**What are the requirements for “emergency treatment use” of FDA test articles in clinical care situations without prior convened IRB review?**

The IRB may allow for “emergency” treatment use of a test article with an IND or IDE in accordance with FDA regulations. For drugs, the situation must meet the definition of “Emergency Use” as stated in 21 CFR 56.102(d): “Emergency use means the use of a test article on 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 IRB approval.” For devices, in the case of serious disease, a device may ordinarily be made available for treatment use after all clinical trials are completed; in the case of an immediately life-threatening condition, the device may be made available before completion of clinical trials. (21 CFR 812.36.) The IRB prefers notification of an IRB Chair prior to the emergency use when time permits.

**A. Emergency Use Without Prior Notification or Clearance by IRB**

Although the IRB prefers to be notified before a test article is used in an emergency clinical care situation, there may be cases for which there is no time to notify the IRB. In such cases, the physician may proceed with the emergency use in accord with 21 CFR 56.104(c). The prescribing physician must notify the IRB of the emergency use within (5) working days. The IRB Chair or designee will review the use.

**NOTE:** Consent for emergency use of a test article must be obtained from the subject or their authorized representative using a research consent form. A research consent document, either provided by a sponsor or by the physician and containing all of the FDA required elements, must be reviewed and signed by the subject/subject’s representative even in emergency use cases.

The IRB will provide a written response acknowledging the physician’s submission of the emergency request information. The acknowledgement will remind the physician that she/he must submit safety reports or adverse event reports to either the sponsor who holds the IND/IDE for the test article, or if the PI holds the emergency IND, to the FDA as required by regulation. A copy of such reports should be sent to the IRB Office to the attention of the IRB chair who issued the acknowledgment.

**Limits on Use of Data Obtained from Emergency Use under FDA Exemption**

To be exempt from the requirement for IRB review for the emergency use of a test article in a life threatening situation, an investigator must not use the data in a systematic investigation designed to develop or contribute to generalizable knowledge or else the exemption no longer applies. To comply with this limitation, investigators must follow these three rules:

1. Do not use the emergency use exemption to circumvent the general requirement for prior IRB review;

2. Do not use data from an emergency in a prospective research study; and
3. Do not report data from an emergency use in a retrospective research study, unless granted specific approval by the IRB.