# MCW Office of Research
# Standard Operating Procedure

## EMERGENCY USE OF INVESTIGATIONAL DRUGS, DEVICES OR BIOLOGICS

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

Applies to: Faculty and Staff involved in human research

**PURPOSE:**
Federal regulations allow physicians to utilize an investigational drug, device or biologic for life-threatening emergencies with their patients when no alternative therapy or treatment has been successful.

This policy only addresses situations in which there is not sufficient time to obtain prospective IRB approval. If there is time to obtain prospective IRB approval, please see *IRB SOP: Expanded Access Use of an Investigational Drug, Device or Biologic.*

**DEFINITIONS:**
**Emergency Use of an Investigational Drug:** The use of an investigational drug or biological product 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 IRB approval.

**Emergency Use IND:** In an emergency situation, the request to use an unapproved investigational drug may be made via telephone or other rapid means of communication, and authorization to ship and use the drug may be given by the FDA official over the telephone. In these situations, known as emergency IND (eIND) requests, shipment of and treatment with the drug may begin prior to FDA's receipt of the written IND submission that is to follow the initial request.

**Emergency Use of an Investigational Device:** Emergency use is the use of an investigational device in an emergency situation. It is intended to provide patients and physicians with access to devices intended to treat life-threatening or serious diseases or conditions when there is no available alternative and no time to obtain FDA approval. Emergency use may apply even if the investigational device is being studied in a clinical trial under an IDE: if a physician needs to use the device in a manner inconsistent with the approved investigational plan; or a physician who is not part of the clinical study, wishes to use the device to treat a patient with a life-threatening or serious disease or condition. Emergency use of an investigational device may occur before an IDE is approved and when a device is not being studied under an IDE.

**Life-threatening Situation:** With regards to 21 CFR 56.102(d), both life-threatening and severely debilitating, are defined below.

- **Life-threatening**:
    1. Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and

2. Diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival.

- **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.

## PROCEDURE:

### Emergency Use of an Investigational Device/Drug:

1. Physicians should contact the HRPP office immediately if they are considering using an investigational article in an emergency use situation in order to determine if an IDE/IND must be filed or not with the FDA prior to the use. In addition, federal regulations require repeated use of the same investigational articlet to have IRB review and approval prior to use.
2. When a Physician has used an investigational article to treat a patient with a life-threatening event, the Physician must complete and submit an initial eBridge submission to the IRB to report the use or imminent prospective use of the article. Federal regulations require for physicians to notify the IRB of the use within 5 working days.
3. The IRB eBridge submission must include:
    a. Emergency Use IDE/IND number or Authorization from the FDA to ship the investigational article; 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 test article
        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.
4. Following the emergency use of an investigational article, the patient should be monitored to detect any possible problems arising from the use of the investigational article.
5. Any follow-up reports should be submitted to the IRB, the Sponsor and/or the FDA in which summary information regarding the patient outcome is presented. The MCW IRB requires follow-up reports to be submitted at 30 days and 90 days post-use via eBridge CPR submission.

### Use of Data from an Emergency Use

- FDA: The emergency use of a test article is a clinical investigation, the patient is considered a subject, and the FDA may require data from an emergency use to be reported in a marketing application.
- DHHS: Under DHHS regulations, a patient may not be considered to be a *research* subject whenever emergency care is initiated without prior IRB review and approval. Thus "emergency use of a test article" cannot be claimed as research, nor may the outcome of such care be included in any report of a research activity. Investigators may not aggregate such data with research data, even if the emergency protocol is identical to that of a research protocol subsequently approved by the IRB, nor may the

investigator include the outcome of such care in any report of a research activity.

**REFERENCES:**
21 CFR 56.102 (d)
21 CFR 56.104(c)
21 CFR 812.35(a))
21 CFR 312.36
FDA Guidance: Emergency Use of an Investigational Drug or Biologic Information Sheet
FDA Guidance on Investigation Device Exemption Polices and Procedures

**SUPPORTING DOCUMENTS:**
*IRB SOP: Expanded Access Use of an Investigational Drug, Device or Biologic*

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