Institutional Review Board Procedure No. 16

EFFECTIVE DATE: ***April 26, 2024***

PROCEDURE TITLE:

Promoting Objectivity in Research - Financial Interest Disclosure

To be reviewed every three years by:
Institutional Review Board

REVIEW BY: ***April 25, 2027***

PROCEDURE

This Procedure implements the requirements of Institutional Review Board Policy No. 1 *Authority of the Institutional Review Board*, which requires the Trinity Health Mid-Atlantic (THMA) Institutional Review Board (IRB) establish policies and procedures to ensure that the THMA's IRB operations fully comply with applicable laws, regulations and professional standards, and the *Ethical and Religious Directives for Catholic Health Care Services*, including promoting the conduct of ethical and compliant research.

Scope

This policy applies to all Research (as defined herein) conducted at all units of Trinity Health Mid-Atlantic.

Policy

All Investigators, as defined in this policy, who engage in Research will disclose all significant financial and fiduciary interests to Trinity Health Mid-Atlantic (THMA) on an ongoing basis.

The physicians and associates of THMA are committed to conducting their institutional activities in accordance with the highest standards of integrity and ethics and in compliance with all applicable laws and regulations related to conflicts of interest and objectivity in Research. To promote the ethical conduct of Research, THMA has established this policy and related forms and procedures to identify and address conflicts of interest in the context of Research. Financial interests in Research are distinct because financial interests are discretionary, and because the perception is widespread that they may entail special risks. Specifically, opportunities to profit from Research may affect – or appear to affect – an Investigator's judgment about enrollment, the clinical care provided to participants, and even the proper use of protected health information. Financial interests also threaten scientific integrity when they foster real or apparent biases in study design, review, data collection and analysis, adverse event reporting, or the presentation and publication of Research findings. The purpose of this policy is to set forth information about and procedures to identify and address conflicts of interest in the context of Research.

Definitions

1. Conflict of Interest (COI) is any situation or relationship that biases or has the real or perceived potential to bias the review of, design, conduct, analyses, reporting, or outcome of a research study. A COI can be real or perceived; financial or non-financial..
2. External Entity means any natural person, corporation, partnership, sole proprietorship, association, organization, holding company, joint stock company, receivership, trust, governmental agency or subdivision regardless of whether organized for profit, nonprofit or charitable purposes.
3. Equity Interest means any stock, option or other ownership interest in an External Entity. "Equity Interest" also includes ownership interests in a non-publicly traded corporation (e.g. "founder's shares") even where such value of the ownership interest is not readily ascertainable through reference to public prices.
4. Family Member means the Investigator's spouse and dependent children.
5. Financial Conflict of Interest (FCOI) means that THMA has determined the conflict could directly and significantly affect the design, conduct or reporting of Research.
6. Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the institution including research, research consultation, teaching, clinical practice, institutional committee memberships, and services on panels such as Institutional Review Boards (IRB) or Data Safety Monitoring Boards.
7. Investigator means the Principal Investigator (PI) and any other personnel, regardless of title or position, who is responsible for the design, conduct, or reporting of research, which may include (by way of example and not as an exclusive list): co-investigators, research coordinators, graduate or undergraduate students, technical support staff, biostatisticians, and data managers. This definition refers to the function of individuals in the Research project, and not their amount or source of remuneration and includes unfunded personnel.
8. Manage or Management means to take action to address a Financial Conflict of Interest which includes reducing or eliminating the Financial Conflict of Interest to ensure that the design, conduct and reporting of Research is free from bias or the appearance of bias.
9. PHS means the Public Health Service of the U.S. Department of Health and Human Services (DHHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH). Examples of PHS funding mechanisms include:
    a. Grants and Contracts
    b. Cooperative agreements
    c. Career Development Awards
    d. Center Grant of Individual Fellowship Awards
    e. Any activity where funding is provided by PHS
10. Remuneration means salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship)

11. Research means a systematic investigation, study or experiment designed to develop or contribute to general knowledge relating broadly to public health, including behavioral and social-sciences research. This definition also encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
12. Significant Financial Interest (SFI) means an Investigator's (and/or his/her Family Members') financial interest consisting of one or more of the following that reasonably appears to be related to the Investigator's institutional responsibilities:
    a. If the Investigator (and/or his/her Family Members') has an Equity interest in a publicly traded entity, then a SFI exists if the value of any Remuneration received from the External Entity in the twelve months preceding the disclosure, and the value of any equity interest in the External Entity as of the date of disclosure, when aggregated, exceeds $5,000.
    b. If the Investigator (and/or his/her Family Members) has an Equity interest in a non-publicly traded entity, then a SFI exists if the value of any Remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's Family Members) holds any Equity Interest (e.g., stock, stock option, or other ownership interest) in the External Entity, regardless of whether the value of such Equity Interest is readily ascertainable.
    c. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
    d. Reimbursed or sponsored travel that is not related to the Investigator's Institutional Responsibilities, such as travel required for awarded Grant activity. Note: travel may be paid on behalf of the Investigator and not directly reimbursed to the Investigator so that the exact monetary value may not be readily available but still must be estimated.
    e. A SFI does not include the following:
        i. Salary, royalties or other remuneration paid by THMA to the Investigator and intellectual property rights assigned to THMA;
        ii. Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a);
        iii. Income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001 (a).
        iv. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles.

Procedure

Management of FCOI

1. To the extent possible and reasonable under the circumstances, the IRB Administrator and Chair will work with the Investigator to develop the means for the Research to take place while protecting the objectivity of the Research, its participants and uphold/maintain

scientific integrity. Listed below are several possible resolutions for Management of the FCOI that may be recommended:

a. Public disclosure of FCOI (e.g., when presenting or publishing the Research, to staff members working on the project or to the IRB);
b. For Research projects involving human subjects research, disclosure of FCOI directly to research participants in the informed consent form and during the process of consenting a patient for participation in the clinical trial;
c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the FCOI;
d. Modification of the research plan;
e. Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the Research;
f. Reduction or elimination of the SFI (e.g., sale or divestiture of an Equity Interest); or
g. Severance of relationships that create FCOI.

2. The IRB will:

a. Review the Management plan in conjunction with the proposed Research and may make additional recommendations to the Management plan. Any additions to the plan will be documented and forwarded to the Investigator. The IRB may not remove any measures from the Management plan.
b. Determine the appropriate strategies to properly oversee and manage potential Conflicts of Interest, taking into consideration the possible remedies as outlined above.
c. Inform the Investigator of the actions taken and decisions made by the IRB.

Reporting of FCOI

1. If PHS is a funding source to any Research activity, THMA will provide to PHS all FCOI information prior to the expenditure of funds and within sixty days of any subsequently identified FCOI.

2. THMA shall provide a written response to any requestors (within five business days of the request) information concerning a SFI that meets the following three criteria:

a. The SFI was disclosed and is still held by the Investigator (or/and others as defined above);
b. THMA has determined that the SFI is related to the PHS-funded research; and
c. THMA has determined that the SFI is a FCOI.

Such written response shall include the following information:

- Investigator's (or/and others as defined above) name;
- Investigator's title and role with respect to the research project;
- Name of the External Entity in which the SFI is held;
- Nature of the SFI; and
- Approximate dollar value of the SFI (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments

of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Sanctions

Sanctions and penalties for non-compliance with this policy or Management plans arising from this policy will be determined by the Institutional Official with advice from the IRB. Sanctions may include, but are not restricted to:

1. Removal of Investigator from participation in Research;
2. Letter of reprimand;
3. Termination of grant support;
4. Notification to funding agencies and/or professional journals and societies;
5. Suspension; or
6. Dismissal.

Maintenance of records

All records related to the implementation of this policy (e.g., disclosure forms, minutes of meetings called to review and manage conflicts, and notifications to funding agencies) shall be maintained by the Institutional Official or the IRB Office. These records will be kept in a secured fashion for a period of at least three years following the termination or completion of the research activities.

Responsibility

Successful implementation of this policy assumes a shared responsibility by the Investigator and THMA.

Investigator Responsibilities

1. All Investigators who are responsible for the design, conduct, or reporting of research must completely and accurately disclose all SFIs prior to submission of a grant application, on an annual basis or as changes occur. Examples include SFIs in any External Entity that:
    a. sponsors the Investigator's research;
    b. has made or pledged a gift to THMA that benefits the Investigator's research;
    c. has products, services or research interests that could reasonably appear to be affected by Investigator's research;
    d. sells goods or services to THMA that will be used in Investigator's research; or
    e. Employs an Investigator's Family Member
2. The Investigator is required to submit an updated disclosure within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

3. Investigators must complete training on FCOI prior to engaging in research. Re-training must be completed at least every four years and immediately when any of the following circumstances apply:
    a. An Investigator is new to THMA;
    b. THMA revises its conflict of interest policies or procedures in any manner that affects the requirements of Investigators; or
    c. THMA finds that the Investigator is not in compliance with this policy or Management plan.

THMA Responsibilities

1. Maintain a written policy on FCOI that complies with applicable laws and regulations.
2. Maintain the FCOI policy publicly.
3. Develop, provide and monitor FCOI training.
4. Review each submitted Significant Financial Interest Disclosure Form to identify any potential FCOI in accordance with applicable laws and regulations. At THMA the IRB Chair/designee will carry out this function.
5. Any identified potential FCOI will be reviewed by the IRB, which will then determine and document mitigation actions to manage the FCOI.
6. Establish adequate enforcement mechanisms and provide for sanctions or other administrative actions to ensure researchers are in compliance with the management plan.
7. If THMA carries out research through a sub-recipient (e.g., subcontractors or consortium members), THMA must take reasonable steps to ensure that the sub-recipient's FCOI policy is in compliance with requirements for disclosure. THMA must also incorporate as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of THMA or of the subrecipient will apply to the subrecipient's Investigators.
8. If the sub-recipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement that its policy complies with the requirements for disclosure. If the subrecipient cannot provide such certification, the written agreement between THMA and the subrecipients shall state that subrecipient investigators are subject to THMA' FCOI policy and specify time period(s) for the subrecipient to report all identified FCOI to THMA.

RELATED PROCEDURES AND OTHER MATERIALS

FDA regulations 21 CFR part 54

Federal Public Health Service regulations 42 CFR part 50, subpart F; and 45 CFR part 94

National Science Foundation Grant Policy Manual 510, as amended by 60 FR 35820 (1995).

The states of Pennsylvania, Maryland, and Delaware follow federal regulations in this area and do not maintain state rules or regulations governing financial conflicts of interest in human subjects research.

RESPONSIBLE DEPARTMENT

Further guidance concerning this Procedure may be obtained from the Trinity Health Mid-Atlantic Institutional Review Board.

APPROVALS

Initial Approval: October 30, 2020

Subsequent Review/Revision(s): April 26, 2024