Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Approval Date Guidelines and Turnaround Times
Version:	1.00
Effective Date:	February 3, 2025
Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

POLICY STATEMENT

It is the policy of the Fred Hutchinson Cancer Center (Fred Hutch) Institutional Review Office (IRO) that Institutional Review Board (IRB) approved activities are given approval dates per *HRP-302 - WORKSHEET - Approval Intervals*. *HRP-150 - IRB Turnaround Times* provides the turnaround time for IRO staff to process and to provide the approval documents to principal investigators (PI) in a timely manner.

DEFINITIONS

None

PRINCIPLES/OVERVIEW

HRP-302 - WORKSHEET - Approval Intervals is used by the IRO staff to determine the approval dates for all activities related to IRB review (i.e., initial review, continuing review, and modifications).

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to IRO staff, IRB members, employees of Fred Hutch, investigators from other institutions who submit research studies to the Fred Hutch IRB for review and approval, study monitors, and auditors or sponsors.

PROCEDURES

1. Approval Date Guidelines

a. *HRP-302 - WORKSHEET - Approval Intervals* outlines the approval dates given for different outcomes resulting from the IRB review and approval process.

b. IRB approval dates are communicated to investigators through a formal IRB determination letter.

2. Determining Approval Dates at Initial and Continuing Review

Note: The terms “Last day of approval period” and “Approval end date” are synonymous and are both used within Hutch IRB.

Note: The below “Last day of approval period” information for either Full or Designated Review will not apply to Exempt determinations, Not Human Research determinations, or studies determined to not require Continuing Review according to the 2018 Requirements of the Common Rule. (Please see *HRP-133 - POLICY - Status Reports for IRB Files* for further details.)

a. Full review: The “Approval date” is the date of the convened IRB meeting where the criteria for approval were determined to be met and the “Last day of approval period” is the date of the convened meeting plus the approval period minus one day. The “Last day of approval period”

indicates the last day the study is approved. The Expiration Date is the day after this date, which is the first date that the study is no longer approved and when study activities must stop. For example, if a study is approved from 10/2/2023 to 10/1/2024, the study may use its approved documents, such as an approach letter or consent form, until midnight on 10/1/2024. No research activity may be conducted on the 10/2/2024.

The “Effective date” for full review activities is determined as follows:

i. Full review items ”Approved” at a convened meeting: The “Effective date” is the same date as the IRB Committee meeting. For example, if the IRB Committee meeting was 1/10/2023 and the initial study was “Approved”, the approval period for the initial study is 1/10/2023 to 1/9/2024 and the “Effective date” is 1/10/2023.

ii. Full review items approved with “Modifications required to secure approval” at a convened meeting: The “Effective date” is the date IRB staff or a Designated Reviewer verify that the required modifications have been made.

The “Approval date” in this scenario is the date of the convened IRB Committee meeting. For example, if the IRB approved the study with modifications required to secure approval at a meeting on 1/20/2023, and IRB staff reviewed PI’s response and verified that the required modifications had been made on 1/29/2023, the initial approval period for this study is 1/20/2023 to 1/19/2024. The “Effective date” is 1/29/2023, which is the date IRB staff or the Designated Reviewer confirmed the required modifications were made.

Designated review: The “Approval date” is the date the Designated Reviewer granted approval. The “Last day of approval period” is the “Approval date” plus the approval interval minus one day. For example, if the Designated Reviewer approved the study on 1/10/2023, the approval period is 1/10/2023 to 1/9/2024.

3. Finalizing and Stamping IRB Approved Documents

a. The “IRB Approval” stamp is applied to the following documents:

i. Protocol
ii. Consent Forms and Consent Scripts
iii. Recruitment or Participant-Facing Materials, some examples are listed below:
- Surveys
- Questionnaires
- Web Content
- Flyers

iv. Product information (i.e., Investigator Brochure(s), Package Inserts, Device Manuals, etc.)

b. In general, the following documents to <u>not</u> receive an “IRB Approval” stamp:

i. IRB forms and supplements
ii. Ancillary review documentation (e.g., SRC approval, Radiation Safety, OGC documentation, etc.)
iii. DSMB/DSMC minutes and reports
iv. Charters
v. HIPAA authorization forms

c. At the time of continuing review, approved IRB documents that have <u>not</u> been modified are not finalized or re-stamped.

4. Correcting Wrong Approval Dates

a. If a correction is needed, for example, if an IRB determination letter listed incorrect approval dates, a corrected letter will be issued through Hutch IRB, which notifes the PI, Primary Contact, and PI Proxies.

5. IRB Turnaround Times

HRP-150 - IRB Turnaround Times indicates the timeframe in which approved documents should be processed and forwarded back to the PI, PI Proxies, and Primary Contact. These guidelines also indicate the turnaround time to forward documents to appropriate IRO staff, IRB Chair, Institutional Officials, or regulatory agencies.

SUPPORTING DOCUMENTS

HRP-133 - POLICY - Status Reports for IRB Files

HRP-150 - IRB Turnaround Times

HRP-302 - WORKSHEET - Approval Intervals

REFERENCES

FDA Guidance: IRB Continuing Review after Clinical Investigation Approval

OHRP Compliance Activities: Common Findings and Guidance (July 10, 2002) - #42

OHRP Guidance on IRB Continuing Review of Research

OHRP Guidance on Written IRB Procedures

VERSION HISTORY

Version	Effective Date
-	-