

Phoebe Putney Health System, Inc.

POLICY TITLE: FINANCIAL CONFLICT OF INTEREST

ENTITY: PPMH

Approved by: IRB CHAIR

Review Period: 3 Years

Contact Information: IRB COORDINATOR

Effective Date: 10-26-2016

Review Date: 08-28-2019

Scope: The Financial Conflict of Interest policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

Purpose: To establish standards for the management, reduction or elimination of disclosed financial conflicts of interest in research activities conducted within Phoebe Putney Memorial Hospital (PPMH). In order to ensure the design, conduct or reporting of research will not be biased by any conflicting interest of the investigator(s) or any other member of the research team responsible for the research, researchers submitting protocols involving human subjects must disclose all financial interests that could be perceived as a potential conflict of interest to the IRB at the time of review of the study.

Definitions:

Conflict of Interest: A "Conflict of Interest" exists where a "Significant Financial Interest" of a "Covered Individual" would reasonably appear to be affected by the clinical research, or is held in entities that would reasonably appear to be affected by the clinical research, or where some circumstance would cause an independent observer to reasonably question whether an individual's professional actions or decisions are determined by consideration of personal gain, financial or otherwise.

Covered Individual: Includes any investigator, member of the investigator's research staff, student, fellow, trainee, or administrator who conducts or supports research involving human subjects at PPMH and who is in a position to influence the design, conduct or reporting of the research. For purposes of this policy, "covered individual" includes the individual's spouse and dependent children except as noted otherwise.

Financially Interested Company: Means a commercial entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the research. The term includes companies that compete with the sponsor of the research or the manufacturer of the investigational product, if the covered individual actually knows that the financial interests of such a company would reasonably appear to be affected by the research. This term also includes any entity acting as the agent of a financially interested company, such as a contract review organization.

Financially Interested Individual: Means a covered individual who holds a “Significant Financial Interest” that would reasonably appear to be affected by the individual’s research involving human subjects.

Significant Financial Interest: Includes the following interests of the covered individual (and his or her spouse and dependent children), or of any foundation or entity controlled or directed by the individual of his or her spouse:

1. Salary, consulting fees, honoraria (including honoraria from a third party; if the original source is a financially interested company), gifts, or “in-kind” compensation from a financially interested company (or entitlement to same), whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement with the sponsor), that when **aggregated** exceeds \$5,000 during the prior twelve-month period or is expected to exceed \$5,000 over the next twelve-month period.
2. Other business income, such as dividends, rents, capital gains, interest, etc., from a financially interested company (or entitlement to the same) that when **aggregated** exceeds \$5,000 during the prior twelve-month period or is expected to exceed \$5,000 over the next twelve-month period.
3. An equity interest, in the form of stock, stock options, real estate, or any other interest (e.g., recourse loans to a financially interested company) that when **aggregated** is greater than or equal to a 5% ownership interest or that exceeds \$5,000 in value in a *publicly-traded* financially interested company.
4. Equity interests as defined above (or entitlement to same) of **any** amount in a *non-publicly-traded* financially interested company.
5. Royalty income or the right to receive future royalties under a patent, patent application or copyright, where the research is directly or indirectly related to the licensed technology or work.
6. Any non-royalty payments (or entitlements to same) in connection with the research that are not directly related to the reasonable costs of the research (as specified in the agreement with the sponsor). This includes any bonus, incentives or milestone payments to the covered individual in excess of reasonable costs incurred as well as other types of financial support (e.g., funding research staff salaries).
7. Service by a covered individual or his/her spouse as a Board Member, Officer, Director, Partner, Trustee, etc., for a financially interested company, whether or not remuneration is received for such service.
8. An appointment to serve on the scientific advisory board of a financially interested company unless the covered individual has no current significant financial interest in the financially interested company or the investigational product and agrees not to hold such an interest for a period of at least three years following completion of any related research conducted at or under the auspices of PPMH.

Policy:

A potential conflict of interest exists in any situation in which a financial interest related to a research study or other considerations may compromise or have the appearance of compromising a member of the research team’s professional judgment in designing, conducting or reporting research. PPMH researchers are expected to perform their duties without having their loyalty divided or compromised.

Procedure:

1. The principal investigator (PI) will certify to the following at the time of initial and each continuing review period on behalf of himself/herself as well as all research team members who may be in a position to influence the design, conduct or reporting of the research ("covered individuals"):

We have read and understand PPMH's Financial Conflict of Interest policy; have made all financial disclosures required by it, if any; and will comply with any conditions or restrictions imposed by the IRB or PPMH to manager, reduce or eliminate actual or potential conflicts of interest.

2. The PI will also complete a PPMH IRB "Financial Conflict of Interest Disclosure Form" on behalf of himself/herself and all covered individuals of the research team. If there is a conflict or potential conflict, the PI will identify the conflicted member of the research team and attach any supporting documentation that further defines and/or explains the conflict or potential conflict.
3. If the PI or another covered individual of the research team acquires an equity or intellectual property interest or receives compensation that must be disclosed under the terms of this policy during the IRB approval period, the disclosure should be made as soon as is practicable and not wait until the time of next review.
4. IRB administrative staff will review all Disclosure forms to determine if a conflict or potential conflict has been disclosed. The IRB will review all disclosure to evaluate the extent of the potential conflict and determine whether the covered individual will be able to continue with the study or recommend other appropriate measures for reducing or managing the conflict. The IRB may also determine that the probability of the financial interest affecting the design, conduct or reporting of the research is too remote to warrant any specific conditions or restrictions or it may determine that monitoring procedures to be performed by external organizations are adequate to protect human subjects and the integrity and objectivity of the research.
5. The IRB will be authorized to request other information that it deems necessary to assist in its determination.
6. The covered individual, and the PI if he or she is not the covered individual, will be notified of the outcome of the review and restrictions or conditions imposed, if any.
7. Every effort will be made to maintain the privacy of the information gathered in the IRB's deliberation, within the limits imposed by applicable laws and regulations. Supporting documentation for disclosed conflicts or potential conflicts will not be maintained as part of the IRB study file. Such documentation will be maintained in a separate file until such time as the IRB study file is no longer required to be maintained. [See related policy, "IRB Recordkeeping"]

References:

- PHS 42 CFR Part 50 Subpart F; 45 CFR Part 94

REVISION HISTORY

Revision Number	Description of Changes	Approvals	Date
N/A	Initial release of Policy for PPHS Policy Management System (Compliance 360 Program). This policy replaces all previous versions.	IRB Committee	10-26-2016
0	Reviewed – No Changes	IRB Committee	08-28-2019