



**Policy Title: CONFLICTS OF INTEREST  
IN RESEARCH POLICY**

**Effective Date: 12/15/2022**

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**LOCATION(S) Policy is Applicable to:**

- Saint Francis Hospital and Medical Center
- Mount Sinai Rehabilitation Hospital
- Johnson Memorial Hospital, Inc.
- The Mercy Hospital, Inc.
- Saint Mary's Hospital, Inc.
- Trinity Health Of New England Medical Group

**To be reviewed every three years by  
THofNE IRB**

**Review By: December 2025**

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**POLICY: CONFLICTS OF INTEREST IN RESEARCH POLICY**

**PURPOSE**

The purpose of this Policy is to help ensure that Trinity Health Of New England promotes objectivity in Research by establishing standards to eliminate or implement a plan to manage and monitor the risk that the design, conduct, or reporting of Research will be biased by any conflicting financial interest of an Investigator involved in funded Research. This Policy implements the requirements of the federal regulations outlined in 42 CFR Part 50 and 45 CFR Part 94 and any additional regulations that may be in effect from time to time, governing Investigator responsibilities for promoting objectivity in Research funded by the Public Health Service ("PHS") of the U.S. Department of Health and Human Services ("DHHS"), including the National Institutes of Health ("NIH" PHS-Funded Research).

**SCOPE/APPLICABILITY**

This Policy applies to all persons responsible for designing, conducting, or reporting any funded Research under the auspices of Trinity Health Of New England and/or its subsidiaries.

## **POLICY**

Trinity Health Of New England ("THOfNE") requires that all Investigators promptly and fully disclose, in writing, any significant financial interest (including those of a spouse or dependent child) that reasonably relate to the Investigator's Institutional Responsibilities and, if applicable, comply with a financial conflict of interest management or mitigation plans.

If a financial interest of greater than \$5,000 exists between the research sponsor and the Investigator, a management plan must be established by the Financial Conflict of Interest Committee (FCOI Review Committee), agreed to by the Investigator, and monitored. Any individual with a financial interest with the research sponsor above \$50,000 is precluded from participating in the Research. The FCOI Review Committee shall recommend each management plan to the THOfNE Institutional Review Board (IRB). The IRB shall be responsible for making the final determination with respect to the Investigator's role in the study to ensure participants are protected.

Any significant financial interest that could directly and significantly affect the design, conduct, or reporting of Research shall be managed by the FCOI Review Committee and the Investigator to reduce or eliminate any such effect.

## **PROCEDURE:**

### **Disclosure of Financial Interests**

Each Investigator has an ongoing responsibility to disclose, in writing, all Financial Interests and those of the Investigator's spouse and dependent children that reasonably appear to be related to the Investigator's Institutional/Regional Health Ministry Responsibilities. The Investigator is not charged with making a determination as to whether the Financial Interest constitutes an SFI or a conflict of interest that could affect the design, conduct, or reporting of the Funded Research. That determination is made by a Designated Official, as is further described below.

Investigator disclosures are required as follows:

- a. **Upon Application.** Each Investigator who is planning to participate in Funded Research must disclose Financial Interests to the THOfNE IRB. For PHS funded research each investigator and Senior/Key Personnel must disclose Financial Interests to the THOfNE IRB no later than the time of application. The THOfNE IRB will inform the Research Development and Grants Administration Office of PHS funded research grant applications and sub-awards. With respect to Financial Interests of reimbursed or sponsored travel, disclosures will include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- b. **Annually.** Each Investigator who is participating in Funded Research must submit an updated Financial Interest Disclosure for Funded Research Form at least annually during the period of the award. Such Disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph "a" above or in any subsequent disclosure of Financial Interests and shall consist of updated information regarding any previously disclosed Financial Interests (e.g., the updated value of a previously disclosed equity interest or compensation received).

- The annual submission of Financial Interest Disclosure for Funded Research applies to research that is overseen by the THOfNE IRB, Single IRB and External IRB research, to which the THOfNE IRB has agreed to rely on an outside IRB to oversee the research.
- The THOfNE IRB Coordinator is responsible for tracking and reporting the annual submission of Financial Disclosure Forms for funded research overseen by THOfNE IRB, External IRB research, and Single IRB research.
- The THOfNE IRB Coordinator is responsible for reporting Conflicts of Interest to:
  - i. THOfNE FCOI Committee for Research overseen by the THOfNE IRB, Single IRB and External IRB research overseen by an outside IRB.
  - ii. Appropriate Federal Funding agencies for Single IRB.
  - iii. External IRBs responsible for overseeing the External IRB research.

**New Financial Interest.** Each Investigator who is participating in Funded Research must submit a disclosure within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Financial Interest.

### **Review of Investigators' Disclosures and Financial Interests**

All THOfNE Investigators' Financial Interest Disclosure for Funded Research shall be submitted to the IRB in accordance with the frequency noted above.

The IRB shall track the completion of the Investigator's disclosure forms and provide regular reports to the Designated Official.

#### *PHS-Funded Research*

The Designated Official shall review all disclosures of Financial Interests to determine a) if an SFI exists; b) if the SFI is related to PHS-Funded Research; and c) if a FCOI exists. The Designated Official may request additional information to make the determination if an FCOI exists.

Where appropriate, the Designated Official may involve the Investigator and/or the FCOI Review Committee to assist in the determination of whether an SFI is related to PHS-funded Research and/or constitutes an FCOI, the development and implementation of any action plans, and compliance with management plans, as applicable. Management plans must be implemented when an SFI is related to any Funded Research.

The FCOI Review Committee shall be chaired by the Designated Official and shall include the Chair of the IRB and at least four additional members from THOfNE. Members of the FCOI Review Committee shall be appointed by the Designated Official. The FCOI Review Committee shall assist the Designated Official in fulfilling his/her responsibilities.

#### *Non-PHS Funded Research*

With respect to non-PHS Funded Research, an SFI exists when an Investigator has a financial interest greater than \$5,000 with the research sponsor; this is also considered an FCOI. If the financial interest between the Investigator and the research sponsor is greater than \$50,000, the individual is precluded from participating in the research study.

### **Determination of a Financial Conflict of Interest:**

A FCOI exists when THOfNE, through the Designated Official or the FCOI Review Committee, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the Funded Research or where the individual's financial interest could be affected by the outcome of the Research.

When appropriate, the FCOI Review Committee will assist the Designated Official in the review of the facts and on a case-by-case basis to determine (1) whether the Investigator's SFI is related to Funded Research and, if it is, (2) assist in the development and monitoring of a management plan.

The Designated Official shall maintain documentation supporting the determination that a FCOI exists and provide a copy of the final decision and management plan, if necessary, to the Investigator and the FCOI Review Committee. If the FCOI relates to a study involving human subjects, the IRB shall receive a copy of the recommended management plan. The IRB is responsible for making the final determination regarding the Investigator's role in the study.

Upon receipt of the decision that a FCOI exists, the Investigator must either acknowledge it or submit an appeal. Funding will be held until the Investigator agrees to comply with the management plan.

### **Investigator Appeals:**

The Investigator has 10 days from receipt of the final decision to submit an appeal in writing to the Designated Official. The appeal should include the specific provisions being challenged, the reason for the appeal, and the justification for a different outcome. The Investigator may request permission to present his or her case in person. The Investigator may also provide an alternative management plan and any supplemental information that might be helpful to the Designated Official or the FCOI Review Committee in making its determination. This decision shall be final, and no further appeals shall be considered.

### **Management Plans**

The Designated Official shall be responsible for ensuring management plans are established when an FCOI exists. Conditions or restrictions that may be imposed to manage an FCOI include, but are not limited to, the following:

- a. Public Disclosure of the FCOI (e.g., when presenting or publishing the Research);
- b. For Funded Research projects involving human subjects research, Disclosure of the FCOI directly to the human subjects as approved by the Institutional Review Board;
- c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Funded 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 Funded Research;
- f. Reduction or elimination of financial interest (e.g., sale of an equity interest); and
- g. Severance of relationships that create the Financial Conflict of Interest.

The existence of an FCOI related to a clinical research project creates a rebuttable presumption that stringent management of the FCOI is appropriate. In any case, in which the DHHS determines that a PHS-Funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required, the Institution shall require the

Investigator involved to disclose the FCOI in each public presentation of the results of the Research and to request an addendum to previously published presentations.

### **Review of Existing SFIs and Retrospective Review during ongoing PHS-Funded Research**

The Designated Official, acting directly or in conjunction with the FCOI Review Committee, will take the following actions with respect to a Financial Conflict of Interest in ongoing PHS-Funded Research:

**Review of Existing SFI:** Whenever THOfNE identifies an SFI that was **NOT** disclosed timely by an Investigator or, for whatever reason, was not previously reviewed during ongoing PHS-Funded Research (e.g., was not timely reviewed or reported by a sub-recipient), the Designated Official will, within sixty (60) days, undertake the same review, determinations, and management plan implementation set forth above.

**Retrospective Review:** Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI that is determined by the Institution to constitute an FCOI, failure by the Institution to review or manage such an FCOI, or failure by the Investigator to comply with an FCOI management plan, the Designated Official shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-Funded Research to determine whether any PHS-Funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in design, conduct, or reporting of such Research.

The Designated Official shall document the retrospective review in accordance with federal requirements set in 42 CFR, Part 50, Subpart F, §50.605(a)(3)(ii)(B)(1)-(9), for PHS-funded research grants or cooperative agreements, or 45 CFR Part 94, §94.5(a)(3)(ii)(B)(1)-(9), for PHS-funded research contracts, and if appropriate, will update the previously submitted FCOI report, describing the new management plan.

**Notification and Mitigation Report:** If the Designated Official finds bias in the design, conduct, or reporting of PHS-Funded Research, the Office of Research Compliance will notify the PHS awarding component promptly and submit a mitigation report, including all key elements as noted below in the Reporting of Financial Conflict of Interest section.

**Interim Measures:** At any time, the Designated Official may determine that interim measures are necessary with regard to the Investigator's participation in the PHS-Funded Research.

### **Reporting of Financial Conflict of Interest**

Prior to Trinity Health Of New England's expenditure of any funds under PHS-Funded Research, the Designated Official shall provide to the PHS, as required, an FCOI report regarding any Investigator's FCOI (unless eliminated) and ensure that a management plan has been implemented.

The FCOI Report to PHS will contain all the information required under federal regulations at 42 CFR, Part 50, Subpart F, § 50.605(b)(3) and 45 CFR, Part 94, § 94.5(b)(3), as applicable. For newly acquired FCOIs during ongoing PHS-Funded Research described above, the Designated Official shall provide to the PHS awarding component, within sixty (60) days, an FCOI Report ensuring that the Institution has implemented a management plan.

For FCOIs not previously disclosed, reviewed, or managed during ongoing PHS-Funded Research described above, the Designated Official shall, if the retrospective review results in a finding of bias in the design, conduct or reporting of the PHS-Funded Research, promptly submit its mitigation report to the PHS awarding component. In accordance with 42 CFR, Part 50, Subpart F, § 50.605(a)(3)(iii) and 45 CFR, Part 94, § 94.5a(3)(iii), the mitigation report shall include the key elements documented in the retrospective review and a description of the impact of the bias on the PHS-Funded Research and the Regional Ministry's plan of action or actions taken to eliminate or mitigate the effects of the bias.

After the submission of any initial FCOI Report with regard to ongoing PHS-Funded Research, the Designated Official shall provide the PHS awarding component with annual FCOI Reports that address the status of the Financial Conflict of Interest and any changes to the management plan for the duration of the PHS-Funded Research (including extensions with or without funds) in the time and manner specified by the PHS awarding component.

The Designated Official, on behalf of THOfNE, shall, upon request of the PHS, make information available to the PHS relating to any Investigator disclosure of Financial Interests and THOfNE's review of, and response to, such Disclosure, whether or not the disclosure resulted in the THOfNE's determination of a financial conflict of interest.

#### **Notification and Training:**

THOfNE shall make publicly available this Policy and any other relevant documents relating to compliance with these requirements on the THOfNE external website.

Each Investigator shall complete training on Investigator responsibilities with respect to this Policy as follows:

1. Prior to engaging in PHS-Funded Research and at least once every four years thereafter.
2. When this Policy is revised in any manner that affects the requirements of Investigators.
3. When an Investigator is new to THOfNE,
4. When an Investigator is not in compliance with this Policy or a management plan, as determined by the Designated Official.

#### **Sub-Recipient Investigators**

If any portion of the Funded Research is performed by a sub-recipient, THOfNE will take reasonable steps to ensure that sub-recipient investigators comply with the sponsor's applicable Financial COI policy and regulations. THOfNE will establish by written agreement with the sub-recipient Institution or Investigator the applicable governing FCOI policy.

The sub-recipient will certify that its Institution's FCOI policy complies with the respective sponsor's regulations and, further, that the sub-recipient will report identified FCOIs for Investigators to THOfNE within thirty (30) days so that THOfNE has sufficient time to report those FCOIs to the sponsor.

Alternatively, if a sub-recipient does not have a sponsor-compliant FCOI policy, the sub-recipient Investigator will be governed by this Policy.

## **Confidentiality**

Information submitted by Investigators will be treated as confidential and will not be disclosed except as required by law or as may be necessary or required under this Policy.

## **Sanctions**

Sanctions and penalties may be imposed for failure to comply with this Policy, including but not limited to a) failure to make timely, full, and accurate disclosures; b) failure to update the Disclosure Form as necessary; or c) failure to provide the information requested by THOfNE.

Sanctions may include suspension or dismissal, non-renewal of appointment, denial of eligibility to engage in Research funded through THOfNE, or other appropriate penalties. The FCOI Review Committee shall be responsible for determining what sanctions, if any, are to be imposed.

## **Maintenance of Records**

The Designated Official shall maintain all records related to Investigator disclosures of Financial Interests and related documentation, their review (and/or the FCOI Review Committee's review) of and response to such disclosures and all actions under this Policy, or retrospective review, if applicable for at least three (3) years following the date the final expenditures report is submitted to the PHS or until the resolution of any federal action involving those records, whichever is longer.

## **DEFINITIONS:**

**Designated Official** means a ministry official designated to solicit and review disclosures of Significant Financial Interests from Investigators. The Designated Official shall be the Trinity Health Of New England Vice President, Chief Compliance Officer

**Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.

**Financial Conflict of Interest** ("FCOI") means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of funded Research.

**Funded Research** means any funded Research including, but not limited to, PHS-Funded Research.

**Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of THOfNE including but not limited to Research, research consultation, teaching, professional practice, administration such as service on committees, boards, and panels. (e.g., Institutional Review Board)

**Institutional Review Board** means the governing body responsible for ensuring the protection of the rights and welfare of subjects participating in Research.

**Investigator** means the Principal Investigator and any other person (regardless of title or position) who is responsible for the design, conduct, or reporting of Research or proposed for such funding, which may include, for example, collaborators or consultants.

**Manage** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest to ensure, to the extent possible, that the design, conduct, and reporting of Research will be free from bias.

**Public Health Service ("PHS")** means the Public Health Service of the U.S. Department of Health and Human Services ("DHHS") and any components of PHS to which the authority involved may be delegated, including the National Institutes of Health ("NIH") and any other sponsor who requests application of the PHS FCOI regulation to the administration of their research awards.

**Senior/Key Personnel** means the project director or principal Investigator and any other person identified as senior/key personnel on the grant application, contract proposal, progress report, or any other report submitted to the PHS for PHS-Funded Research or other agency or organization for non-PHS Funded Research by THOfNE.

**Research** means a systematic investigation, study, or experiment, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, including behavioral and social-sciences Research. The term encompasses basic and applied Research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug).

**Significant Financial Interest ("SFI") means:**

5. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities.
  - a. With regard to any **publicly traded** entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the Disclosure and the value of any equity interest in the entity as of the date of Disclosure when aggregated exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
  - b. With regard to any **non-publicly traded** entity, an 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 spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
  - c. Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests that exceed \$5,000.
  - d. Reimbursed or sponsored travel. Amount of reimbursed travel expenses related to the investigator's Institutional Responsibilities or the occurrence of any sponsored travel paid on behalf of the Investigator.
  
6. Exceptions: "Significant Financial Interest" does not include the following types of financial interest:
  - e. Salary, royalties, or other remuneration paid by THOfNE to the Investigator, if the Investigator is currently employed or otherwise currently holding an appointment at THOfNE;



- f. Intellectual property rights assigned to THOfNE and agreements to share in royalties related to such rights;
- g. 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; and
- h. Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, or travel expenses that are reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, a research institute that is affiliated with an institution of higher education.

**RESPONSIBLE DEPARTMENT:**

- THOfNE Integrity and Compliance
- THOfNE IRB
- Saint Francis Hospital and Medical Center Research and Grants Department
- THOfNE Legal Department

References:

<https://www.aahrpp.org/TipSheetDownload.ashx?fileName=Tip%20Sheet%2010%20in%20pdf.pdf>

<https://grants.nih.gov/grants/policy/coi/index.htm>

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-002.html>

<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50#subpart-F>

<https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94>

**RELATED PROCEDURES AND OTHER MATERIALS:** N/A

**APPROVALS:** December 2021, December 2022