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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