MCW IRB Committee Procedures

EMERGENCY USE OF INVESTIGATIONAL DRUGS, DEVICES, OR BIOLOGICS

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

Applies to: Institutional Review Board Committees

PURPOSE:
To outline the process and steps the IRB Committee takes in reviewing and evaluating notification of an emergency use of an investigational drug, biologic or device by a physician.

DEFINITIONS:

Emergency Use: for an investigational drugs, biologics, or devices 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:

1. Under federal regulations, the IRB Committee is charged to review a physician's submission for emergency use of an investigational product (e.g. a drug, device or biologic) within 5 working days of the use. The IRB Committee or designee will conduct a review as outlined in this procedure.
2. The HRPP office will forward the submission to the IRB Chair or designee in accordance with *Staff: Assigning Primary Reviewers and Use of Consultants.*
3. For emergency use submissions of an investigational product, the IRB Chair or designee will review the event with with regards to the federal regulations, the subject's condition, the alternatives, and if consent was obtained or the subject was notified of the use appropriately.
4. Because the emergency use of an investigational product is not considered research, the IRB Chair or designee will review the submission to ensure all elements are addressed per the federal regulations. The IRB Chair or designee will complete the *IRB Member Form: Emergency Use Reviewer Checklist.*

The specific criteria are made available to all members via the HRPP website.

IRB Review

1. The IRB Chair or designee will consult with the physician and the HRPP office to determine if there have been any emergency uses of the same investigational product (device, drug or biologic) for the same indication at our institutions. FDA regulations *typically* require prospective IRB review and approval for repeated uses of the same investigational product at an institution.
    a. If an investigational product has been used before via emergency use setting, additional information will be provided to the IRB Chair or designee.
2. The IRB Chair or designee will review the eBridge SmartForm and the consent form (if applicable), along with the additional documentation.
    a. For investigational drug/biologic, IRB eBridge submission must include:
        i. Emergency Use IND or IDE number or Authorization from the FDA to ship the investigational product; and
        ii. Approval from the Sponsor for use of the investigational product; and
        iii. 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:
            1. The patient was confronted by a life-threatening situation necessitating the use of the investigational drug or biologic
            2. Informed consent could not be obtained because of an inability to communicate with or obtain legally effective consent from the patient
            3. Time was not sufficient to obtain consent from the patient's legal representative
            4. 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. Independent assessment from an uninvolved physician
            6. Documentation provided to FDA including any follow-up reports.
3. The IRB Chair or designee will acknowledge if the notification meets the federal regulations.
4. An IRB decision letter will be issued to the Investigator, along with the consent form in accordance with *Staff: Creation and Processing of IRB Meeting Minutes and Decision Letters.* The IRB Decision Letter will include instructions to the Investigator to file follow-up reports regarding the patient outcomes 30 days and 90 days post-use.
5. The IRB Chair will inform the convened Committee of the Emergency Use of the investigational product at their next IRB meeting.

REFERENCES:

21 CFR 56.102
21 CFR 56.104(c)
21 CFR 812.35(a)
21 CFR 312.36
21 CFR 312.300
21 CFR 312.305
21 CFR 312.310
FDA website and guidance documents

SUPPORTING DOCUMENTS:
IRB Member Form: Emergency Use Reviewer Checklist
Staff: Assigning Primary Reviewers and Use of Consultants.
Staff: Creation and Processing of IRB Meeting Minutes and Decision Letters

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