Emergency Use of an Investigational Drug or Biologic 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 drug, there is no time to use existing procedures to get FDA approval for the use.

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 CCI/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. **Emergency Use** is defined as the use of an investigational drug with a human subject in a life-threatening situation in which no standard acceptable drug is available and in which there is not sufficient time to obtain CCI/IRB approval. (See also Treatment Use (Section I. E.) of the Investigational Drug, Biologic and Device Policy

   a. Emergency use of an unapproved investigational drug or biologic must be done under an IND (Investigational New Drug).
   b. 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.
   c. 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.

ONCE THE ABOVE CRITERIA HAVE BEEN MET, THE FOLLOWING POLICY AND PROCEDURES APPLY

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 drug or biologic the treating physician must:
   a. Obtain informed consent from the patient or a legal representative;
   b. Obtain permission from the Department Chairman;
   c. Obtain approval from the Pharmacy Department. Storage, inventory and dispensing of the investigational agent are generally required through the Pharmacy.
   d. Obtain CCI/IRB acknowledgement prior to the use of the drug or biologic when required by the manufacturer/sponsor.
      i. In such instances the physician must submit to the CCI/IRB the Request for Emergency Use of Investigational Drug or Biologic Form. The IRB Chair or designee will provide the physician with written acknowledgment.

2. After use of the drug or biologic the treating physician must:
   a. Submit the Request for Emergency Use of Investigational Drug, Biologic or Device Form to the CCI/IRB within five days of the emergency use only when prior IRB acknowledgement is not obtained.
   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. If the enrollment of additional subjects is anticipated in the future, a full protocol must be submitted to the CCI/IRB for review and approval at a convened meeting.

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.