



Origination 2/7/2022
Last Approved 3/27/2025
Effective 3/27/2025
Last Revised 2/7/2022
Next Review 3/26/2028

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

Vulnerable Populations Research

Scope:

This policy applies to all Phoebe Putney Health System, Inc. affiliates including Phoebe Putney Memorial Hospital, Inc., Phoebe Physician Group, Inc., Phoebe Sumter Medical Center, Inc., and Phoebe Worth Medical Center, Inc.

Purpose:

Due to issues with the ability to give consent to research, the Phoebe Putney Memorial Hospital, Inc. Institutional Review Board (IRB) does not allow research to be conducted on vulnerable populations.

Definitions:

Vulnerable Participant – any individual who lacks the ability to fully consent to participate in a study.

Vulnerable Populations include the following:

- Pregnant women – the period of time from implantation until delivery.
- Human fetuses, and neonates – the product of conception from the time of implantation until delivery.
- Prisoners – anyone involuntarily confined to detained in a penal institution, including individuals detained pending arraignment, trial, or sentencing.
- Children – persons who have not attained the legal age for consent to treatments or

procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

- Cognitively impaired persons – person having either a psychiatric disorder, an organic impairment, or a developmental disorder which affects cognitive or emotional functions.
- Economically or educationally disadvantaged persons.

Policy:

The IRB does not allow research to be conducted on Vulnerable Populations. Research studies proposing the involvement of Vulnerable Populations or including Vulnerable Participants will not be considered or approved by the IRB.

Procedure:

N/A

References:

21 CFR 56.111

46 CFR 46 Subparts B, C, and D

Approval Signatures

Step Description	Approver	Date
CEO Final Approval	Deborah Angerami: CEO	3/27/2025
CMO Approval	Jason Smith: CMO, PPMH	3/10/2025
Chief Operating Officer	Jane Gray: PPMH Chief Operating Officer	3/7/2025
Owner/Legal Approval	Janine Sarti: Deputy General Counsel	1/30/2025

Applicability

Phoebe Putney Memorial Hospital

History

Sent for re-approval by Pardue, Sharon: Paralegal on 1/30/2025, 12:28PM EST

No Changes to the Policy. This Policy was approved by the IRB Committee on January 29, 2025.

Last Approved by Sarti, Janine: Associate General Counsel on 1/30/2025, 2:05PM EST

Last Approved by Gray, Jane: PPMH Chief Operating Officer on 3/7/2025, 4:20PM EST

Last Approved by Smith, Jason: CMO, PPMH on 3/10/2025, 10:10AM EDT

Administrator override by Williams, Mary: Paralegal on 3/12/2025, 5:34PM EDT

Owner changed from Janine Sarti to Dawn Benson.

Last Approved by Angerami, Deborah: President/CEO PPMH on 3/27/2025, 3:16PM EDT

Activated on 3/27/2025, 3:16PM EDT

COPY