Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Status Reports for IRB Files
Policy:	2.28
Version:	4.00
Effective Date:	March 28, 2023
Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

Version History	Effective Date
3.00	02-24-2020
2.00	12-30-2019
1.00	01-21-2019

POLICY STATEMENT

Periodic 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, Hutch IRB sends the Principal Investigators (PIs) of these eligible research studies an automated email reminder every year on the anniversary of the initial approval.

DEFINITIONS

See *HRP-001 - SOP - Glossary of Terms and Acronyms* 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 Emails is to help the Institutional Review Office (IRO) maintain a centralized record of all active, 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 has progressed to a study status of "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] The rationale will be included either in the minutes if determined at a full meeting, or in Hutch IRB if determined via designated review.

2. PI Responsibility

Upon receipt of the automated Hutch IRB status report email, it is the responsibility of the PI to consider whether any changes to the study are needed or whether any new information needs to be reported. 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 a Reportable New Information (RNI) in an appropriate timeframe.

3. 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 Email to the PI and Primary Contact and PI proxies to ask them to consider whether the current study status in Hutch IRB is accurate and to make any updates to study funding.

SUPPORTING DOCUMENTS

IRB Policy 1.11 Reporting Obligations for PIs (032)

IRB Policy 2.5 Modification to On-Going Activities (025)

HRP-001 - SOP - Glossary of Terms and Acronyms

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

REFERENCES

45 CFR 46.104
45 CFR 46.109
45 CFR 46.115