Emergency Use of an Investigational Device Policy and Procedure

Each of the following conditions must exist to justify emergency use:

1. The patient is in a life-threatening condition that needs immediate treatment;
2. No generally acceptable alternative for treating the patient is available; and
3. Because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use.

In the event that a device is to be used in circumstances meeting the criteria listed above, the device developer should notify the Center for Devices and Radiological Health (CDRH) Program Operation Staff, by telephone (301-594-1190) immediately. Nights and weekends, contact the Division of Emergency and Epidemiological Operations (202-857-8400).

I. Definitions

Life threatening includes the scope of both life-threatening and severely debilitating, as defined below.

1. **Life threatening** means 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, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

2. **Severely debilitating** means diseases or conditions that cause major irreversible morbidity, such as blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis, or stroke.

3. **Medical Device**: Defined, in part, as any health care product that does not achieve its primary intended purpose by chemical action or by being metabolized. Medical devices also include diagnostic aids, such as reagents and test kits for in vitro diagnosis.

4. **Emergency Use** is defined as the use of an investigational device with a human subject in a life threatening situation in which no standard acceptable device is available and in which there is not sufficient time to obtain CCI/IRB approval.

   a) The emergency use provision in the FDA regulations is an exemption from prior review and approval by the IRB and applies to the treatment of one subject.
   b) If the investigator anticipates the enrollment of additional subjects in the future, a full protocol must be submitted to the CCI/IRB for review and approval at a convened meeting.
II. Informed Consent

1. Even for emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative, unless the FDA requirements for exception from informed consent are met [21CFR 50.23(a)].
2. The sponsor will more than likely supply the consent form and the CCI/IRB will not be involved in the review or approval of the consent form.
3. In instances where the sponsor's consent is not available, use the [Emergency Use Consent template](#).

III. Physician Responsibilities

1. *Prior to use* of the investigational device the treating physician must:
   
   a. Obtain an independent assessment by an uninvolved physician;
   b. Obtain informed consent from the patient or a legal representative;
   c. Obtain permission from the Department Chairman;
   d. Obtain authorization from the IDE holder, if an approved IDE for the device exists.
   e. At the manufacturer/sponsor’s request, obtain IRB acknowledgement prior to the use of the device. In such instances the physician must submit to the IRB the [Request for Emergency Use of an Investigational Device Form](#). The IRB Chair or designee will provide written acknowledgment.

2. *After use* of the device the treating physician must:
   
   a. Notify the IRB **within five days** of the emergency use when prior IRB acknowledgement is not required by submitting to the IRB the [Request for Emergency Use of an Investigational Device Form](#).
   b. When the clinical outcome is known, submit to the IRB:
      
      i. The [Final Report for the Emergency Use of an Investigational Drug, Biologic or Device Form](#),
      ii. All adverse event reports, and
      iii. A copy of the signed informed consent document.
   c. Evaluate the likelihood of a similar need for the device occurring again, and if future use is likely, immediately initiate efforts to obtain IRB approval and an approved IDE for the device's subsequent use; and
   d. If an IDE for the use does exist, notify the sponsor of the emergency use, or if an IDE does not exist, notify FDA of the emergency use (CDRH Program Operation Staff) and provide FDA with a written summary of the conditions constituting the emergency, subject protection measures, and results.
IV. IRB Contact

1. For Emergency Use at Jacobi Medical Center or North Central Bronx Hospital, contact the Committee on Clinical Investigations of Yeshiva University at 718-430-2237.
2. For Emergency Use at Montefiore Medical Center hospitals contact the MMC Institutional Review Board at 718-798-0406.