



Title:	Emergency Use of an Investigational Drug or Device
Policy:	2.4
Version:	8.00
Effective Date:	February 24, 2020
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Meghan Scott, IRO Director
	 2/20/2020
	<i>Signature/date</i>

Version History	Effective Date
7.00	01-21-2019
6.02	06-15-2015
6.01	08-01-2014
6.00	03-26-2014
5.01	04-04-2012
5.00	03-18-2011
4.03	05-17-2010
4.01	10-09-2008
4.00	01-14-2008
3.00	08-01-2007
2.00	03-22-2007
1.00	12-05-2006

POLICY STATEMENT

It is the policy of the Fred Hutchinson Cancer Research 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 Fred Hutch IRB or the University of Washington Human Subjects Division (UWHSD) manages the notification of emergency use, depending on the activity.

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

DEFINITIONS

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

Emergency Use

Human Subject

Test Article

PRINCIPLES/OVERVIEW

The Emergency Use Notification (EUN) procedures have been developed to assure compliance with Food and Drug Administration (FDA) and Health and Human Services (HHS) regulations relating to the protection of research subjects and the responsibilities of the investigator and the institution.

The FDA allows only one use of an investigational agent without prior review by the full IRB. See <http://www.fda.gov/oc/ohrt/irbs/drugsbiologics.html>. However, it is Fred Hutch policy that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue. See www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm.

Under Department of Health and Human Services (DHHS) requirements, patients receiving a test article in an emergency use situation as defined under 21 CFR 56.102(d) may not be considered to be a *research* participant; and data obtained during the emergency use may not be classified as human subjects research nor may the outcome of such use be included in any report of research activity subject to DHHS regulations.

Under FDA regulations the emergency use of a test article, other than a medical device, is considered a clinical investigation, the patient is considered a participant, and the FDA may require data from an emergency use of a test article to be reported in marketing applications.

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

1. Emergency Use Notification Procedures for Investigational Drugs and Devices Managed by Fred Hutch IRB

The Fred Hutch IRB is responsible for reviewing the Emergency Use Notification of an investigational drug or device in the following two situations:

- i. Use of investigational drugs or devices used for life-threatening situations involving ADULT patients where the drug or device is *NOT* controlled by the University of Washington Investigational Drug Service (IDS).
- ii. Pediatric (Seattle Children's) transplant patients.

Fred Hutch's Emergency Use Notification Process:

- a. Fred Hutch principal investigators (PIs) proposing to use an FDA-regulated investigational drug controlled by the UW IDS for emergency administration to an adult patient must follow [Section 2](#) of this policy.
- b. The PI must contact the FDA, and the drug or device manufacturer, to ensure their requirements for emergency use of the test article are met.
- c. Fred Hutch PIs must contact the IRO before administering the drug or device to determine that the activity meets the criteria for Emergency Use Notification and that no prior acknowledgements have been obtained for the same activity. This prior notification is also used for IRB tracking purposes to ensure that the investigator files a report with the IRB within the five day time frame required by the regulations. This prior notification of the IRB is not meant, in any way, to be construed as an IRB approval.
- d. Fred Hutch IRO staff facilitates communication with the Fred Hutch IRB Chair or designee. The PI must provide the following information to the IRB Chair or designee:
 - Rationale for the emergency use, including a detailed description of the life-threatening or potentially debilitating situation the person is in, the lack of sufficient time for convened IRB review and provide a rationale for why there is no other approved or acceptable treatment.
 - An indication of the scientific staff members (e.g., physicians) not involved with the study who have discussed and approved the activity,
 - An indication of acknowledgement by the Division Director (or designee) who approved the activity.
- e. If a Fred Hutch IRB Chair or designee provides verbal acknowledgement, the PI may proceed with the emergency use only after obtaining informed consent from the patient or the patient's legally authorized representative or confirming with the Chair that consent cannot be obtained.
- f. An exception to informed consent may be made if both the investigator and a physician who is not otherwise participating in the clinical investigation, certify in writing that criteria under 21 CFR 50.23(a) are met. All criteria must be met including that the person involved is confronted by a life-threatening situation necessitating the use of the test article AND informed consent cannot be obtained because of inability to communicate with the person or obtain legally effective informed consent from that person AND there is not sufficient time to obtain consent from a LAR AND there is no alternative therapy, approved or otherwise recognized that provides an equal or greater likelihood of saving the person's life.
- g. If the activity **DOES NOT** meet the emergency use criteria, the PI must submit a new IRB application for prospective review.¹
- h. Within **5** working days after the emergency use, the Fred Hutch PI must submit an *Emergency Use Acknowledgement Report (047)*, consent form and protocol. (*NOTE: For Clinical Research Division (CRD), the paperwork must first be routed to Clinical Research Support.*) The IRO staff will provide the IRB Chair or designee with the information provided by the PI for review.²
- i. Once the IRO receives the *Emergency Use Acknowledgement Report (EUA) (047)*, the information is entered into the PIRO database and forwarded to the IRB Chair for acknowledgment and signature. The signed EUA is copied and the copy filed in the EUA file, with the original signed version being returned to the PI with a cover letter advising the PI that no further use of the same investigational drug or device can be granted without submission of an

¹ FDA: 21 CFR 50.23, __.24

² FDA: 21 CFR 50.23(c), 56.104(c)

application for full IRB review and approval. A description of the emergency use will be reported on the expedited agenda under “Emergency Use Notification.”

- j. The PI will provide a follow-up report to the IRB on the patient’s outcome within 90 days of the emergency use.

2. Emergency Use Notification Procedures Managed by the University of Washington Human Subjects Division (UWHSD Involving US FDA-Regulated Investigational Drugs, Biologics, or Devices for Adult Patients)

The UWHSD assumes responsibility for Emergency Use Notification (EUN) for patients at the University of Washington Medical Center (UWMC) and the Seattle Cancer Care Alliance (SCCA) Outpatient Division. The UWHSD will handle all EUNs because the UWMC Investigational Drug Service (IDS) Pharmacy is the pharmacy of record for ordering, dispensing and accounting for FDA-regulated investigational agents at these locations.

Follow UWHSD’s Single Patient Emergency Use SOP:

<https://www.washington.edu/research/policies>

The UW EUN process does NOT apply to:

- The use of conventional agents used in novel ways for life-threatening situations.
- Pediatric patients cared for by Fred Hutch physicians. Seattle Children’s IRB does not have a reciprocal agreement with the UW IRB and therefore would not accept a UW EUN approval. Alternatively, emergency use in all transplant pediatric patients will follow the current Fred Hutch IRB procedure ([Section 1](#) above).

If the PI submits a new application using the investigational drug for full IRB Committee review, the new application is submitted to the Fred Hutch’s IRB only if Fred Hutch is the primary academic appointment of the PI.

3. Planned Emergency Research

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

SUPPORTING DOCUMENTS

Emergency Use Acknowledgement Report (047)
IRB Glossary of Terms and Acronyms (050)

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