



## **I. Policy**

### **A. Introduction**

This document outlines the policy and procedures established by MUSC for single emergency use of an investigational drug.

### **B. Single Use of an Investigational Drug**

A physician may use an investigational drug one time under the following circumstances and meeting the following requirements.

1. The physician must document in writing that:
  - a) The participant is confronted by a disease or condition that was life threatening.
  - b) The situation necessitates the use of the investigational article.
  - c) No standard acceptable treatment is available.
  - d) There is not sufficient time to obtain IRB approval.
2. The emergency use will be reported to the IRB within five working days. The physician must provide the IND if the investigational drug has one. Any subsequent use of the investigational product at the organization must have prospective IRB review and approval.

### **C. Informed Consent**

Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by 21 CFR 50 and informed consent will be appropriately documented, in accordance with and to the extent required by 21 CFR 50.27.

### **D. Single Use of an Investigational Drug if Informed Consent is Not Required**

Prior to use of the investigational drug, if informed consent is not required, all of the following must be true and certified in writing by both the treating

physician and a physician who is not otherwise participating in the clinical investigation.

1. The participant is confronted by a life-threatening situation necessitating the use of the test article.
2. Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from the participant.
3. Time is insufficient to obtain consent from the participant's legal representative.
4. No alternative method of approved or generally recognized therapy providing equal or greater likelihood of saving the life of the participant is available.

The above written certification will be submitted to the IRB within five working days after the use of the test article.

**E. Single Use of an Investigational Drug when Immediate Independent Determination of a Physician is Unobtainable**

If the treating physician is unable obtain the independent determination of a physician because the immediate use of the test article was, in the investigator's opinion, required to preserve the life of the participant and there was insufficient time, the treating physician will:

1. Certify in writing prior to use of the test article:
  - a) The participant is confronted by a life-threatening situation necessitating the use of the test article.
  - b) Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from the participant.
  - c) Time is insufficient to obtain consent from the participant's legal representative.
  - d) No alternative method of approved or generally recognized therapy providing equal or greater likelihood of saving the life of the participant is available.
2. After the use of the test article, a physician who is not otherwise participating in the clinical investigation will certify in writing within five working days after use of the article agreement with all of the above conditions.

3. The written certifications from both physicians will be submitted to the IRB within five working days after the use of the test article.

#### **F. IRB Responsibilities**

1. If physicians provided prior notifications of their intent to use a test article in an emergency or their intent to invoke the exception to the requirement to obtain consent, the IRB chair or designee will review the notification to determine whether the circumstances would follow FDA regulations.
2. The written description of the emergency requiring the drug and the rationale for selecting the drug will be received by the IRB Members at the next convened meeting of the IRB.

#### **G. Research Participant**

The emergency use of a test article or the outcomes of the emergency may be considered research and the person receiving the test article may be a study participant. The FDA may require data from an emergency use to be reported in a marketing application.

VA and DHHS regulations pertaining to research involving human subjects do not permit data obtained from patients to be classified as human subjects research, nor may the outcomes of such care be included in any report of a research activity subject to VA regulations pertaining to research involving human subjects.

#### **H. Memorandum of Understanding**

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards".

## **II. Definitions**

Definitions for the following terms used in this document may be found in HRPP Program Guide - Section 1.3 Definitions of Terms

- A. Emergency use**
- B. Severely debilitating**
- C. Legal representative or Legally Authorized Representative**

### **III. Procedures**

- A.** The requesting PI will contact either the IRB administrator or chair and present the nature of the emergency prior to administering an investigational drug for emergency treatment.
- B.** The PI will submit a written clinical summary describing the nature of the emergency and the rationale for selecting the investigational drug for treatment; this summary will be reviewed by the IRB chair; the chair will contact the PI as needed to discuss the request.
- C.** The IRB administrator and chair will jointly decide there is inadequate time to convene a meeting of the IRB allowing the exemption from prospective IRB review.
- D.** The PI will contact the drug manufacturer regarding obtaining the drug under the manufacturer's IND.
- E.** The IRB administrator will prepare a letter for the chair's signature acknowledging awareness of the emergency use but not approving the emergency use. \*This letter also states that any subsequent emergency use of the investigational drug requires IRB prospective review and approval.
- F.** If the drug does not yet have an Investigational Drug IND, the PI must contact the FDA to obtain authorization for the drug to be shipped; the PI will document this authorization.
- G.** The PI will document that informed consent was obtained and from whom.
- H.** If informed consent is waived because:
  - 1. the patient is confronted by a life-threatening condition;
  - 2. the patient cannot give informed consent;
  - 3. time is not sufficient to obtain informed consent from an appropriate surrogate;and, there is no other comparable treatment to save the individual's life, the PI administering the Investigational Drug and an independent physician will document that each condition is met respectively.
- I.** The PI using an investigational drug for emergency treatment must submit to the IRB within 5 working days a written clinical summary describing the nature of the emergency and the rationale for selecting the investigational drug for treatment if not previously submitted to the IRB during initial contact with the IRB.

**J.** The written description of the emergency requiring the drug and the rationale for selecting the drug will be received by the IRB Members at the next convened meeting of the IRB.

**\*Note:** Neither the IRB or the FDA would deny the emergency use of an investigational drug to another individual if the only obstacle is lack of sufficient time for a convened IRB to prospectively review and approve the use.