



**Disclosure & Mitigation of Institutional
Conflicts of Interest in Research**

March 28, 2023

LOCATION(S) Procedure 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:

Institutional Official

Review By:

March 28, 2026

PURPOSE

This Procedure implements the requirements of Integrity & Compliance Policy No. 1, *Integrity and Compliance Program*, which requires Trinity Health Of New England (THOfNE or Institution) to establish policies and procedures to ensure THOfNE's operations fully comply with applicable laws, regulations and professional standards, including promoting the conduct of ethical and compliant research.

THOfNE's Code of Conduct, policies, and procedures, require all who work in Trinity Health, including but not limited to colleagues, Medical Staff members, suppliers, independent contractors, volunteers, consultants, and other business partners to disclose any actual or potential conflicts of interest. THOfNE, including its officials, must balance many competing interests. Ministry-Industry relationships are important to advancing scientific frontiers and essential to enabling the commercial development of academic discoveries for the benefit of the public. In addition, the Institution engages in relationships with a variety of companies that may lead to financial benefit for the Institution in many forms, including royalty payments, other payments, and equity from licensing intellectual property, sponsored educational and research agreements, and major gifts. Such relationships with commercial entities are generally part of legitimate educational, research, and business activities, and predictably will lead in some cases to conflicts of interest. The intent of this Procedure is not to prohibit or discourage such relationships, but, as much as possible, to manage them so that they do not compromise, or reasonably appear to compromise, the integrity of the Institution's Missions, including the safety and integrity of its research. The protection of human research participants, and the protection of the integrity of the Institution and its research programs, must remain an Institutional priority.

PROCEDURE

As a research institution, THOfNE is required to identify, disclose, and address Institutional Conflicts of Interest (ICOI) in all research, including Public Health Service (PHS) funded research, following a standard process in compliance with applicable regulations. THOfNE requires disclosure of all Significant Financial Interests (SFIs), Other Support (OS), and Foreign Components (FC) on an ongoing basis.

Composition of the ICOI Committee

An Institutional Conflict of Interest Committee will be established and will evaluate all disclosures to determine whether an ICOI exists and, as appropriate, will require proper actions be taken to address any ICOI. Proper action may include, but is not limited to, reducing or eliminating the ICOI to ensure that the design, conduct and reporting of research is free from bias, or the appearance of bias, as well as disclosing and reporting each such ICOI in compliance with federal law and regulations.

The ICOI Committee will ordinarily consist of seven to eleven members appointed by the Institutional Official. The ICOI Committee will be comprised of individuals with sufficient independence, expertise, and seniority. The committee should include at least one senior Finance leader, one Supply Chain leader, and clinical, operational or research representatives from THOfNE Ministries, and may also include representation from THOfNE regional departments. The Institutional Official shall chair the ICOI Committee. The ICOI Committee shall meet at least quarterly. A quorum will consist of one more than half of the voting committee members. The vote of a majority of voting members at a meeting when a quorum is present shall constitute the act of the ICOI Committee. A representative of the Legal Services may attend meetings and serve as legal advisor to the ICOI Committee.

In relation to a specific matter before it, the ICOI Review Committee may invite a member of the Institution's community with special expertise not otherwise available to the Committee to serve as a non-voting ad hoc member. At its discretion, the ICOI Review Committee may appoint non-voting, ex-officio members for renewable one-year terms.

Review of Activities for Potential ICOIs

At least quarterly, the IRB will provide a list of all current funding agencies to the ICOI Committee Liaison. The ICOI Committee liaison will send the list to Finance, Supply Chain and Philanthropy, who shall review the list and provide information about any relationship that may present an actual or potential Significant Financial Interest (SFI). Any potential SFI identified shall be reported to the ICOI Committee for review.

Mitigation and Response to Institutional Disclosures

Upon a disclosure or identification of a Significant Financial Interest (SFI), Other Support (SO), and/or Foreign Component (FC), the ICOI Committee will take the actions described below.

Investigation of Disclosed SFI/OS/FC

The ICOI Committee will evaluate each disclosed SFI/OS/FC to determine whether the SFI/OS/FC is an ICOI. An SFI/OS/FC may not necessarily be considered a prohibited arrangement. Rather, the existence of an SFI/OS/FC activates reporting and review requirements in order to protect the integrity of the research and the safety of its participants.

An ICOI evaluation should include, but may not necessarily be limited to, whether the SFI/OS/FC has the potential to affect or appear to affect any of the following:

- Safety of human research subjects;
- Safety of patients;
- Integrity of research;
- Appropriate allocation of resources;
- Independence of clinical care or other professional practice judgment;
- Objectivity in business and contracting decisions.

An ICOI evaluation may result in one of three types of recommendations:

1. The arrangement does not represent a significant actual, potential, or perceived ICOI that needs to be managed;
2. The arrangement can be managed, including required changes. In such case, the ICOI Committee will follow the “Management of ICOI” procedures set forth below; or
3. The arrangement is not manageable and either the activity may not proceed or the financial interest must be eliminated or reduced.

The ICOI Committee will notify the Institutional Review Board and, as applicable, the appropriate individual(s) responsible for the activity, of the Committee’s determination as to whether the SFI/OS/FC is or is not an ICOI, and if it is determined to be an ICOI, whether it can be managed. The IRB has final authority to decide whether the interest and its management, if any, allows the research to be approved. The Institutional Official may not approve research that has not been approved by the IRB.

Management of ICOI

To the extent possible and reasonable under the circumstances, the ICOI Committee will work with the investigator or External Entity to develop the means for the research to take place while protecting the objectivity of the research, the safety of its participants and upholding scientific integrity. Listed below are several possible resolutions for management of a ICOI that may be pursued:

1. Disclosure of the ICOI in informed consent processes;
2. Where the ICOI involves an Institutional Official, formal recusal of the conflicted official from the chain of authority over the project and possibly also from authority over salary, promotion, and space allocation decisions affecting the investigator, as well as communication of the recusal arrangements to the official's superior and colleagues;
3. Where the ICOI involves an Institutional Official, designation of a "safe haven" (e.g., a non-conflicted senior individual) with whom the investigator can address ICOI-related concerns;
4. Use of an external IRB;
5. External monitoring of the study, particularly endpoint assessments;
6. Disclosure of the ICOI in public presentations and publications, and to all individuals, including (but not limited to) students and other trainees, engaged in the design, conduct or reporting of the research;
7. Disclosure of the ICOI to other centers in a multi-center trial; and/or
8. Disclosure to the sponsors of the research as required by the sponsor and all applicable regulations and laws.

The ICOI Committee will determine the appropriate strategies to properly oversee and manage potential conflict(s), taking into consideration the possible management mechanisms and sanctions as outlined above.

The ICOI Committee shall inform the Investigator and/or External Entity of the actions taken, and decisions made by the Institutional Conflict of Interest Committee and notify the relevant IRB(s) of the ICOI and the related Management Plan.

The approved Management Plan must include assignment of responsibility for actions. Monitoring to ensure Institutional and External Entity compliance with the Management Plan will occur by the IRB through the annual review of the approved research for the length of the research.

Noncompliance

1. When an SFI/OS/FC is not disclosed timely by the External Entity or Institution, or for whatever reason was not previously reviewed, the ICOI Committee shall, within sixty (60)

days, review the SFI/OS/FC, determine if it is related to PHS-funded research, and determine if an ICOI exists. If an ICOI exists and can be managed, a Management Plan will be implemented to manage the ICOI going forward, and, if applicable, report to PHS according to federal regulation. The IRB shall monitor compliance with the Management Plan on an ongoing basis until the completion of the research project.

2. When THOfNE finds that an External Entity is not in compliance with the Institutional Conflict of Interest policies or Management Plan, the External Entity will immediately be informed of these procedures, their responsibilities regarding disclosure of significant financial interests, and the Federal regulations.
3. Whenever a SFI is not identified or managed in a timely manner, the Committee shall, within one hundred twenty (120) days of the determination of noncompliance, complete a review to determine whether the External Entity's activities and the research (and specifically when it is PHS funded research), or any portion thereof, was biased in the design, conduct or reporting of such research.
4. If bias is found, the Institutional Official is required, if applicable, to promptly notify and submit a mitigation report to PHS, and to submit ICOI reports annually.
5. In any case in which the Department of Health & Human Services determines that a PHS-funded research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, biologic, or other test article has been designed, conducted, or reported by an External Entity with an ICOI that was not managed or reported as required by federal regulation, the External Entity involved is required to:
 - a. Disclose the ICOI in each public presentation of the results of the research; and
 - b. Request an addendum to previously published presentations.

Sanctions

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

- a. Removal of Institution from participation in research;
- b. Letter of reprimand; or
- c. Notification to funding agencies and/or professional journals and societies.

Maintenance of Records

All records related to the implementation of this Procedure (e.g., disclosure forms, minutes of meetings called to manage conflicts, minutes of the Institutional Conflict of Interest Committee and notifications to funding agencies) shall be maintained by the Institutional Official or designee.

These records will be kept in a secured fashion for a period of at least three (3) years following the termination or completion of the research activities.

Public Accessibility

This Procedure will be made available via a publicly accessible website by each Ministry conducting research.

Implementation Responsibilities

The ICOI Committee will review a list of active studies and their sponsors to identify any potential ICOI in accordance with applicable laws and regulations and will document mitigation actions necessary to manage any identified ICOI.

SCOPE/APPLICABILITY

This Procedure applies to all research regardless of funding and includes PHS funded research conducted at THOfNE.

DEFINITIONS

Conflict of Interest means a situation in which a SFH, FC or OS may compromise, or have the appearance of compromising, an investigator's judgment in conducting, reviewing, or reporting research.

External Entity means any natural person, corporation, partnership, sole proprietorship, association, organization, holding company, joint stock company, receivership, trust, foreign entity, foreign institution of higher education, foreign governmental agency, or subdivision (e.g., local, provincial, or equivalent governments of the United States of America or another country), regardless of whether organized for profit, nonprofit or charitable purposes.

Foreign Component (FC) means the existence of any significant scientific element or segment of a project out of the United States, such as performance of work by a researcher or recipient in a foreign location, or performance of work by a researcher in a foreign location employed or paid for by a foreign organization.

Institutional Conflict of Interest (ICOI) means a SFI/OS/FC that THOfNE has determined could directly and significantly affect, or create the appearance of affecting, the design, conduct, reporting, review, or oversight of research.

Institutional Conflict of Interest Committee or ICOI Committee means a multi-disciplinary committee designated to manage institutional conflicts of interest in research activities.

Institutional Responsibilities means the Institution's professional responsibilities regarding research, research consultation, teaching, clinical practice, institutional committee memberships, and services on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Manage or Management Plan means to act to address an Institutional Conflict of Interest which includes reducing or eliminating the Institutional Conflict of Interest to ensure that the design, conduct and reporting of research is free from bias or the appearance of bias.

Ministry means a direct subsidiary, affiliate, or operating division of THOfNE that maintains a governing body that has day-to-day management oversight of a designated portion of THOfNE operations. A Ministry may be based on a geographic market or dedication to a service line or business.

Other Support (OS) means all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Policy means a statement of high-level direction on matters of strategic importance to THOfNE or a statement that further interprets THOfNE's governing documents.

Procedure means a document designed to implement a policy or a description of specific required actions or processes.

Senior / Key Personnel means all individuals designated in an application who contribute to the scientific development or execution of a project in a substantive measurable way, whether or not they request salaries or compensation.

Significant Financial Interest (SFI) means:

- A. Royalties: The Institution has the potential to receive significant milestone payments and/or royalties from the commercialization of a product based at least in part on technology that is the subject of Institutional research.
- B. Non-publicly traded equity: Through its technology licensing activities or investments related to such activities, the Institution may obtain an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded company that is (i) the sponsor of research at the Institution or (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the Institution, or based at least in part on technology developed here.
- C. Publicly traded equity: Through technology licensing activities or investments related to such activities, the Institution may obtain a significant ownership interest or an entitlement to significant equity (including options and warrants), in a publicly-traded company that is (i) the sponsor of research at the Institution, or (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the Institution, or based at least in part on technology developed here.

- D. Governance/Fiduciary roles: Through technology licensing activities or investments related to such activities, the Institution may obtain the right to appoint one or more directors to the governing board of any company that is (i) the sponsor of research at the Institution, or (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the Institution, or based at least in part on technology developed here.
- E. Gifts from companies: The Institution may be offered or receive significant gifts (including, but not limited to, gifts in kind, discounts, fellowships, and unrestricted educational grants) from a company or a foundation established by or closely affiliated with a company that is (i) sponsoring or offering to sponsor research at the Institution, (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the Institution, or based at least in part on technology developed here, or (iii) a company known to be a business competitor of companies described in (i) or (ii) above.

The following circumstances, among others, should be evaluated in the gifting context:

1. Whether a gift is of sufficient magnitude that even when held in the general endowment, it might affect, or reasonably appear to affect, oversight of research at the Institution;
2. Whether a gift is held for the express or limited benefit of a department, service line, institute or other unit where some or all of the research is conducted; or
3. Whether any Institutional Official who has the authority to affect or reasonably appear to affect the design, conduct, reporting, review, or oversight of the research has also been actively involved in solicitation of the gift, or in the management of the gift once received by the Institution.

Gifts, pledges, and solicitation of gifts to or by the Institution (or any Ministry, department, service line, institute or other unit of the Institution) are important to THOfNE's Mission. However, no charitable donation may be contingent upon the outcome of any research or business transaction conducted at or by the Institution. The Institution affirms that it will not solicit or accept gifts that in any way limit the ability of investigators to conduct, report and/or publish the results of research in accordance with the highest scientific, medical, professional, and ethical standards. The foregoing shall not be deemed to restrict the ability of any donor to contribute to a fund set aside for a particular purpose as a result of designated giving (sometimes referred to as donor-restricted funds), provided that the funds are not in any way conditioned on the outcome of research as described in this paragraph. An example of a donor-restricted fund would be funds from a campaign to support the construction of a new building for the Institution.

RESPONSIBLE DEPARTMENT

Further guidance concerning this Procedure may be obtained from the Integrity & Compliance Office.

RELATED PROCEDURES AND OTHER MATERIALS

APPROVALS

Initial Approval:

Subsequent Review/Revision(s):

10/25/2022