Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Emergency Use or Compassionate Use of an Investigational Drug or Device
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) to comply with federal regulations and institutional policies governing emergency use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain Institutional Review Board (IRB) approval. “Not sufficient time” for IRB review and approval is defined by Fred Hutch as seven (7) business days or less.

The University of Washington Human Subjects Division (UWHSD) or Seattle Children’s IRB manages the notification of emergency use, depending on the location of the activity. For non-emergency uses, Fred Hutch IRB reviews the activity.

Fred Hutch does not conduct, or plan to conduct, planned emergency research as described in 21 CFR 50.24.

DEFINITIONS

None

PRINCIPLES

Emergency Uses:

Whenever possible physicians are to notify the appropriate IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use. The appropriate IRB for emergency uses depends on the location of administration of the emergency use:

- The University of Washington Human Subjects Division (HSD) manages the notification of emergency use when the use will or did occur at the Fred Hutchinson Cancer Center in-patient clinic or at the University of Washington (regardless of the primary appointment of the physician). The physician follows UW HSD’s Single Patient Emergency Use SOP.
- The Seattle Children’s IRB manages the notification of emergency use when the use will or did occur at Seattle Children’s (regardless of the primary appointment of the physician). The physician follows the Seattle Children’s IRB Policy for Emergency Use.

Compassionate Use or Expanded Access Use:

Compassionate uses (for devices) and expanded access uses (for drugs or biologics) are scenarios in which there is sufficient time (more than 7 days) to obtain prospective IRB review and approval. Compassionate use and expanded access are reviewed by the Fred Hutch IRB if Fred Hutch is the primary academic appointment of the PI.

Physicians must notify the IRB in advance of a proposed compassionate use of an unapproved device by submitting prospective review. Such use is generally reviewed by the fully convened IRB unless the activity constitutes no greater than minimal risk.

Investigators must notify the IRB in advance of a non-emergency expanded access use of an investigational drug, whether for an individual patient or a group of patients, by submitting a new IRB application for prospective review. Such use is generally reviewed by the fully convened IRB unless the activity constitutes no greater than minimal risk.

Expanded access and compassionate uses generally cannot be claimed as research. However, expanded access of a drug or biologic meets the definition of a clinical investigation and requires an investigational new drug (IND) application be submitted to the FDA.

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.

PROCEDURES

The physician consults with Clinical Research Support (CRS) Regulatory Affairs to determine whether the activity may meet criteria for emergency use, compassionate use, or expanded access. CRS Regulatory Affairs supports the physician with required submissions to the FDA. If the activity meets the criteria for emergency use, notification to either UW HSD or Seattle Children's IRB must occur.

If the activity meets the criteria for compassionate use or expanded access, the physician submits the activity to the Fred Hutch IRB by creating and submitting a New Study in Hutch IRB and attaching *HRP-250 - FORM - IRB Application (Contact)* to the submission. A fully convened IRB reviews the item per institutional policy. IRB staff informs the physician of the results of the evaluation by issuing a formal result letter indicating that the IRB has approved the activity, requires modifications to secure approval, or has deferred or disapproved the activity. All formal IRB correspondence is sent to the PI, Primary Contact, and PI Proxies. These individuals 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. For additional details on the new study process and what to submit, see *HRP-121 - POLICY - New Application*.

SUPPORTING DOCUMENTS

HRP-121 - POLICY - New Application

HRP-250 - FORM - IRB Application (Contact)

REFERENCES

21 CFR 50.23

21 CFR 50.24

21 CFR 50.25

21 CFR 56.104

45 CFR 46.116

FDA Information Sheets: Emergency Use of an Investigation Drug or Biologic, Emergency Use of Unapproved Medical Devices (1998)

FDA Information Sheets: Frequently Asked Questions: IRB Procedures

OHRP Compliance Activities: Common Findings and Guidance #13, 41, and 72

OHRP Guidance on Informed Consent Requirements in Emergency Research dated October 31, 1996

VERSION HISTORY

Version	Effective Date
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