Compassionate Use: This term is used primarily by the device arm of the FDA. Compassionate use provides a pathway to a

iv. an independent assessment from an uninvolved physician
v. authorization from the device manufacturer on the use of the device
vi. a monitoring schedule to meet the needs of the patient, recognizing the investigational nature of the device

b. <u>If there is no IDE for the device:</u>
    i. A compassionate use request for a single patient or group may be submitted to FDA by the physician or device company along with the information included in the supplement above and a description of the device provided by the manufacturer.

4. An eBridge submission must be completed and submitted for IRB review prior to use of the device. Refer to *IRB SOP: Submitting New Projects* for further information. The MCW IRB is responsible to conduct initial reviews and maintain ongoing monitoring of all devices used in human subjects under its jurisdiction. This includes the FDA expanded access device pathways mentioned above.

    a. <u>Compassionate Use:</u> MCW IRB requires FDA approval of the Compassionate Use request prior to issuing IRB approval.
        i. The physician must include the following information in the eBridge submission.
            1. FDA approval document, including the FDA issued approval number
            2. Draft of the informed consent document that will be used
            3. An independent assessment from an uninvolved physician

2. There is no comparable or satisfactory alternative device available to treat or diagnose the disease or condition in the intended patient population;
3. The device is under investigation in a controlled clinical trial for the same use under an approved IDE, or all clinical trials have been completed; and
4. The sponsor of the controlled clinical trial is pursuing marketing approval or clearance of the investigational device with due diligence.

ii. The treating physician must include the following information in the eBridge submission.
1. FDA approval document
2. IDE Sponsor protocol
3. Draft informed consent document
4. Device instructions for use/ device manual

iii. Following the treatment use of an investigational device, the patient should be monitored to detect any possible problems arising from the use of the investigational device.

iv. The sponsor of a treatment IDE must submit progress reports on a semi-annual basis to FDA [21 CFR 812.36(f)] until the filing of a marketing application. The treating physician must submit a copy of these reports to MCW IRB at the time of CPR.

v. The sponsor of a treatment IDE is responsible for submitting all other reports required under 21 CFR 812.150.

5. If any problems occur as a result of using the device, these should be reported promptly to the IRB (via a Reportable Event), the Sponsor and/or FDA.

Humanitarian Use Devices (HUD)

1. To be considered for HUD status, an investigator or the device sponsor must submit a request for HUD designation to the FDA. The FDA will determine if it should grant a Humanitarian Device Exemption (HDE) for use of the device.
2. The FDA requires IRB review and approval for local use of an HUD, including convened Committee review and, at a minimum, annual continuing review, which may be expedited. This is the only situation where federal regulations require IRB approval and monitoring of an activity that is clearly not research. However, if the HUD is being used in research or in a clinical investigation, the IRB must comply with all FDA regulations related to IRB review of research.
3. FDA regulations require that the investigator and/or sponsor clearly state that the device is an HUD and that the effectiveness of the device has not been demonstrated.
4. When an Investigator wishes to utilize a HUD to treat a patient population; the Investigator must complete and submit an initial eBridge submission for IRB review. Refer to *IRB SOP: Submitting New Projects* for further information. The MCW IRB is responsible to conduct initial reviews, grant approvals and maintain ongoing monitoring of all HUD devices, used in human subjects under its jurisdiction.
5. The Investigator must include the following information in the eBridge submission:
    - generic and trade name of the device
    - FDA HDE #
    - date of HUD designation
    - indications for the use of the device
    - description of the device
    - contraindications, warnings, and precautions for use of the device
    - adverse effects on health

- alternative practices and procedures
- marketing history
- summary of projects using the device
- A clinical consent form for the patient that includes a clear statement that the device has not been proven safe or effective in the way most devices are approved.
    - Teams may choose to use the MCW HUD Humanitarian Device Exemption (HDE) consent form template.

6. The MCW IRB will review the submission and issue an approval letter if the criteria for the use of HUD have been met.
7. Investigators are required to submit continued progress reports to the IRB to continue the use of an HUD once approval has been obtained. See *IRB SOP: Continuing Progress Reports* for additional information.

REFERENCES:
21 CFR 312 subpart I
21 CFR 812.36
FDA website and guidance documents for Expanded Access for Medical Devices

SUPPORTING DOCUMENTS:
IRB SOP: Submitting New Projects
IRB SOP: Continuing Progress Reports
IRB SOP: Emergency Use of Investigational Devices

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