

## **GUIDELINES FOR EMERGENCY TREATMENT INVOLVING INVESTIGATIONAL DRUGS, DEVICES OR BIOLOGICS**

### ***A. Emergency Treatment is not included in "Research" Data***

Federal regulations in the protection of human subjects do not permit research activities to begin without prior IRB review and approval. These regulations, however, do not limit or interfere with the authority of a physician to provide **emergency medical treatment** for patients, subject to FDA requirements for release and emergency use of an unapproved drug, biologic, or device on a single patient.

When emergency treatment is initiated without prior IRB review and approval, the patient data may not be included as research data in a prior or subsequent IRB-approved project.

### ***B. FDA Regulation of Emergency Use***

The emergency use provision in the FDA regulations is an exemption from prior review and approval by the IRB of a ***single*** patient use of a drug, device, or biologic considered to be investigational. The emergency use exemption of an investigational drug, biologic or device is permitted only if each of the following conditions exist as outlined in 21 CFR 56.102(d):

- A life-threatening or severely debilitating situation exists necessitating the use of the investigational drug, biologic or device;
- No standard acceptable alternative treatment is available; and
- Because of the immediate need to use the drug, biologic or device, there is not sufficient time to use existing procedures to obtain IRB approval for the use.

For purposes of this section, the following terms have the following meanings:

"Emergency use" of an investigational drug, biologic or device is defined as the use of an investigational article with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain approval from the IRB.

"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.

"Severely debilitating," means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

The FDA regulations do not provide for expedited IRB approval in emergency situations. An IRB must either convene or give "full board" approval of the emergency use or, if the conditions of 21 CFR 56.102(d) are met and it is not possible to convene a quorum within the time available, the use may proceed without any IRB approval.

Some manufacturers will agree to allow the use of the test article, but their policy requires “an IRB approval letter” before the test article will be shipped. If it is not possible to convene a quorum of the IRB within the time available, the IRB may send the sponsor a written statement with the IRB is aware of the proposed use and considers the use to meet the requirements of 21 CFR 56.104(c). Although this is not an “IRB approval”, the acknowledgement letter has been acceptable to manufacturers and has allowed the shipment to proceed.

### ***C. Patient Consent in an Emergency***

Even in an emergency use situation, the Principal Investigator is required to obtain informed consent to the treatment from the patient or the patient’s legally authorized representative (as specified under State law) unless both the Principal Investigator and an independent physician certify in writing that all of the following conditions exist:

- The patient is confronted by a life-threatening situation necessitating the use of the investigational drug, biologic or device;
- Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the patient;
- Time is not sufficient to obtain consent from the patient’s legal representative; and
- No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the life of the patient.

If time is not sufficient to obtain the determination by an independent physician, the determination should be obtained within five-six (5-6) working days after the use of the investigational article and be reported to the IRB within 5 working days. See **Model Emergency Use Consent Form**.

### ***D. Informing the IRB of Emergency Use***

Principal Investigators are required to submit a written report on the emergency use to the IRB and to the applicable hospital administration within five (5) working days. However, this notification should not be construed as an IRB approval. If the subject’s consent was not obtained to the emergency use, the written report must include a written determination by a non-participating staff physician that the four conditions specified in Section VII.C above are met. The report is reviewed by the Chair to ensure that the emergency use meets the applicable regulations. The Principal Investigator is informed that if he/she anticipates the need to use the investigational article in additional subjects, prior review and approval by the IRB is required. See **Notification of Emergency Use of Investigational Product**.

In addition, if an IDE for the device exists, the Principal Investigator must notify the sponsor of the emergency use. If an IDE did not exist, the Principal Investigator must notify the FDA of the emergency use and provide the FDA, with a copy to the IRB, of a written summary of the conditions constituting the emergency, subject protection measures and results. Subsequent emergency use of the device may not occur unless the physician obtains approval of an IDE for the device and its use, as well as IRB approval.