EMERGENCY USE OF INVESTIGATIONAL DRUGS OR BIOLOGICS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:
To provide patients and physicians with access to investigational drugs/biologics to address

Serious Disease or Condition: A disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.

PROCEDURE:

Emergency Use of an Investigational Drug/Biologic:

1. The treating physician should contact the HRPP office immediately if they are considering using an investigational drug/biologic for an emergency use situation to determine if an IND must be filed or not with the FDA prior to the use. If the patient meets emergency criteria, call FDA to obtain FDA authorization for the expanded access use.
2. The treating physician should also ensure that the Sponsor is willing to provide the investigational drug/biologic for emergency use and request a letter of authorization to cross reference the existing IND held by the Sponsor.
3. When a treating physician has used an investigational drug/biologic to treat a patient with a life-threatening event, the physician must complete and submit an initial eBridge submission within 5 working days of its use.
4. The IRB eBridge submission must include:
    a. Emergency Use IND number or Authorization from the FDA to ship the investigational drug/biologic; and
    b. Approval from the Sponsor for use of the investigational product; and
    c. The consent form that was used to consent the patient, or, if informed consent was unable to be obtained from the patient or his/her legally authorized representative, a letter from a physician not otherwise participating in the intervention certifying that:
        i. The patient was confronted by a life-threatening situation necessitating the use of the investigational drug or biologic
        ii. Informed consent could not be obtained because of an inability to communicate with or obtain legally effective consent from the patient
        iii. Time was not sufficient to obtain consent from the patient's legal representative
        iv. No alternative method of approved or generally recognizable therapy was available that would provide an equal or greater likelihood of saving the patient's life.
5. The FDA submission to the appropriate Review Division in the Center for Drug Evaluation and Research (CDER) must be submitted within 15 working days. Include:
    a. Form FDA 3926
        i. Ensure to not select box 10.b
    b. Treating physician's CV
    c. Letter of Authorization from sponsor
6. Following the emergency use of an investigational drug/biologic, the patient should be monitored to detect any possible problems arising from the use of the investigational drug/biologic.
7. If emergency use is approved by FDA for extended duration, the treating physician must submit reports to FDA in accordance with 21 CFR 312.64.