Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Suspension or Termination of IRB Approval
Policy:	1.10
Version:	7.00
Effective Date:	March 28, 2023
Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

Version History	Effective Date
6.00	02-24-2020
5.00	01-21-2019
4.02	06-19-2017
4.01	05-15-2009

POLICY STATEMENT

This policy describes how the Fred Hutchinson Cancer Center (Fred Hutch) Institutional Review Board (IRB) Chair (or designee) or the IRB Committee makes determinations for suspending or terminating research and the IRB process for determining which incidences require prompt reporting to Institutional Officials and applicable federal agencies.

DEFINITIONS

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

Institutional Official / Organizational Official

Noncompliance

Suspension of IRB Approval

Termination of IRB approval

Unanticipated Problems that Involve Risk to Research Participants or Others

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to Institutional Review Office (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.

PRINCIPLES/OVERVIEW

It is the responsibility of the IRB to determine if any reports received from a study investigator and/or research staff warrant study suspension or termination and to promptly report such findings to the appropriate Institutional Officials and applicable federal agencies.

PROCEDURES

1. Reporting Requirements

Reporting by Principal Investigators and Study Staff: Principal investigators and their study staff are required to submit Reportable New Information (RNI) submissions in Hutch IRB in accordance with IRO policies:

- *IRB Policy 1.9 Noncompliance* (029)
- *IRB Policy 2.6 Unanticipated Problems Involving Risks to Subjects or Others* (0224)

Reporting by Others: Persons other than principal investigators and study staff reporting should report in accordance with *IRB Policy 1.9 Noncompliance* (029).

2. Type of Review

Once a RNI is submitted, IRO staff will route the submission to a Designated Reviewer for review. Generally, RNI submissions are assigned to the Chair of the Committee that initially approved the research; however, RNIs may be reviewed by any Designated Reviewer. The Designated Reviewer will be provided with *HRP-378 - WORKSHEET - IRB Chair or Designee Report Checklist for Unanticipated Problems or Noncompliance* for the review.

The Designated Reviewer may also discuss the RNI submission with the IRO Director and/or Assistant Director and General Counsel, if appropriate. The Designated Reviewer will determine the method of IRB review of the report based on the possible increase of risk to research participants, the welfare and safety of research participants; or, if data integrity of the study is affected due to continued noncompliance or an unanticipated problem which meets the criteria as defined above. The Designated Reviewer is authorized to suspend or terminate the study in order to protect the rights and welfare of currently enrolled participants, including studies that have an exempt determination. The Designated Reviewer will forward the report to be reviewed by the full IRB Committee, one of the following methods of review will be used:

1. Regularly scheduled IRB meeting: The IRB will review the event at a regularly scheduled meeting if the event occurred before the meeting date. The IRB staff notifies the PI that the incident will be reviewed at the next scheduled IRB meeting.
2. Emergency meeting: An emergency meeting is a meeting that takes place outside the regularly scheduled IRB meeting dates. If review must take place immediately, an emergency meeting is scheduled. The PI will be notified that an emergency meeting will be scheduled.

3. Actions and Decisions by Convened IRB

The IRB Committee will be forwarded a copy of *HRP-378 - WORKSHEET - IRB Chair or Designee Report Checklist for Unanticipated Problems or Noncompliance* and may make any of the following determinations:

- Require a response from the PI with a plan for corrective actions.
- Initiate audits of the active protocols involved.
- Require that research participants previously enrolled in the study be contacted and provided with additional information and/or re-consented.
- Require more frequent review of the study.
- Suspend or terminate the study.
- Freeze the sponsored research grant account.
- Determine that the data collected cannot be used for publication.
- Report to the sponsor, administrative officials, and governmental agencies, e.g., FDA, OHRP.
- Disqualify the PI from conducting research involving human research participants at Fred Hutch.

4. Suspensions or Termination of IRB Approval

If the committee determines the previously approved research is not being conducted in accordance with the IRB's requirements or that the research encountered new findings or new information that may have changed the risks-benefits assessment, the IRB may suspend or terminate IRB approval of the research, including studies that have an exempt determination.[1]

Actions taken when Study Approval is Suspended by the IRB (if applicable):

- Accrual of new research participants into the study will cease
- Currently enrolled research participants will be notified of the Suspension.
- The PI will be informed via a result letter if the IRB requires or permits follow-up for safety considerations.
- If the IRB requires/permits follow-up with research participants for safety considerations, adverse events should be reported to the IRB and sponsor (if applicable).
- If the IRB requires the withdrawal of research participants, they will consider the rights and welfare of research participants.

Actions taken when Study Approval is Terminated by the IRB:

- Currently enrolled research participants are notified of the termination.
- Procedures for withdrawal of research participants consider the rights and welfare of research participants.
- The research participants are informed if the IRB requires or permits follow-up for safety considerations.
- If the IRB requires/permits follow-up with research participants for safety considerations, adverse events should be reported to the IRB and sponsor (if applicable).

Any suspension or termination of IRB approval shall be communicated to the PI within 24 hours of the IRB's determination by the IRB Operations Manager (or designed). The initial communication will be followed by a formal result letter within 48 hours of the suspension or termination. The result letter will include a statement of the reasons for the IRB's action. The PI, Primary Contact, and PI Proxies will receive an automated email notification from Hutch IRB that provides a link to the submission, where the formal result letter is available for download. Any suspension or termination of IRB approval will be reported to appropriate institutional and government officials as detailed in *IRB Policy 2.8 IRB Requirements for Reporting to Institutional Official and External Officials* (021). If the study is a UW Consortium study, the UW HSD will be notified.[2]

IRO staff will notify the IRB Director (or designee) to ensure the study status in Hutch IRB is updated to Suspended or Terminated, as determined by the IRB.

In the case of suspension, the PI may request, in writing with appropriate rationale, that the IRB permit currently enrolled research participants to receive treatment and/or intervention based on their health needs.

The PI may request to re-open a previously suspended or terminated study and must submit their request in writing to the IRB. Such requests will receive full IRB review upon receipt.

SUPPORTING DOCUMENTS

IRB Policy 1.9 Noncompliance (029)

IRB Policy 2.6 Unanticipated Problems Involving Risks to Subjects or Others (0224)

IRB Policy 2.8 IRB Requirements for Reporting to Institutional and External Officials (021)

HRP-001 - SOP - Glossary of Terms and Acronyms

HRP-378 - WORKSHEET - IRB Chair or Designee Report Checklist for Unanticipated Problems or Noncompliance

[1] HHS: 45 CFR 46.113; FDA: 21 CFR 56.113
[2] HHS: 45 CFR 46.108(a)(4)(ii); FDA: 21 CFR 56.108(b)(3)

REFERENCES

45 CFR 46.108

45 CFR 46.113

21 CFR 56.108

21 CFR 56.113

OHRP Guidance on Reporting and Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events January 15, 2007

Office of Human Research Protections (OHRP) Compliance Activities: Common Findings and Guidance #71 (a)-(c) and (m)-(o), and #72

Food and Drug Administration (FDA) Information Sheets: Continuing Review After Study Approval