



I. PURPOSE:

To ensure organizational compliance with the emergency use provision in federal regulation 21CFR56.104(c) and 21CFR56.102(d). This policy is not intended to provide guidance about or to restrict a provider's ability to prescribe and use FDA approved drugs, biologics, or devices in an "off-label" manner.

II. POLICY:

UnityPoint Health Des Moines (UPHDM) and the Food and Drug Administration (FDA) wish to support a physician's obligation to treat a seriously ill patient with all available modalities. The emergency use provision in federal regulations allows physicians restricted access to experimental treatments that would otherwise be off-limits. This policy aims to support physicians and other members of the healthcare team by clarifying the strict emergency use requirements, and, by outlining the necessary procedures to help ensure physicians are in full compliance with those requirements.

III. DEFINITIONS:

**A. Research Use:**

Most administration/use of unapproved devices, drugs, or biologics is part of a systematic clinical trial or other clinical investigation designed to test the safety and/or efficacy of the test article. All such clinical investigations, including pilot studies, require prior Institutional Review Board (IRB) review and approval. In addition, almost all clinical studies are conducted under an Investigational Device Exemption (IDE), or an Investigational New Drug (IND) exemption obtained from the FDA, which require that research protocols be filed with the FDA prior to study commencement.

**B. Emergency Use:**

Emergency use of an unapproved device, drug, or biologic is intended to benefit a single patient who is not eligible for a study approved at the treating institution, or when there is no appropriate study available at the institution. Generally, emergency use of a test article requires either an IND or an IDE. FDA regulations provide an "emergency use" exemption from rules requiring IRB review and approval. However, reporting the use to the IRB is required by the FDA, and UPHDM requires consultation with the IRB prior to use, if possible.

IV. PROCEDURES:

**A. Meeting the Emergency Use Criteria:** All of the following criteria must be met to comply with federal regulations and UPHDM policy on emergency use of unapproved drugs, biologics, and devices:

1. The test article is used one time per institution to treat a single patient.

2. The patient has a condition that is life-threatening or severely debilitating.
  3. No standard treatment is available
  4. There is not sufficient time to obtain prior IRB review and approval
  5. The IRB is notified of the emergency use within five working days; when possible the treating physician should consult with the IRB prior to use.
  6. Consent will be sought and documented from the prospective participant or the participant's legally authorized representative (LAR) unless the criteria for the exception to the requirement for consent are met. See section D of this policy for criteria.
  7. The treatment is not part of a systematic investigation designed to develop or contribute to generalizable knowledge. That is, this treatment will not be incorporated into a project that meets the Department of Health and Human Services definition of research requiring IRB review.
- B. Contacting the IRB: Detailed instructions are provided in the Emergency Use Form and Compliance Check list.
1. The physician planning to use an unapproved drug, biologic or device under emergency use provisions must contact the IRB office prior to the procedure, if at all possible.
  2. The IRB office will ensure that the physician has access to the Emergency Use form and Compliance checklist.
  3. If the sponsor requires a letter from the IRB documenting that the FDA criteria for emergency use have been met before they will ship or release the test article, then the physician will be required to speak with the IRB Chair or Vice-Chair. Early interaction between the IRB office and the physician will help to expedite the preparation of the letter.
- C. Obtaining Informed Consent: Patient protection measures are specified under the emergency use regulation.
1. Written informed consent, signed by the patient or the patient's LAR is required. If written informed consent is not possible, there are special provisions for an informed consent waiver (See section...).
  2. The "Consent Form and HIPAA Authorization for Emergency Use Procedure" is available on the IRB website ( ) and should be used when obtaining informed consent.
  3. A signed copy of the informed consent must be included in the post-use written report to the IRB.
- D. Waiver of Informed Consent: Federal regulations allow a waiver under the following conditions:
1. If prior consent is not possible, federal regulations allow a waiver if the treating physician and a physician not involved in clinical investigation of the test article certify in writing that:
    - a. The patient is confronted with a life-threatening condition.
    - b. The physician cannot communicate with the patient.
    - c. Time is not sufficient to obtain consent from the patient's LAR.
    - d. No alternative method of approved or generally recognized therapy is available that provides equal or greater likelihood of saving the patient's life.
  2. If immediate use of the test article is needed to preserve the patient's life, and there is not sufficient time to secure an independent physician's determination that the four conditions described above apply, then the treating physician must have the written determination reviewed and signed by an independent physician within five working days after the emergency use of the test article.
  3. Include a copy of the written determination with the post-use written report.

- E. Notifying the FDA: the FDA must be notified by the holder of the IND or IDE.
1. For industry-sponsored IND/IDE, the physician must notify the manufacturer or sponsor about the emergency use, and the sponsor notifies the FDA for IND/IDE approval.
  2. For physician sponsored IND/IDE, or if no IND/IDE exists, the physician must notify the FDA about the emergency use, the contact information is available at <http://www.fda.gov/regulatoryinformation/guidances/ucm126491.htm>.
- F. Submitting a Post-Use Written Report: Within five working days after the emergency use occurrence, the treating physician is required to submit a written report to the IRB. To facilitate the preparation of the report utilize the "Emergency Use Form and Compliance Checklist". The report must contain the following information:
1. Physician's name, department address, phone numbers.
  2. Name of test article
  3. Name of sponsor
  4. Date of IRB notification
  5. Date the test article was used
  6. Name of patient
  7. Rationale for test article use
  8. Results of test article use. If not available within the initial reporting period of 5 days, results must be reported to the IRB within 10 working days of the occurrence.
  9. The IND/IDE number, if applicable
  10. Copy of the signed Informed Consent document or justification to waive informed consent.
  11. A copy of the document notifying the FDA of the test article use. This document will be generated by the holder of the IND/IDE.
- NOTE: Any adverse event that results from the emergency use of an investigational drug or device is subject to reporting requirements outlined in IRB Policy and Procedures IV. G Unanticipated Problems Involving Risk to Research Participants or Others.
- G. **IRB Oversight:**
1. In order to help physicians comply with regulations related to emergency use, the IRB determines whether each use complies. Most often, this is done when the physician discusses the proposed use with the IRB chair or vice-chair before the patient is treated. When prior consultation is not possible, the chair will review the post-use written report.
  2. In addition, if the post-use written report indicates that consent was waived, the IRB chair or vice chair will review the waiver to determine whether it complies with FDA requirements.
  3. For both the use itself and, if applicable, for a waiver of consent, the IRB will issue a letter certifying compliance or informing the physician of noncompliance. In the case of noncompliance, the IRB will follow its usual procedure to determine whether the noncompliance is a serious or continuing problem requiring additional action.