

## HUMAN RESEARCH PROTECTION PROGRAM DEPARTMENTAL POLICY AND PROCEDURE

### 7.5 EMERGENCY USE OF AN INVESTIGATIONAL DRUG OR DEVICE

RESPONSIBLE OFFICE: Human Research Protection Program Department (HRPPD)

EFFECTIVE DATE: November 5, 2021

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#### I. POLICY STATEMENT

- A. The emergency use provision in the Food and Drug Administration (FDA) regulations [[21 CFR 56.104\(c\)](#)] allows physicians a onetime use of an **unapproved** investigational drug, biologic, or device (referenced hereafter as “test article”). This policy is intended to assist physicians by outlining the FDA emergency use requirements and the necessary procedures to ensure both the treatment of seriously ill patients in a life-threatening situation and compliance with FDA regulatory requirements.
- B. The FDA expects the physician to assess the potential benefits from the use of an unapproved device and to have substantial reason to believe that the benefits will exist in addition to determining whether the patient meets the qualifying criteria for emergency use.
- C. FDA and Department of Health and Human Services (DHHS) regulations differ as follows:
  - a. Under **FDA regulations** although an emergency use is considered a “clinical investigation, it allows an exemption from IRB review. Patients who receive a test article in an emergency use are considered participants. The FDA may require data from an emergency use to be reported in a marketing application.
  - b. **DHHS regulations** do not permit data obtained from patients who receive a test article via the emergency use pathway to be classified as human participants research, nor do they permit the outcome of such care to be included in any report of a research activity subject to DHHS regulations.
- D. Sufficient time to obtain IRB approval prior to use
  - a. For the purposes of this policy, there is sufficient time to obtain IRB approval if the physician decides that the test article is not needed prior to the next scheduled IRB meeting and the application for the use of the test article can be submitted at least one week prior to that meeting.
  - b. On the other hand, if there is insufficient time to prepare the application and to get it reviewed at Full Board before its use is needed to treat the condition, then the emergency use without IRB approval criteria may be met. The clinician should not delay treatment if waiting for Full Board review would jeopardize the patient’s health or safety.

#### II. SCOPE

- A. This policy and these procedures apply to any physician who identifies the need for the emergency use of an unapproved drug or device to treat a life-threatening or severely

debilitating condition for a patient who does not meet criteria for treatment on an existing IRB approved protocol.

### **III. PROCEDURES FOR POLICY IMPLEMENTATION**

A. When reviewing a request for Emergency Use of a test article, the IRB or IRB Chair considers the following specific protections:

a. An IND/IDE is required for emergency use of test articles as follows:

i. Drugs: the IND may be either:

1. Previously existing, or
2. An emergency IND (eIND) obtained from the FDA

ii. Devices: the IDE may be either:

1. Previously existing, or
2. Non-existent – the FDA has stated, using its enforcement discretion, it has not objected if a physician chooses to use an unapproved device in such an emergency, provided that the physician later justifies to FDA that an emergency actually existed, UT Southwestern policy allows for this circumstance in the following situations:
  - a when an IDE for an unapproved device does not exist, or
  - b the proposed use is not approved under an existing IDE, or
  - c the physician or institution is not approved under the IDE,

b. Whether exemption from prior IRB approval may be allowed, and

c. Whether Exception from informed consent may be allowed or whether informed consent must be obtained

B. The process for Emergency Use can be broken down into three categories: Prior-Use Requirements, Use, and Post-Use Requirements.

a. **Prior-Use Requirements.**

i. Qualifying Criteria for Emergency Use – Physicians who wish to use a test article for Emergency Use must complete and submit an Emergency Use Request Notification (Emergency Use of an Investigational Drug, Biological, Device for Patient Care) provided by the HRPP to document the following criteria are met in order to comply with federal regulations and University policy:

1. The patient has a condition that is life-threatening or severely debilitating,
  2. No standard treatment is available,
  3. There is not sufficient time to obtain IRB review and approval for an unapproved investigational drug, biologic, or device,
  4. Understanding that Emergency Use permission may be granted only one time to treat a single patient.
- ii. Specific information for Emergency Use of Drugs/Biologics:
1. Contact the Sponsor/Manufacturer: Determine whether the test article can be made available for the emergency use under the sponsor/manufacturer's IND.
    - a. NOTE: If the sponsor/manufacturer of the test article requires a letter from the IRB before shipping the test article, an acknowledgement letter of the emergency use can be provided (which should not be construed as IRB approval).
  2. Contact the FDA: If the manufacturer of a drug or biologic declines permission to use its IND, the physician may contact the FDA to obtain an IND. The physician may also contact the FDA for additional information and guidance, and for notification about the emergency use.
  3. Contact the appropriate Investigational Drug Pharmacy: If the emergency use involves a drug or biologic, you must comply with institutional policies regarding the receipt, storage, and dispensation of the drug/biologic.
- iii. Specific information for Emergency Use of Devices:
1. The emergency use of any unapproved device may occur:
    - a. When a physician wants to use the device in a way not approved under the IDE,
    - b. When a physician is not an investigator under the IDE, or
    - c. When an IDE for the device does not exist.
  2. Contact the Sponsor/Manufacturer: Obtain authorization from the IDE sponsor, if an IDE exists (if possible).

3. **IMPORTANT NOTE:** Contacting the FDA for prior use notification or approval is not required for shipment or emergency use of the unapproved device. The FDA does not need to be notified prior to the emergency use of a device when a patient meets the criteria for emergency use.
  4. Contact the appropriate Institutional Research office and/or Investigational Pharmacy (if applicable)
  5. If possible, seek an independent assessment (written) of an uninvolved physician regarding the emergency use of the unapproved device.
- iv. Contact the Human Research Protection Program Department (HRPPD)
1. Contact the UT Southwestern IRB Director, IRB Chair, or HRPPD staff as soon as possible. Calls regarding emergency use are handled as expeditiously as possible. The treating physician should discuss the case to determine if it meets the FDA criteria for emergency use and, if relevant, whether the use meets FDA criteria for waiving consent. If contact with an IRB Chair, IRB Director, or HRPPD staff is not possible, the physician should proceed with the emergency use if the patient meets the qualifying criteria.
  2. **IMPORTANT NOTE:** Contacting the HRPPD or concurrence by a UT Southwestern IRB Chair or Vice Chair **should not be construed as IRB approval.**
- v. Whenever possible, the HRPPD/IRB will respond to physician inquiries prior to the emergency use of a test article, and will provide contact information for the appropriate IRB Chair/Vice Chair. In addition, if needed, an acknowledgment letter of the emergency use can be provided after concurrence with the IRB Chair (**which should not be construed as IRB approval**).

**b. Use of the Test Article**

- i. Obtain informed consent or determine whether Exception from informed consent may be allowed.
  1. Written informed consent is required and must be obtained (21 CFR 50) and documented (21 CFR 50.27) from the patient or the patient's legally authorized

representative unless the criteria for an exception from the informed consent requirement is met.

2. Exception from the informed consent requirement may occur if both the treating physician and a physician not otherwise involved in the emergency use, certify in writing that all of the following criteria are met ([21 CFR 50.23\(a\)](#)):
  - a. The prospective recipient is confronted by a life-threatening situation necessitating the use of the test article.
  - b. Informed consent cannot be obtained from the recipient because of an inability to communicate with, or obtain legally effective consent from, the recipient.
  - c. Time is not sufficient to obtain consent from the recipient's legal representative.
  - d. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the recipient.
  - e. If there is not sufficient time to obtain an independent written certification of the criteria for an exception from informed consent prior to the use of the test article, the determinations of the treating physician must be made, reviewed and evaluated in writing by a physician who is not involved in the emergency use, and submitted to the IRB within 5 working days after the emergency use of the test article ([21 CFR 50.23\(b\)](#) and [21 CFR 50.23\(c\)](#)).

**c. Post-Use Requirements**

- i. The PI must submit the following to the HRPPD within 5 working days after the test article use:
  1. Copy of the completed Notification of Emergency Use of a Test Article Form
  2. Copy of the signed informed consent form (redacted) or certification of informed consent waiver

3. Copy of the completed Emergency Use Request Notification for Drug/Biologic or Device
- ii. Notify the FDA and Sponsor/Manufacturer
    1. The physician must provide outcomes or safety information as required by the FDA.
    2. For Drugs/Biologics: If the treating physician is the IND holder, any follow-up information should be reported to the FDA.
    3. For Devices: The FDA requires the following post-use reporting:
      4. If an IDE exists, the physician must provide the IDE sponsor a report. The sponsor is required to submit a report to the FDA within 5 working days the sponsor is aware of the emergency use.
      5. If an IDE does not exist, the physician must submit a report to the FDA within 5 working days of device use.
      6. The report should include a summary of the conditions constituting the emergency, the patient protections measures taken, and patient outcome information.
  - iii. The physician should consider possible future use of the test article at UT Southwestern and, if necessary, initiate efforts to obtain IRB approval and regulatory clearance (IND or IDE) for such future uses.
  - iv. The HRPPD staff will review the Notification of Emergency Use and make a preliminary determination of whether the treating physician met FDA regulations and guidance.
    1. The HRPPD staff will forward the Notification of Emergency Use to the IRB Chair or designee who will review the Report Form and determine whether the treating physician met FDA regulations and guidance.
    2. If there are any questions or concerns regarding the report from the IRB Chair or designee, questions or concerns to the treating physician may be communicated with the assistance from the HRPPD staff.
    3. HRPPD staff will prepare and schedule the report for discussion at a convened IRB meeting.

- v. The HRPPD will maintain documentation of all emergency use reports submitted to the IRB.

d. **IRB Review**

- i. The convened IRB will review the documents submitted by the PI and determine either:
  - 1. The regulatory criteria for emergency use **were met**, or
  - 2. The regulatory criteria for emergency use **were not met** and will be reviewed as possible noncompliance.
- ii. Noncompliance with emergency use requirements will be processed as described in the 9.3 NONCOMPLIANCE REVIEW
- iii. See 8.1 IRB MINUTES for details concerning documenting emergency use of a test article
- iv. After the IRB meeting, the use is reported in accordance with 8.2 REPORTING POLICY AND PROCEDURE and the 1.5. COMMUNICATION WITH OTHER COMMITTEES AND OFFICES.

**IV. DEFINITIONS**

SEE GLOSSARY OF HUMAN RESEARCH TERMS

**V. REFERENCES**

Resource
21 CFR 50 – <a href="#">PROTECTION OF HUMAN SUBJECTS</a>
45 CFR 46 – <a href="#">PROTECTION OF HUMAN SUBJECTS</a>
45 CFR 164 – <a href="#">SECURITY AND PRIVACY (HIPAA PRIVACY RULE)</a>
21 CFR 56 – <a href="#">INSTITUTIONAL REVIEW BOARDS</a>

**VI. REVISION AND REVIEW HISTORY**

Revision Date	Author	Description
November 2021	HRPP	Updated to define that patients receiving emergency use are participants and that the FDA may require data to be included in marketing applications
June 2021	HRPP	Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.
August 2017	HRPP	New Policy Development
March 2012	IRB Office	IRB Written Procedures