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

Principal Investigator Recordkeeping Responsibilities

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:

The purpose of this policy is to clarify a principle investigator's record keeping requirement as it relates to human subject research.

Definitions:

N/A

Policy:

IRB has adopted a consistent and conservative approach to the retention of human subjects research review records. All records described in this policy shall be accessible for inspection and copying by authorized representatives of the IRB, by authorized representatives of the federal funding agency, if any, and any federal oversight body with relevant authority.

Procedure:

1. Records Retained by the Principal Investigator. The principal investigator shall have primary responsibility for curating their research records for a minimum of three years post-study termination, including signed consent forms and completed surveys, research notebooks, as well as digital records or another media form.
2. For FDA-regulated research. In accordance with 21 CFR 312, an investigator or sponsor shall retain the records and reports for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified.
3. In accordance with 21 CFR 812, an investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.
4. Departing Principle Investigator. In the event of exigent circumstances where the investigator cannot retain research records, or if the investigator intends to leave their position, the investigator should identify the successor responsible for maintaining those institutional records, and for determining whether the original records or verified copies shall be retained by the IRB. In the event an investigator leaving their position removes the original research data, they must leave a verified copy and agree to provide access to the IRB to the original data, as well as to other individuals or entities having a legitimate need for access.

References:

- 45 CFR 46.115 IRB Records
- 21 CFR 56.115 IRB Records
- 21 CFR 312 Investigational New Drug Application
- 21 CFR 812 Investigational Device Exemptions
- 42 CFR 93.317 Retention and custody of the research misconduct proceeding record
- OMB Circular A-110 Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (part 50, Reports and Records)
- US Department of Health and Human Services, Office of Research Integrity, on Responsible Conduct of Research – Lab Management/Notebook and Data Management

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

Sent for re-approval by Pardue, Sharon: Paralegal on 7/15/2025, 11AM EDT

> There are no changes to this policy and it was approved by the IRB Committee at the April 23, 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, 9:39AM EDT

Last Approved by Angerami, Deborah: President/CEO PPMH on 8/1/2025, 1:33PM EDT

Activated on 8/1/2025, 1:33PM EDT