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 set forth 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 Public Health Service of the U.S. Department of Health and Human Services (“PHS”), including the National Institutes of Health (“NIH”PHS-Funded Research).

SCOPE/APPLICABILITY

This Policy applies to all persons responsible for designing, conducting or reporting of any funded Research under the auspices of Trinity Health Of New England (Saint Francis Hospital and Medical Center, Saint Mary’s Hospital, Mount Sinai Rehabilitation Hospital, Mercy Medical Center, or Johnson Memorial Hospital).
POLICY

Trinity Health Of New England 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 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 (Review Committee), agreed to by the Investigator and monitored. Any individual with a financial interest with the research sponsor in excess of $50,000 is precluded from participating in the research. The Review Committee shall recommend each management plan to the Trinity Health Of New England 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 Review Committee and the Investigator to reduce or eliminate any such effect.

PROCEDURE:

DEFINITIONS:

Designated Official means a ministry official designated to solicit and review disclosures of Significant Financial Interests from Investigators.

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 Saint Francis Hospital and Medical Center, Saint Mary’s Hospital, Mount Sinai Rehabilitation Hospital, Mercy Medical Center, or Johnson Memorial Hospital 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 Saint Francis.

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:
1. 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.

2. Exceptions: “Significant Financial Interest” does not include the following types of financial interest:
a. Salary, royalties, or other remuneration paid by Trinity Health Of New England (Saint Francis Hospital and Medical Center, Saint Mary’s Hospital, Mount Sinai Rehabilitation Hospital, Mercy Medical Center, or Johnson Memorial Hospital) to the Investigator, if the Investigator is currently employed or otherwise currently holding an appointment at Saint Francis Hospital and Medical Center, Saint Mary’s Hospital, Mount Sinai Rehabilitation Hospital, Mercy Medical Center, or Johnson Memorial Hospital;

b. Intellectual property rights assigned to Trinity Health Of New England (Saint Francis Hospital and Medical Center, Saint Mary’s Hospital, Mount Sinai Rehabilitation Hospital, Mercy Medical Center, or Johnson Memorial Hospital) and agreements to share in royalties related to such rights;

c. 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

d. 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.

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 a 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 Research Development and Grants Administration Office no later than the time of application along with the Trinity Health Of New England Grant Routing Form or submission of a formal proposal for the Funded Research. 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 include updated information regarding any previously disclosed Financial Interests (e.g., the updated value of a previously disclosed equity interest or compensation received).

c. **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.

Trinity Health Of New England Financial Interest Disclosure for Funded Research Form can be accessed on the Trinity Health Of New England external website.
**Review of Investigators’ Disclosures and Financial Interests**

All Trinity Health Of New England Investigators’ Financial Interest Disclosure for Funded Research shall be submitted to the Research Development and Grants Administration Office in accordance with the frequency noted above.

The Research Development and Grants Administration Office shall track the completion of the Investigator’s disclosure forms and provide regular reports to the SF Vice President of Finance.

**PHS-Funded Research**

The SF Vice President of Finance 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 SF Vice President of Finance may request additional information to make the determination if an FCOI exists.

Where appropriate, the SF Vice President of Finance 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 SF Vice President of Finance and shall include the Chair of the IRB and at least four additional members from the Saint Francis Hospital and Medical Center, one member from Saint Mary’s Hospital, one member from Mount Sinai Rehabilitation Hospital and one member from Mercy Medical Center with relevant research experience or other experience. Members of the Review Committee shall be appointed by the SF Vice President of Finance.

The FCOI Review Committee shall assist the SF Vice President of Finance in fulfilling his/her responsibilities as the Designated Official.

**Non-PHS Funded Research**

With respect to non-PHS Funded Research, a SFI exists when an Investigator has a financial interest greater than $5,000 with the research sponsor; this is also considered a 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 Trinity Health Of New England, through SF Vice President of Finance or the 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 Review Committee will assist the SF Vice President of Finance 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 SF Vice President of Finance 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 on the study.

Upon receipt of the decision that an 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 SF Vice President of Finance. 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 SF Vice President of Finance or the FCOI Review Committee in making its determination. This decision shall be final and no further appeals shall be considered.

**Management Plans**

SF Vice President of Finance 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 a financial interest (e.g., sale of an equity interest); and
- g. Severance of relationships that create the Financial Conflict of Interest.

The existence of a 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 SF Vice President of Finance, 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 Trinity Health Of New England 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 subrecipient), the SF Vice President of Finance 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 SF Vice President of Finance 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.

SF Vice President of Finance 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 SF Vice President of Finance 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, SF Vice President of Finance 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 (Saint Mary’s Hospital, Mount Sinai Rehabilitation Hospital, Mercy Medical Center, or Johnson Memorial Hospital) expenditure of any funds under PHS-Funded Research, the SF Vice President of Finance 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 SF Vice President of Finance 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 SF Vice President of Finance 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 SF Vice President of Finance 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 SF Vice President of Finance or the Research Development and Grants Administration Office on behalf of Trinity Health Of New England shall, upon request of the PHS, make information available to the PHS relating to any Investigator disclosure of Financial Interests and the Trinity Health Of New England’s review of, and response to, such disclosure, whether or not the disclosure resulted in the Trinity Health Of New England’s determination of a financial conflict of interest.

Notification and Training:

Trinity Health Of New England shall make publicly available this policy and any other relevant documents relating to compliance with these requirements on the Trinity Health Of New England 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 Trinity Health Of New England,
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, Trinity Health Of New England will take reasonable steps to ensure that sub-recipient investigators comply with the sponsor’s applicable Financial COI policy and regulations. Trinity Health Of New England 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 Trinity Health Of New England within thirty (30) days so that Trinity Health Of New England 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 Disclosure Form as necessary; or c) failure to provide information requested by Trinity Health Of New England. Sanctions may include suspension or dismissal, non-renewal of appointment, denial of eligibility to engage in research funded through Trinity Health Of New England 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 SF Vice President of Finance shall maintain all records related to Investigator disclosures of Financial Interests and related documentation, SF Vice President of Finance 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.

RESPONSIBLE DEPARTMENT:

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

References:
https://www.aahrpp.org/TipSheetDownload.ashx?fileName=Tip%20Sheet%202010%20in%20pdf.pdf
https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50#subpart-F
RELATED PROCEDURES AND OTHER MATERIALS: N/A

APPROVALS: Approved by the THOfNE IRB Board Members at the December 15, 2021 IRB meeting