

Title:	Emergency Treatment Notification
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	<i>Signature/date</i>
Effective Date:	January 14, 2008
Policy:	2.4

POLICY STATEMENT

It is the policy of the Fred Hutchinson Cancer Research (FHCR) 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 IRB approval.

The FHCR Institutional Review Board (IRB) or the University of Washington Human Subjects Division (UWHSD) manages the notification of emergency use, depending on the activity.

It is also the policy of the FHCR IRB that whenever emergency use of a test article is initiated without prior IRB review and approval, it is considered research and the patient is considered to be a research subject.

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

DEFINITIONS

Emergency use: The 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 IRB approval.

REFERENCES

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

21 CFR 56.102(d)

21 CFR 56.101(c)

21 CFR 56.104(c)

21 CFR 56.109(2)

21 CFR 50.23

21 CFR 50.24

21 CFR 50.25(d)

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

OHRP Guidance on Informed Consent Requirements in Emergency Research dated October 31, 1996
45 CFR 46.103(b)
45 CFR 46.116(f)

PRINCIPLES/OVERVIEW

The emergency treatment notification (ETN) 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.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to Institutional Review Office (IRO) staff, IRB members, employees of FHCRC and investigators from other institutions who submit research studies to the FHCRC IRB for review and approval.

PROCEDURES

1. Emergency Treatment Notification Procedures Managed by FHCRC IRB

The FHCRC IRB is responsible for Emergency Treatment Notification involving the following two situations:

- i. Investigational device and conventional agents used in novel ways for life threatening situations involving ADULT research patients.
- ii. Pediatric (Children Hospital and Regional Medical Center (CHRMC)) transplant patients.

FHCRCs Emergency Treatment Notification Process:

- a. FHCRC PIs proposing to use an FDA regulated investigational drug for emergency treatment of an adult patient must follow section 2 of this policy.
- b. 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>. If the emergency treatment involves an investigational drug, device or biologics, U.S. FDA must be contacted and its requirements must be met.
- c. FHCRC PIs must contact the IRO to determine IRB Chair contact, to assure that activity meets the criteria for ETA & that no prior acknowledgements have been obtained for the same activity.
- d. FHCRC IRO staff facilitates communication with the FHCRC IRB Chair or designee. The PI will provide the following information to the IRB Chair or designee:
 - Rationale for the activity,
 - 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 Director of Clinical Research Division (CRD) (or designee) who approved the activity.
- e. If an FHCRC IRB Chair or designee provides verbal acknowledgement, the PI may proceed with the emergency treatment only after obtaining informed consent from the research participant or the participant's legally authorized representative.
- f. Within 5 working days of the administration of the Emergency Treatment the FHCRC PI must submit an *Emergency Treatment Acknowledgement Report*, consent form and

protocol. (**NOTE:** For Clinical Research Division (CRD) the paperwork must first be routed to the Protocol Office of the Research Trials Office.) The IRO staff will provide the IRB Chair or designee with the information provided by the PI for review.

- g. Once the IRO receives the *Emergency Treatment Acknowledgement Report*, the information is entered into the PIRO database and forwarded to the IRB Chair for acknowledgment and signature. The signed ETA is copied and filed in the ETA file, with the original signature copy being returned to the PI with a cover letter advising the PI that no further IRB acknowledgement of the same treatment activity or use of an investigational drug or device can be granted without submission of an application for full IRB review and approval. A description of the emergency treatment will be reported in the expedited agenda under "Emergency Treatment Notification".
- h. If the activity **DOES NOT** meet the Emergency Treatment criteria the PI submits a new application using the investigational drug for full IRB Committee review.

2. Emergency Treatment Notification Procedures Managed by the UWHS D Involving US FDA–Regulated Investigational Drugs or Biologics for Adult Research Patients

The UWHS D assumes responsibility for ETN for patients at the University of Washington Medical Center (UWMC) and the Seattle Cancer Care Alliance (SCCA) Outpatient Division. The UWHS D will handle all ETNs 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.

UWHS D's ETA Process:

- a. FHCRC PIs proposing to use an FDA regulated investigational drug for emergency treatment of an adult patient must contact one of the following UW HSD administrators:

- Carol Wilkinson at (206) 543-7667
- Lyn O'Doran at (206) 685-9379
- Jonna Butz at (206) 616-9321

After hours contact, investigators should call:

- Dr. Sheree Miller, (206) 598-6054, (206) 598-6060
- Dr. Asaad Awan, (206) 731-5448, (206) 731-8602
- Dr. Alan Wilensky, (206) 731-3576
- Dr. Zane Brown, (206) 543-3714, (206) 685-2464
- Dr. Margaret Neff, (206) 731-4165, (206) 731-3356

- b. 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>.
- c. UWHS D facilitates communication with the UW IRB Chair. If an UW IRB Chair provides verbal acknowledgement, the PI may proceed with the emergency treatment after obtaining informed consent from the research participant or the participant's legally authorized representative.
- d. UWHS D prepares a letter to the PI, stating the conditions of use, the name of the investigational drug and the UW IRB Chair's name acknowledging the emergency use. The letter requests a memo from the PI to be sent to UWHS within five (5) business days. This memo describes the outcome of the use and attach one copy of the consent document that was used.
- e. The UW IRB reviews the memo from the PI at its next meeting.

- f. The ETA process does NOT apply to:
- Investigational devices or the use of conventional agents used in novel ways for life threatening situations.
 - Pediatric patients cared for by FHCRC physicians. Children's Hospital and Regional Medical Center (CHRMC) IRB does not have a reciprocal agreement with the UW IRB and therefore would not accept a UW ETN approval. Alternatively, emergency treatment for all transplant pediatric patients will follow the current FHCRC IRB ETA procedure.
- g. If the PI submits a new application using the investigational drug for full IRB Committee review, the new application is submitted to the FHCRC's IRB only if FHCRC is the primary academic appointment of the PI.
- h. If the UW IRB Chair wishes to consult with FHCRC's IRB Chair prior to acknowledging the emergency use, FHCRC's IRO facilitates that communication.

3. Planned Emergency Research

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

SUPPORTING DOCUMENTS

Emergency Treatment Acknowledgement Report
Screener: Emergency Treatment Acknowledgment