MCW IRB Committee Procedures

REVIEW OF EXPANDED ACCESS USE REQUESTS - DEVICES

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 requests for expanded access use of an investigational device by a physician.

When a patient has a serious or life-threatening condition that is not addressed by current approved treatments, options may exist to use an investigational device (i.e. one that has not been approved or cleared by FDA) to treat the patient. A variety of FDA mechanisms exist to grant this expanded access, including:

1. Compassionate Use (or Individual Patient/ Small Group Access)
2. Treatment Investigational Device Exemption (IDE)

Note: This policy only addresses these pathways which still require both IRB and FDA approval prior to expanded access. If a physician needs to treat a patient in an emergency capacity in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB or FDA approval, please see *IRB SOP: Emergency Use of Investigational Devices.*

DEFINITIONS:
Expanded Access: A pathway for patients with serious or life-threatening disease or conditions to access an investigational medical device that has not been approved or cleared by FDA for treatment outside of a clinical trial when no comparable or satisfactory alternative therapy options are available.

Clinical Trial: A research project in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

Compassionate Use: This term is used primarily by the device arm of the FDA. Compassionate use provides a pathway to accessing investigational devices that have not received FDA approval or clearance for patients for whom the treating physician believes the device may provide a benefit in diagnosing, monitoring, or treating their disease or condition.

Compassionate use can be for devices that are being studied in a clinical trial under an IDE for patients who do not meet the requirements for inclusion in the clinical investigation but for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. It can also be used for devices that are not being studied in a clinical investigation (i.e., an IDE for the device does not exist). This provision is typically approved for individual patients but may be approved to treat a small group.

Treatment IDE: An approved IDE specifies the maximum number of clinical sites and the maximum number of human subjects that may be enrolled in the study. During the course of the clinical trial, if the data suggest that the device is effective, then the trial may be expanded under a new IDE to include additional patients with life-threatening or serious diseases.

Humanitarian Use Device (HUD): A medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.

PROCEDURE:

1. Under Federal Regulations, the IRB Committee is charged to review a physician's application for expanded access use of an investigational device, prior to the use.
2. For the review of the expanded use submission, the HRPP office will assign IRB Reviewers in accordance with *Staff: Assigning Primary Reviewers and Use of Consultants*
    a. For projects which involve a Humanitarian Use Device, the IRB Committee considers the project and reviews it in conjunction with the federal regulations regarding the conduct, design and consenting process of these projects.
3. The IRB Committee Chair or Full Committee will review the submission to ensure the appropriate regulatory elements are addressed per the federal regulations. The IRB Committee will complete the *IRB Member Form: Expanded Access Reviewer's Checklist.*
4. The IRB Committee Chair or Full Committee will determine if the submission meets the criteria for approval, per the federal regulations. 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.*
5. The IRB Decision Letter will include instructions to the Investigator to file follow up reports regarding the patient's outcome at the end of the treatment period or no later than 12 months after the initial approval was granted. The follow up must be submitted via eBridge CPR submission.

REFERENCES:

21 CFR 312 subpart I
21 CFR 812.36
FDA website and guidance documents

SUPPORTING DOCUMENTS:
IRB Member SOP: Emergency Use of Investigational Devices
IRB Member Form: Expanded Access Reviewer Checklist
IRB Staff: C2 Checklist for Treatment Use Submissions
Staff: Assigning Primary Reviewers and Use of Consultants
Staff: Creation and Processing of IRB Meeting Minutes and Decision Letters

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