

Conflict of Interest in Externally Funded Research and Sponsored Projects Policy

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SECTION I. PURPOSE

The University of St. Thomas is committed to integrity and adherence to the highest ethical standards. It recognizes that conflicts of interest in sponsored projects, including research activities, have the potential to create real or apparent bias that might undermine the validity of research, programs, or activities of those projects.

The purpose of this policy is to identify and evaluate financial conflicts of interest that may affect sponsored project decisions, transactions and operations at St. Thomas and manage them so that these projects can be undertaken without compromising integrity. In addition to upholding St. Thomas's ethical standards, this policy is intended to comply with funding agency regulations (including those of the Public Health Service (PHS), National Science Foundation and other federal agencies) that require institutions to maintain a conflict of interest in research policy.

SECTION II. APPLICABILITY

This policy applies to all individuals, regardless of title or position, responsible for the design, conduct or reporting of Sponsored Projects, as defined below, at or under the auspices of St. Thomas ("Covered Persons"). This could include faculty, staff, students, student workers, volunteers and contractors. It applies to all externally funded Sponsored Projects at St. Thomas, whether supported by a Funded Agreement or otherwise.

This policy does not supersede St. Thomas's other policies governing conflicts of interest, including the [Employee Conflict of Interest policy](#). Covered Persons are expected to comply with such policies in addition to this policy.

SECTION III. DEFINITIONS

When used in this policy, the following terms have the following meanings:

- a. ***Conflict of Interest in Research and Sponsored Projects Committee*** means the Committee designated to advise the Designated Official as described in the policy. The Committee shall consist of the Associate Vice Provost for Faculty Advancement and Research, Controller (or designee), Director of the Institutional Review Board and Faculty Director of Research. The General Counsel (or designee) and Director of Sponsored Programs will serve as ex officio members.
- b. ***Designated Official*** means the Vice Provost for Academic Affairs.
- c. ***Financial Conflict of Interest*** means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of a Sponsored Project (including an

Investigator's judgment concerning a Research interest e.g. Research participant welfare, Research integrity).

- d. **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.
- e. **Funded Agreement** means any agreement signed by St. Thomas that provides funding to the University, in whole or in part, from federal, state or private funds. Examples of Funded Agreements include grants, gifts and federal procurement contracts.
- f. **Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of St. Thomas, including, but not limited to, activities such as research, teaching, service on behalf of St. Thomas, and committee memberships.
- g. **Investigator** means the principal investigator or project director and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of a Sponsored Project, or proposed for such funding, taking into account the degree of independence with which the person works.
- h. **Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. 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). When used in this policy, Research shall refer only to externally funded research, whether supported by a Funded Agreement or otherwise.
- i. **Significant Financial Interest** means anything of monetary value or potential monetary value within the past 12 months held by an Investigator (or by the Investigator's spouse or dependent children), and that reasonably appears related to the Investigator's Institutional Responsibilities, as follows:
 - i. **Compensation and other payments for service exceeding \$5,000:** compensation (e.g., salary, income, consulting fees, honoraria, paid authorship or any other payment) from an outside public or private entity, including but not limited to payments linked to sponsors or products under study, that exceeds \$5,000.
 - ii. **Equity Interest** –
 - i. Publicly-traded entities – Any equity interest (e.g., stock, stock option, or other ownership interest) that exceeds \$5,000.
 - ii. Private entities - Any equity interest regardless of value.
 - iii. **Intellectual property rights and interests** (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 - iv. **Service** as a director, trustee, partner, officer, or in another position of management for an outside organization.
 - v. **For PHS-Funded Research Investigators Only** (U.S. Public Health Service, including NIH, FDA, CDC, etc.): Travel reimbursed or sponsored (i.e., paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) by an entity, and related to the Investigator's Institutional Responsibilities that exceeds \$5,000 in value (in aggregate for a single entity). This provision does not apply to travel reimbursed or sponsored by St. Thomas or another university (or affiliated research institute); a federal, state, or local government agency; or medical center or academic teaching hospital.

The term "Significant Financial Interest" does not include:

- salary or other remuneration paid by St. Thomas to the Investigator if the Investigator is currently employed or otherwise appointed by St. Thomas;

- 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; or
 - income from seminars, lectures, teaching engagements, service on advisory committees or review panels, or travel reimbursed or sponsored by or for St. Thomas or another university (or affiliated research institute); a federal, state, or local government agency; or medical center or academic teaching hospital.
- j. ***Sponsored Projects*** refer to research, training, scholarship or other activities that are funded through external entities through formal agreements. These projects typically involve grants, contracts, or cooperative agreements from government agencies, private foundations, corporations, or other organizations that provide financial support for specific work with defined objectives and deliverables. The term encompasses all activities defined as “Research” under this policy.

SECTION IV. REQUIRED DISCLOSURES OF SIGNIFICANT FINANCIAL INTERESTS (SFIs)

All Investigators responsible for the design, conduct or reporting of Sponsored Projects at or under the auspices of St. Thomas must disclose any SFIs, and those of the Investigator’s spouse and dependent children, that reasonably appear to be related to the Investigator’s Institutional Responsibilities. SFIs must be disclosed for the duration of the Sponsored Project and for at least one year upon completion of the study.

SECTION V. WHEN DISCLOSURES ARE REQUIRED TO BE FILED

Investigators must disclose SFIs:

- **Before Application for Funding**: Each Investigator must disclose SFIs no later than the time of application or submission of a formal proposal, if applicable. If no application or proposal is required, the disclosure must be made prior to expending any external funds.
- **Upon Discovery or Acquisition of a New SFI**: Each Investigator must submit a disclosure within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) a new SFI; and
- **Annual Disclosures for Active Awards**: Each Investigator must submit an updated disclosure of SFIs at least annually during the award period and one year after completion. The updated disclosure will include any new information that was not previously disclosed to St. Thomas, and will include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

SECTION VI. HOW DISCLOSURES ARE MADE

Investigators must complete and submit the SFI Disclosure Form (available [here](#)) to the Designated Official.

SECTION VII. DUTIES OF PRINCIPAL INVESTIGATORS

Principal investigators are responsible for informing any co-investigators that meet the definition of an Investigator under this policy that they are required to complete a SFI Disclosure Form for the externally funded Sponsored Project.

SECTION VIII. REVIEW OF SFIs

SFI Disclosures will be reviewed and, if necessary, managed (see section IX) prior to the expenditure of any external funds on the Sponsored Project.

Submitted SFI Disclosure Forms will be reviewed by the Designated Official to determine whether an Investigator's SFI is related to the Sponsored Project and, if so, whether the SFI is a Financial Conflict of Interest, as defined in this policy. Other University officials may be involved as determined appropriate by the Designated Official.

An Investigator's SFI is related to the Sponsored Project when the Designated Official reasonably determines that the SFI:

- could affect or be affected by the Sponsored Project; or
- is in an entity whose financial interest could affect or be affected by the Sponsored Project.

A Financial Conflict of Interest exists when the Designated Official reasonably determines that the SFI could directly and significantly affect the design, conduct or reporting of the Sponsored Project.

SECTION IX. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

If the Designated Official determines that a Financial Conflict of Interest may exist, the Designated Official will consult with the Conflict of Interest in Research and Sponsored Projects Committee ("Committee"), who shall advise the Designated Official on whether a conflict exists and, if so, how to manage, reduce or eliminate the conflict. After consulting with the Committee, the Designated Official will make a final determination on whether a Financial Conflict of Interest exists and what conditions or restrictions should be imposed to manage the conflict. If a conflict exists, the Designated Official will notify the relevant Investigator in writing.

Conditions or restrictions that might be imposed by St. Thomas to manage, reduce or eliminate conflicts include but are not limited to:

- public disclosure of relevant SFIs (e.g., when presenting or publishing the Sponsored Project);
- for Research projects involving human subjects research, limitations to recruitment and consent processes conducted by the Investigator, disclosure of Financial Conflicts of Interest directly to participants, possible disapproval of the Research;
- monitoring of research by independent reviewers;
- modification of the Sponsored Project plan;
- disqualification from participation in the portion of the activity that would be affected by the SFI;
- divestiture of the SFI; or
- severance of the relationships that create actual or potential conflicts.

The management plan will be in writing and will be provided to the Investigator. The Investigator must agree to the management plan in writing before beginning work on the Sponsored Project. Copies of the signed management plan will also be provided to the Controller's Office and other internal personnel/office(s) involved in managing the conflict.

SECTION X. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST FOR ONGOING SPONSORED PROJECTS

When in the course of an ongoing Sponsored Project:

- an Investigator new to the project discloses a SFI;
- an existing Investigator discloses a new or changed SFI; or
- the University identifies a SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the University

The Designated Official will, in consultation with the Controller's Office, suspend activity on the project, and implement a management plan for the project within 60 days of the SFIs' disclosure or discovery, if it is determined that the SFI constitutes a Financial Conflict of Interest.

In addition, where an Investigator's SFI was not timely disclosed or reviewed, the Designated Official will complete a retrospective review of the Investigator's activities associated with the Sponsored Project to determine whether the activities conducted during the period of noncompliance was biased in the design, conduct or reporting of the project. The review will be conducted within 120 days of St. Thomas determining a Financial Conflict of Interest exists. Depending on the results, the University will take corrective actions as specified in Section XII. In the above instances, depending on the nature of the Financial Conflict of Interest, the Designated Official may implement additional interim measures with regard to the Investigator's participation in the Sponsored Project between the date of disclosure and the implementation of the University's management plan.

SECTION XI. APPEALS OF CONFLICT DECISIONS AND MANAGEMENT PLANS

If an Investigator disputes that a Financial Conflict of Interest exists or disagrees with the provisions of a management plan, the Investigator may appeal the disputed determination to the Provost within 10 business days of being informed about it in writing. The appeal must be in writing and emailed to the Provost, with a copy to the Designated Official, department chair and dean. The appeal will be decided on the papers without a hearing. The Provost may solicit additional information from the Investigator, Designated Official and others and will determine whether to affirm, reject or modify the Designated Official's decision that a conflict exists and/or the disputed term(s) of the management plan. The Provost's decision will be final and binding and will be communicated in writing to the Investigator, Designated Official, department chair and dean.

SECTION XII. INSTITUTIONAL REVIEW BOARD

The Institutional Review Board ("IRB") maintains its own conflict of interest procedures as a routine part of human subjects review. Prior to applying to IRB for approval, Investigators conducting relevant Research must first complete the conflict of interest review process in this policy. Assuming the Research is not disapproved under this policy, Investigators will then be expected to complete IRB's separate conflict of interest process. The IRB has the final authority to decide under its own policies and processes whether conflicts of interest related to human subjects Research exist and/or are managed to the extent that allows the study to be approved, and whether to disapprove such a study due to conflicts. Nothing in this policy and no determination made under this policy supersedes that authority. Investigators may appeal IRB conflict of interest decisions under IRB's appeal processes.

SECTION XIII. TRAINING

All Investigators must complete University-approved conflict of interest training at least every four years. See Appendix A for additional training requirements for Investigators working on Research funded by the Public Health Service.

SECTION XIV. DELEGATION

The Designated Official generally may delegate their duties under this policy to another St. Thomas employee. However, the Designated Official may not delegate their duties to make final determinations regarding 1) whether a Financial Conflict of Interest exists; and 2) the contents of any management plan or retrospective review.

SECTION XV. NON-COMPLIANCE

Covered Persons are expected to comply fully and promptly with this policy, including the requirements of disclosure. Covered Persons who deliberately or repeatedly fail to disclose fully and truthfully conflict of interest situations or fail to comply with any plan for managing a disclosed conflict will be subject to applicable disciplinary processes, which could include suspension or termination from the Sponsored Project or employment.

In addition to University sanctions, violations of full and prompt disclosure may result in the loss of grant funding and sanctions regarding future funding from outside entities, including federal agencies. Individuals may also be subject to criminal sanctions or civil liability under applicable law.

In the event the University discovers that a failure to comply with this policy has biased the design, conduct or reporting of the Research in accordance with the processes outlined above, the University will promptly notify the sponsor of the Research as required by applicable law or the Funded Agreement and describe any corrective action(s) taken or to be taken.

SECTION XVI. REPORTING AND RECORDS

The University will provide to external sponsors initial and ongoing reports of its management of Financial Conflicts of Interest as required by law, the Funded Agreement and this policy. The Designated Official is responsible for the retention of disclosure forms, management plans and other records for at least three years from the date of submission of the final expenditures report, or as otherwise required by law or the Funded Agreement.

SECTION XVII. ADDITIONAL REQUIREMENTS OF CERTAIN FUNDED AGREEMENTS

The terms of the Funded Agreement will be followed to the extent they require more stringent conflict of interest disclosures or procedures than this policy.

The additional requirements identified on **Appendix A** will apply to Research funded by the Public Health Services (including the National Institute of Health), the National Sciences Foundation and other federal agencies.

Appendix A to Conflict of Interest in Externally Funded Research and Sponsored Projects Policy

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In addition to the requirements of the St. Thomas Conflict of Interest in Research policy, the following requirements apply to Research funded by Public Health Service (including the National Institute of Health), the National Science Foundation, or other federal agencies:

PHS-sponsored Research

Reporting of Financial Conflicts of Interest

As required by PHS regulations, the Designated Official will submit initial and annual Financial Conflict of Interest reports to the PHS awarding component for a Research project. Additionally, within 60 days, the Designated Official will submit a Financial Conflict of Interest report for any conflict discovered after submission of the initial report.

Training

Investigators must complete University-approved conflict of interest training before engaging in any PHS-funded Research. In addition, the training must be completed immediately if this policy is revised to affect the requirements for Investigators, if an Investigator is new to St. Thomas or if an Investigator is not in compliance with the policy or a management plan.

Subrecipients

If St. Thomas carries out the PHS-funded Research using a subrecipient, the University will incorporate as part of a written agreement with the subrecipient terms that establish whether the University's or the subrecipient's policy on conflict of interest in research will apply to the subrecipient Investigators. If the subrecipient's policy will apply, the subrecipient will certify as part of the agreement that its policy complies with the PHS regulations on Objectivity in Research. Additionally, the agreement shall specify time period(s) for the subrecipient to report all identified Financial Conflicts of Interest to St. Thomas to enable the university to provide timely reports to PHS. Alternatively, if St. Thomas's policy on conflict of interest will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures of SFIs to the University. Such time periods shall be sufficient to enable St. Thomas to comply with timely review, management and reporting obligations under the PHS regulations.

Monitoring

For PHS-funded Research, the Investigator's management plan will be monitored on an ongoing basis until the completion of the Research project.

Mitigation Plans for Retrospective Reviews of PHS-funded Research

If St. Thomas determines in the conduct of a retrospective review of PHS-funded Research that the Research or any part of it was biased, the Designated Official will draft a mitigation report to address any such issues as required by PHS regulations. St. Thomas will notify the PHS awarding component of its determination and will submit the mitigation report to PHS.

Public Access of Disclosed Significant Financial Interest

St. Thomas will make available to the public upon request information concerning any SFI disclosed to the University that meets the following criteria:

- a. The disclosed SFI is still held by the senior/key personnel of the active PHS project;
[NOTE: *Senior/key personnel* means a project director or principal Investigator and any other individual identified as senior/key personnel by St. Thomas in the grant application, progress report or any other report submitted to PHS by St. Thomas.]
- b. St. Thomas determines that the SFI is related to the PHS-funded Research; and
- c. St. Thomas determines that the SFI is a Financial Conflict of Interest.

The information request must be made to the Designated Official who will respond within five (5) business days of receipt of the request. Information will be provided to the extent required by applicable PHS regulations.

NSF-sponsored Research

NSF maintains its own conflict of interest in research requirements that are generally consistent with PHS's. The Designated Official will provide notice to the NSF Office of General Counsel if St. Thomas finds that it is unable to satisfactorily manage a Financial Conflict of Interest.

Other Federal Agency Research

Investigators are required to follow the conflict of interest requirements of other federal funding agencies and should consult with the Designated Official to determine compliance requirements.