI, or the designated IRO contact, to respond to this request in the timeframe described below.

5. Failure to Respond to the Status Report Request

If the PI or IRO contact does not respond to the Status Report Request within ten (10) business days of the Status Report Request, IRO staff will contact the PI and IRO contact as a reminder that the response is due and requires confirmation. If the PI or IRO contact does not respond to the Status Report Request within another five (5) business days, IRO staff will again follow-up with the PI or IRO contact.

If the PI or IRO contact fails to respond to the follow-up contact attempts, the PI's senior operations director will also be contacted. If no response is received within five (5) business days of the final attempt, the study will be presumed to be completed and the IRB file will be closed per *IRB Policy 2.9 Closure and Re-Open* (08).

[1] HHS: 45 CFR 46.109(f)(1), 46.115(a)(3)

6. IRO Staff Responsibilities

a. The IRO staff emails a Status Report Request to PIs and IRO contact, and follows up as needed, for each relevant research activity approved at Fred Hutch as noted above. Refer to *Continuing Review Report and Status Report Notification Procedures* (0107) for instructions.

b. The IRO staff utilizes the screeners as appropriate for the research activity to ensure that all information is received in the IRO. Screeners that may be used include:

Screener: External IRB Cover Sheet – Continuing Review or Other (0127)
Screener: Status Report Requests (0431)

If any necessary information is missing, the PI or IRO contact is contacted. The information can only be processed once all deficiencies are rectified. Once complete, the activity is administratively reviewed following the appropriate screener.

c. If IRO staff is unable to resolve concerns with the PI or IRO contact, or if there are concerns regarding possible unreported noncompliance, the IRO staff will discuss with the IRO Assistant Director. An IRB Chair may be consulted, and/or the item may be escalated to a convened IRB meeting as needed.

d. If the PI or IRO contact responds to the Status Report Request and requests closure of the IRB file, IRO staff will confirm that all closing criteria are met and proceed with closing the file as outlined in *IRB Policy 2.9 Closure and Re-Open* (08).

SUPPORTING DOCUMENTS

IRB Policy 1.11 Reporting Obligations for PIs (032)
IRB Policy 2.5 Modification to On-Going Activities (025)
IRB Policy 2.9 Closure and Re-open (08)
Continuing Review Report and Status Report Notification Procedures (0107)
Glossary of Terms and Acronyms (050)
Screener: Status Report Requests (0431)
Screener: External IRB Cover Sheet – CRR or Other (0127)
Status Report Request Template (External IRBs) (0443)
Status Report Request Template (Fred Hutch IRB) (0427)

REFERENCES

45 CFR 46.104
45 CFR 46.109
45 CFR 46.115