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**EFFECTIVE DATE:** *April 26, 2024***PROCEDURE TITLE:***Conflict of Interest of Institutional Official, IRB Members, and Staff**To be reviewed every three years by:  
Institutional Review Board***REVIEW BY:** *April 25, 2027*

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**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.

IRB Members, the Institutional Official (IO) and the IRB Administrator will disclose all perceived or real conflicts of interest to the THMA IRB on an ongoing basis.

**Defining Conflict of Interest**

A 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 or IRB review. A COI can be real or perceived; financial or non-financial.

**Persons Affected:** the Institutional Official, IRB members, IRB Administrator, research administration officials and staff, and designees may all have potential conflicts of interest. These COIs may arise because of:

- One's indirect or direct involvement in the actual research;
- The intellectual property involved in research discoveries or industry-academic partnerships, from the financial incentives offered by pharmaceutical or biotech companies to researchers or physicians for conducting trials or enrolling participants;
- A particular role or relationships within particular institutions; and/or
- An immediate family member's involvement in the research or sponsor of the research (such as dependent children or a spouse).

## **Role of Persons Affected**

The Institutional Official, IRB Members, and Staff may find themselves in situations that present conflicts of interest, such as where:

- An investigator must report to, or is under the supervision of, an Institutional Official or an IRB member or vice versa;
- The Institutional Official or an IRB member competes for research grants or contracts in the same or similar field as an investigator whose research is scheduled for review;
- The Institutional Official or an IRB member is an immediate family member (dependent children or spouse) or has a direct reporting or supervisory relationship to the Principal Investigator (PI) or research team member;
- The Institutional Official or an IRB member or immediate family member of the Institutional Official or an IRB member currently receives any compensation from any enterprise involved in the study under consideration or from any direct competitor;
- A member or immediate family member of the Institutional Official or an IRB member has a proprietary interest in the research, such as a licensing agreement, copyright, patent, or trademark;
- A member or immediate family member of the Institutional Official or an IRB member could derive benefit (financial benefit, career advancement, or otherwise) based upon the outcome of the study; or
- An IRB member has an interest (financial or non-financial) that the member believes conflicts with or biases his/her ability to objectively review a study.
- An IRB member has a primary role in the oversight, design or conduct of the study or has a role in the analysis or management of the data;
- The IRB member is the PI or site PI (listed as PI on the IRB application; investigator requesting that the study open at this institution).
- A clinical member (physician, nurse, pharmacist, etc.) of the IRB who may or may not at some time identify, enroll or help care for a study participant does not have a COI unless one of situations described above also applies.

## **Disclosing Conflicts of Interest**

Disclosure is accomplished through the following methods, as indicated below by role:

### **A. IRB members, the Institutional Official and Staff**

- **Family Members:** Financial compensation that immediate family members receive as related to the research also must be disclosed when the family member is related to an IRB Member, Institutional Official or staff.
- All IRB members and staff will agree to **keep the information brought to the IRB in confidence and will disclose all conflicts as they come about** by signing a one-time *IRB Confidentiality and Conflict of Interest Agreement*.

## Managing Conflicts of Interest

### A. IRB Members

IRB members who have a COI are prohibited from participating in the IRB's initial or continuing review of research. Such conflicts must be disclosed, and the IRB member may *not* take part in the discussion or voting (members with a COI should recuse themselves from voting). The IRB member may provide information to the IRB if the IRB requests information from the member. In some cases, the member with a COI may wish, or may be asked by the IRB, to leave the meeting during the discussion and voting of the research proposal. Recusals of IRB members will be documented in the meeting minutes within the specific study involved. Members that recuse are not counted towards quorum. See 45 CFR 46.107(e) and 21 CFR 56.107(e).

Each IRB member is responsible for disclosing potential or actual conflicts of interest to the IRB Administrator as soon as possible. This disclosure should occur prior to the next scheduled IRB meeting, or at the beginning of the next IRB meeting, if not declared previously.

If an IRB member has questions regarding a potential conflict, the member should contact the IRB Administrator or the IRB Chair, in advance of the next scheduled IRB meeting.

### B. Staff

Staff (e.g., IRB Administrator) with a COI should declare the COI to the IRB Chair prior to the next scheduled IRB meeting, or at the beginning of the next IRB meeting, if not declared previously. In some cases the staff member with a COI may wish or be asked by the IRB Chair to leave the meeting during the discussion and voting of the research proposal.

### C. Consultants

If the IRB evokes the assistance of a consultant, the consultant will be asked to sign an *IRB Confidentiality and Conflict of Interest Agreement* in advance of reviewing any IRB materials, including study documents.

### D. Guests

If the IRB has a guest in attendance, the guest will be asked to sign an *IRB Confidentiality and Conflict of Interest Agreement* in advance of reviewing any IRB materials, including study documents, unless the guest is a staff member, researcher or member of the research study team who has already reviewed the research under discussion. These steps will serve to ensure that intellectual property is kept confidential.

#### **E. Institutional Official**

The Institutional Official, designee, and members of his/her staff will not serve on the IRB and will at all times refrain from unduly influencing the IRB. The Institutional Official is required to disclose any actual or potential COI if he or she is involved in conducting research at THMA.

### **The IRB's Management of Disclosed Conflict of Interests**

#### **A. Researchers: Maintaining objectivity in Research and the IRB's review of management plan**

The IRB will review the Financial Conflict of Interest (FCOI) Management Plan at the meeting at which the research study is discussed in order to consider the Plan in the context of the study under review and revise the Plan as required to further mitigate the FCOI. The IRB is the final authority on whether a study may be approved.

##### **1. Considerations and Additional Protections**

The Department of Health and Human Services (DHHS) recommends that IRBs take into account the following considerations related to conduct and oversight of research when there is a conflict of interest. These considerations may help to ensure that financial interests do not compromise the rights and welfare of research participants.

- Discussing and determining whether the methods used for the management of the FCOI adequately protect the rights and welfare of the participants;
- Discussing and determining whether other actions are warranted to minimize the risks to participants; and
- Discussing and determining the kind, amount, and level of detail of information to be provided to research participants regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.

Other protections that the IRB may impose on the FCOI Management Plan include one of more of the following:

- Adding a disclosure to the informed consent form.

- Requiring additional training or education requirements for the investigator and study staff.
- Requiring a non-conflicted sub-investigator, monitor, or other study staff member to assist or conduct certain parts of the research such as the informed consent process.
- Requiring a designee without a conflict to collect and report study data.
- Modifying the recruitment and retention plans to account for the existing conflict. Divestiture of financial interests either in part or in full.

## **2. IRB Motions and IRB Minute Documentation**

The IRB may accept, modify (only to add something) or reject the FCOI Management Plan at its discretion, and the IRB meeting minutes should document the action taken by the IRB.

### **B. The IRB's Management of Conflict of Interest for the Institutional Official, IRB Members, and Staff**

- IRB members will not review nor be assigned to review any studies for which they have a declared COI.
- IRB members will recuse themselves from voting and will not take part in the discussion, unless asked for additional information.
- A COI disclosed by staff will be recorded in the IRB meeting minutes for the specific study.
- If the Institutional Official has a conflict he/she cannot participate in the discussion or review of the research being considered.

### **Conflict of Interest Education and Training**

The IRB requires researchers, study team members, IRB members, staff, and the Institutional Official to complete research ethics education and training, which includes financial conflicts of interest and ethical conduct.

### **RESPONSIBLE DEPARTMENT**

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

## **RELATED PROCEDURES AND OTHER MATERIALS**

Trinity Health Research Integrity & Compliance Procedure ICR.4 *Education and Training Requirements for Individuals Involved in Human Subjects Research*

## **APPROVALS**

**Initial Approval:** August 28, 2020

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