



I. Policy

A. Introduction

The following details the policy and procedures established by MUSC for emergency use of an investigational device.

B. IDE Requirement

The emergency use of an Investigational Device requires an IDE.

C. IRB Consultation

The emergency use of an Investigational Device requires consultation with the IRB prior to use.

D. Informed Consent

The emergency use of an Investigational Device requires documented informed consent of the patient. If the patient is unable to give informed consent, informed consent may be obtained from a legal representative, spouse, parent or sibling in that order.

E. Waiver of Informed Consent

Documented informed consent may be waived only if ALL of the following conditions are documented including certification that all four conditions are present by another MD not directly involved in the patient's care:

1. The patient is confronted by a life threatening event;
2. Informed consent cannot be obtained because the patient cannot communicate or is not cognitively competent to give consent;
3. Time is not sufficient to obtain consent from an authorized surrogate; and
4. No alternative approved therapy is available with equal or greater likelihood of saving the individual's life.

(Note: IRB may **NOT** approve planned emergency research that is subject to VA Regulations)

F. Reporting of Use

The MD using an Investigational Device for emergency treatment must submit a written report to the IRB within 5 working days of the device's use.

G. Single Use Limitation

**A specific Investigational Device may be used only once as an "emergency" by an institution; subsequent use must be prospectively reviewed and approved by the IRB

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. Legal representative or Legally Authorized Representative

III. Procedures

A. The requesting MD will contact either the IRB administrator or chair and present the nature of the "emergency" prior to investigational device for emergency treatment.

B. The MD will submit a written clinical summary describing the nature of the "emergency" and the rationale for selecting the device for treatment; this summary will be reviewed by the IRB chair; the chair will contact the MD as needed to discuss the request.

C. The IRB administrator and chair will jointly decide if there is inadequate time to convene a meeting of the IRB allowing the exemption from prospective IRB review.

- D.** The MD will contact the device manufacturer regarding obtaining the device under the manufacturer's IDE.
- E.** If the manufacturer holding the IDE requires "IRB authorization", the IRB administrator will prepare a letter for the chair's signature acknowledging awareness of the emergency use but not "approving" the emergency use.
- F.** If the device does not yet have an IDE or if the device is to be used for a purpose other than that authorized with the IDE, the MD must contact the FDA to obtain authorization for the device to be shipped; the MD will document this authorization.
- G.** The MD 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 MD using the Investigational Device and an "independent" MD will document that each condition is met respectively.
- I.** The MD using an Investigational Device 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 device for treatment if not previously submitted to the IRB during initial contact with the IRB.
- J.** The written description of the emergency requiring the device and the rationale for selecting the device will be reviewed at the next convened meeting by IRB members.
- K.** The MD will be notified in writing that any subsequent emergency use of the investigational device requires IRB prospective review and approval.

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