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Owner	Dawn Benson: SVP, General Counsel
Area	Institutional Review Board (IRB)
Applicability	Phoebe Putney Memorial Hospital

Compassionate Use: Investigational Devices Policy

Scope:

This policy applies to all research involving human subjects, including behavioral, biomedical and social sciences and clinicians related to the use and review of expanded access (i.e., Compassionate Use) of investigational devices.

Purpose:

The FDA Expanded Access Program (EAP) allows for compassionate use for treatment purposes in patients when there is an immediately life-threatening condition or in patients with serious diseases or conditions when there are no comparable or satisfactory alternative therapies to diagnose, monitor or treat the patient's disease or condition and the sponsor or manufacturer agrees to provide the investigational medical device for treatment purposes.

This policy describes the responsibilities of clinicians and the Phoebe Putney Memorial Hospital Institutional Review Board (IRB) and processes related to use and review of expanded access (i.e., compassionate use) of investigational medical devices.

Definitions:

Expanded Access – sometimes called "compassionate use" is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical device for treatment outside of clinical trials when there is no comparable or satisfactory alternative therapy options available. In most circumstances, approval by the IRB and FDA is required prior to enrolling the participant.

Note: The terms “emergency use” and “compassionate use/expanded access” are not the same. The FDA’s definition of “emergency use” exemption allows the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain FDA and IRB approval. Refer to Emergency use of Drugs, Biologics, and Devices policy on the Phoebe policy portal.

Investigational Medical Devices

FDA Expanded Access Types for Medical Devices

- Compassionate Use (or Single Patient/Small Group Access)
- Treatment Use
- Emergency Use

Policy:

Expanded access pathways, also referred to as “compassionate use”, are designed to make investigational devices available as early in the medical device evaluation process as possible to patients without therapeutic options, because they have exhausted or are not a good candidate for approved therapies and cannot enter a clinical trial.

Expanded access refers to the use of investigational or unapproved/uncleared medical devices (all referred to as “investigational” throughout this section) outside of a clinical trial, where the primary intent is treatment, rather than research. Because the medical devices have not yet been approved by FDA as safe and effective, it is important to remember that the medical device may not be effective and there may be unexpected serious adverse effects and to take appropriate measures to ensure that this is understood by the patient or their legally authorized representative and to monitor for safety.

1. Expanded User for Investigational Medical Device.

Unapproved medical devices may normally only be used in humans in an approved clinical trial under the supervision of a participating clinical investigator. However, there may be circumstances under which a health care provider may wish to use an unapproved device when a patient is facing life-threatening circumstances or suffering from a serious disease or condition for which no other alternative therapy or diagnostic exists or is a satisfactory option for the patient.

The FDA has made the following mechanisms available for these circumstances:
• Compassionate Use (or Single Patient/Small Group Access)
• Treatment Use
• Emergency Use

The FDA recognizes that there are circumstances in which an investigational medical device is the only option available for a patient faced with a serious or life-threatening disease or condition.

The compassionate use provision provides a path to accessing investigational medical devices that have not received FDA approval or clearance for patients for whom the treating physician believes the medical 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 Investigational Device Exemption 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 or diagnosing their disease or condition. It can also be used for medical devices that are not being studied in a clinical investigation (such as an Investigational Device Exemption for the device does not exist). This provision is typically approved for individual patients but may be approved to treat a small group, if the small group request is under an Investigational Device Exemption.

Compassionate use may not commence until the FDA approves the use, generally via sponsor submission to FDA of an Investigational Device Exemption supplement requesting approval for a compassionate use under section 21 CFR 812.35,(a).

Requirements to determine if expanded access is appropriate

Expanded access may be appropriate when all the following apply:

- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

If expanded access is appropriate, IRB approval is required.

1.1 Procedure for use of Investigational Medical Device:

A physician may seek expanded access and compassionate use of an investigational medical device once it has been determined that there are no available clinical trials for the patient. When enrollment is not possible or feasible, expanded access and compassionate use may be an option for use of an investigational medical device.

The physician must confirm the patient's current disease or condition qualifies for expanded access and compassionate use, meaning that the patient has either a serious or immediately life-threatening disease or condition and there is no available comparable or satisfactory alternative available for the patient.

The physician must then identify the appropriate expanded access request type. If the patient meets criteria for expanded access, the physician must speak with the sponsor or manufacturer to see if they will provide the investigational medical device for expanded access use. The Investigator must work closely with the sponsor or manufacturer, the FDA and the IRB to ensure that proper regulatory procedures are followed. *Refer to the FDA website for more information about expanded access to medical devices.*

1.2 IRB Review

Unless the conditions that permit an emergency use exemption are satisfied, IRB approval must be obtained prior to initiating treatment with the investigational device. When the request is for single-patient compassionate use, the review may be conducted by the IRB Chair (or designee). Otherwise, the review must be conducted by the convened IRB.

To request IRB approval for compassionate use, investigators will contact the IRB and submit the following:

- A completed IRB Compassionate Use Form – Medical Device located on the Phoebe IRB Website at Institutional Review Board - Phoebe Putney Health System,
- A completed certificate from a research ethics training course (NIH/NCI,CITI or other)
- Conflict of Interest declarations, and any additional documentation noted within it;
- A copy of the information submitted to the FDA (and FDA approval, if available);
- A copy of the investigational medical device brochure, Instructions for Use, or other similar documentation that provides information regarding the potential risks and benefits of the device;
- A copy of the draft informed consent document.
- A copy of written approval by the PPMH CEO and the medical director over the related practice area.
- An appropriate plan and schedule for treating and monitoring the patient, taking into consideration the nature of the device and the needs of the patient. The plan should include monitoring to detect any possible problems arising from the use of the device.

The IRB may review the expanded access application prior to FDA approval being received but will not approve until receipt of FDA approval has been received. The IRB will provide the investigator with written documentation of its review.

The IRB may consider reliance upon an external IRB for Compassionate Use protocols on a case by-case basis when the IDE is held by a commercial sponsor and an external IRB has already approved the protocol and is willing to accept review and oversight of additional investigators/sites. Investigators should contact the IRB to discuss IRB reliance for Compassionate Use protocols.

1.3 Post-Approval Requirements.

Investigators are responsible for complying with any sponsor or FDA reporting requirements. The post-approval requirements for research described throughout this and other policies apply, including, but not limited to, prospective IRB approval of any proposed modifications to the plan or materials approved by the IRB unless the change is necessary to eliminate apparent immediate hazard to the patient (in which case it must be promptly reported), reporting of unanticipated problems, noncompliance, complaints, and other reportable information, and for continuing review and study closure, as applicable. Additionally, a follow-up report to the FDA is required following a compassionate use by whomever submitted the original request to the FDA. The report should include summary information regarding patient outcome and any problems that occurred as a result of the device. A copy of the follow-up report to the FDA and any other post-approval submissions or reports to the FDA must be submitted to the IRB within 7 business days of the date of submission to the FDA.

1.4 Emergency Use

See Emergency Use: Investigational Drugs, Biologics or Devices IRB Policy.

References:

Humanitarian Use Device (HUD) Policy)

Emergency Use of Drugs, Biologics, and Devices

Compassionate Use Form – Medical Devices

Compassionate Use Form – Investigational New Drug

Supplement G, Financial Conflict of Interest Disclosure Form

Approval Signatures

Step Description	Approver	Date
CEO Final Approval	Deborah Angerami: CEO	8/1/2025
Chief Operating Officer	Jane Gray: PPMH Chief Operating Officer	8/1/2025
Owner/Legal Approval	Dawn Benson: SVP, General Counsel	7/15/2025

Applicability

Phoebe Putney Memorial Hospital

History

Created by Pardue, Sharon: Paralegal on 7/15/2025, 11:04AM EDT

> This is a new policy that was approved by the IRB at the February 26, 2025 IRB Committee Meeting.

Approval flow updated in place by Williams, Mary: Paralegal on 7/15/2025, 11:34AM EDT

Last Approved by Benson, Dawn: SVP, General Counsel on 7/15/2025, 11:46AM EDT

Last Approved by Gray, Jane: PPMH Chief Operating Officer on 8/1/2025, 9:42AM EDT

Last Approved by Angerami, Deborah: President/CEO PPMH on 8/1/2025, 1:29PM EDT

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