MCW Office of Research
Standard Operating Procedure

EMERGENCY USE OF INVESTIGATIONAL DEVICES

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 devices to address immediately life-threatening situations when there is no available alternative and before a written submission can be made. This may apply to:

- Device being studied in clinical trials under an investigation device exemption (IDE)
- Device with no IDE or ongoing clinical studies

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

DEFINITIONS:

Emergency Use: For an investigational device to be used without prior approval, the following conditions must be met:

- The patient has a life-threatening condition that needs immediate treatment.
- No generally acceptable alternative treatment for the condition exists; and
- There is no time to use existing procedures to obtain IRB and FDA approval for the use.

Immediately Life-Threatening Disease: A stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

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 Device:

1. The treating physician should contact the HRPP office immediately if they are considering using an investigational device in an emergency use situation in order to determine if an IDE must be filed or not with the FDA prior to the use.

2. When a treating physician has used an investigational device 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.
    a. If there is an IDE for the device, the IDE sponsor must notify the FDA of the emergency use within 5 days through submission of IDE report. Follow-up report should include:
        i. Summary of the condition constituting the emergency.
        ii. Patient protection measures that were followed.
        iii. Patient outcome information.
    b. If no IDE exist, the treating physician must submit to FDA a follow-up report within 5 days on the use of the device including:
        i. Description of the device used.
            1. If available, include the device manual
        ii. Details of the case.
        iii. Patient protection measure that were followed.
3. The IRB eBridge submission must include:
    a. Emergency Use IDE 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.
    d. Independent assessment from an uninvolved physician
    e. Documentation provided to FDA
4. Following the emergency use of an investigational device, 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.

REFERENCES:

21 CFR 56.102 (d)
21 CFR 56.104(c)
21 CFR 812.35(a)
21 CFR 312.36
21 CFR 312.300
FDA Guidance: Expanded Access for Medical Devices

SUPPORTING DOCUMENTS:
IRB SOP: Expanded Access Use of an Investigational Device

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