

<b>PARKVIEW HEALTH</b>	<b>INSTITUTIONAL REVIEW BOARD MANUAL</b>
Policy & Procedure Title: Emergency Use of a Drug, Biologic, or Medical Device Category: IRB Review Process	

## I. Policy Statement

Use of an investigational drug, biologic or device (“test article”) requires prior PH IRB review and approval. In certain limited circumstances, prospective PH IRB review and approval is not possible due to the emergent nature of a patient’s condition, in this case the Emergency Use of a test article for treatment is exempt from prior PH IRB review and approval.

Emergency situations may arise in which there is a need to use an investigational drug, biologic, or device in a manner inconsistent with an approved investigational plan or by a physician who is not part of the clinical study.

This policy shall provide guidance and establish clear procedures for Emergency Use.

## II. Definition of Terms

**Emergency Use:** The exceptional one time use of an investigational drug, biologic, or device on a patient in a life-threatening situation in which no standard acceptable treatment is available, and in which there is insufficient time to obtain FDA or prospective PH IRB approval.

**Life Threatening:** Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes. The criteria for life threatening do not require the condition to be immediately life threatening or to immediately result in death. Rather the patients must be in a life-threatening situation requiring intervention before review at a convened PH IRB Meeting is feasible.

**Severely Debilitating:** Diseases or conditions that cause major irreversible morbidity including blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

## III. Procedure

- A. Emergency Use of a test article is permitted when:
1. The patient is in a Life-Threatening or serious disease condition requiring immediate treatment, and,
  2. There must be no generally acceptable alternative for treatment available, and,
  3. There is not sufficient time to submit an investigational Protocol or Amendment to the FDA or PH IRB for prospective approval.

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- B. Whenever possible, any use of a test article should be submitted for prior PH IRB review and approval. Accordingly, the PH IRB should be contacted promptly. When the conditions of an emergency exist, the PH IRB Chair may concur with the emergency and the use may proceed without prior PH IRB review and approval. The following conditions must exist for Emergency Use:
1. A life-threatening situation in which no standard acceptable treatment is available, and
  2. There is not sufficient time to obtain full PH IRB approval, i.e. it is not possible to convene a quorum of the PH IRB within the time available.
- C. If concurrence of the PH IRB Chair (or designee) is granted, the matter will be added to the agenda for the next convened PH IRB meeting. Expedited approval for Emergency Use of a test article is not permitted.

**If it is not possible to contact the PH IRB Office or PH IRB Chair**, the treating physician should review the criteria above and proceed with treatment if the use meets the criteria.

- D. A written report of the Emergency Use must be submitted to the PH IRB within 5 working days. The report must contain the following information:
1. Physician's name, office address, phone numbers
  2. Name of test article (unapproved drug, biologic, or device)
  3. Name of sponsor (IND/IDE/HDE holder for test article)
  4. The IND, IDE, or HDE number
  5. Date of PH IRB notification
  6. Date the test article was used
  7. Initials of patient
  8. Rationale for test article use
  9. Results of test article use. If the results are not available within the initial reporting period of 5 working days, then a subsequent report must be submitted to the PH IRB within 10 working days of the occurrence detailing the results of the test article use.
  10. Copy of signed Informed Consent form or justification to waive Informed Consent.

The following templates are provided for your use: PH IRB Emergency Use Form and PH IRB Emergency Post-Use Form.

- E. If the Sponsor requires a written statement that the PH IRB is aware of the proposed use and considers the use to meet the requirements of Emergency Use in order to approve shipment of the test article, PH IRB will provide such correspondence upon request from the Sponsor or treating physician.
- F. PH IRB requires the following patient protection procedures be followed:

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1. Before the test article is used, the physician will:
    - a. Obtain the PH IRB Chair's concurrence.
    - b. Obtain an independent assessment by an uninvolved physician.
    - c. Obtain authorization / approval from the Sponsor or manufacturer.
    - d. Obtain institutional clearance or approval from the Parkview Health Chief Medical Officer, Service Line Executive or designee.
    - e. Obtain Informed Consent from the patient or his/her legally authorized representative (LAR).
    - f. If a medical device is used and does not have an IDE or HDE, a report must be submitted by the physician directly to the FDA that contains a summary of the conditions constituting the emergency, patient protection measures taken (informed consent), and the results.
    - g. Determine if the test article is likely to be used again. If so, the physician must be designated as an Investigator and obtain PH IRB approval of an appropriate Protocol prior to such subsequent use.
    - h. Submit all above correspondence and documentation to the PH IRB as soon as possible, but no later than 5 days after the use. PH IRB Emergency Use Form is provided for your use.
  2. If applicable, the Investigator for the test article will include the Emergency Use in the Continuing Review report for the study as a separate line item.
- G. Emergency Use regulations require that for each situation in which a test article is to be administered, that informed consent be obtained, if possible.
1. **Obtaining Informed Consent:**
    - a. **Before the Emergency Use** every effort should be made to obtain Informed Consent signed by the patient or the patient's LAR.
    - b. In addition to the standard required elements of Informed Consent , **the Emergency Use Consent must clearly state that:**
      - i. The patient is NOT part of a research study, and
      - ii. There is no guarantee of benefit, and
      - iii. The treatment is experimental and not approved by the FDA. PH IRB Emergency Use Consent Template is provided for your use and contains all categories and required language.
    - c. A signed copy of the Informed Consent must be included in the Emergency Post-Use Form.
  2. **If prior Consent is not possible** before use of the test article, both the Investigator and a physician who is not otherwise participating in the clinical investigation or the care of the patient shall certify in writing all of the following:
    - a. The patient is confronted by a Life-Threatening situation necessitating the use of the test article.
    - b. Informed Consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally effective Consent from, the patient.

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- c. Time is not sufficient to obtain Consent from the patient's LAR.
- d. There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.

H. If immediate use of the test article is, in the Investigator's opinion, required to preserve the life of the patient, and time is not sufficient to obtain the independent determination required in Section III F.1(b) and G.2 of this Policy in advance of using the test article, the determinations of the clinical Investigator shall be made and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.

PH IRB Emergency Use Form is provided for your use for documenting situations described in Section III F, G, or H above.

I. The documentation required in Section III F, G, and H of this Policy shall be submitted to the PH IRB within 5 working days after the use of the test article.

**J. Notifying the FDA:**

1. **Industry-sponsored IND/IDE/HDE:** The physician must notify the manufacturer or Sponsor about the Emergency Use and the Sponsor notifies the FDA for IND/IDE/HDE approval.
2. **Physician-sponsored IND/IDE/HDE, or if no IND/IDE/HDE exists:** The physician must notify the FDA about the Emergency Use.

**IMPORTANT NOTE:** Any Adverse Event (AE) that results from the Emergency Use of an investigational drug or device is subject to PH IRB AE reporting requirements.

**IV. References**

- A. [45 CFR 46](#);
- B. [21 CFR 50](#); [21 CFR 56](#)
- C. Emergency Use of an Investigational Drug or Biologic located at <http://www.fda.gov/oc/ohrt/irbs/drugsbiologics.html>
- D. CDRH Guidance for Emergency Use of Unapproved Medical Devices at <http://www.fda.gov/cdrh/devadvice/ide/early.shtml#emergencyuse>
- E. CDRH Guidance for Emergency Use of Unapproved Medical Devices at <http://www.fda.gov/cdrh/ode/idepolcy.html>
- F. FDA Guidance for Emergency Use of Unapproved Medical Devices at <http://www.fda.gov/oc/ohrt/irbs/devices.html#emergency>

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