

## **Office of the Vice President for Research**

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### **Financial Conflict of Interest in Research**

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**Policy Issuance Date:** August 4, 2023

**Purpose:** Lawrence Technological University (LTU) is committed to assuring objective, responsible, and ethical conduct in research.

**Scope:** This policy serves as guidance to investigators and pertains to all persons engaged in the design, conduct or reporting of research.

**Policy:** Disclosure is required by investigators concerning relationships and business affiliations that could reasonably result in the appearance of a financial conflict of interest involving LTU. For the purpose of this policy, "affiliation" is understood to exist if the investigator, spouse, partner or dependent: a) is an owner, shareholder, director, trustee, officer, partner, employee or agent of such organization or formerly occupied any of the foregoing positions; or b) has any other direct or indirect dealings with such organization from which he or she knowingly receives, expects to receive, or has a legal right to receive economic benefit.

**Requirement for continuing education:** LTU investigators must complete Financial Conflict of Interest education and renewal of education no less than every four years.

**Disclosure to be made in writing:** All disclosures shall be made in writing and shall be retained by the Responsible Official.

**Assurance of objective, responsible, and ethical conduct in research:** In the event such financial disclosure has an appearance of potential to influence the objectivity of the conduct of research or bias in reporting of research results, either: a) elimination of the financial interest, b) mitigation of the financial interest, or c) management of the research project shall occur. Management of the research project shall be affected by a Management Plan for institutional oversight of the research project.

**Retrospective review of non-exempt research** – In the event a financial conflict of interest is not identified, eliminated, mitigated or managed pursuant to a Management Plan, and where such project

involves a non-exempt research study, LTU shall, within 120 days of the determination of non-compliance with this policy, complete a retrospective review of the research project to determine whether research, or portion thereof, conducted during the time period of the noncompliance, was potentially biased in the design, conduct, or reporting of such research.

### **When is disclosure required?**

1. **Annual Reporting:** Annual disclosure is required. Annual disclosures are reviewed by the Responsible Official. Investigators are required to disclose Significant Financial Interests at proposal submission and immediately upon discovery while engaged in a funded research project.
2. **Immediate Disclosure of Significant Financial Interest:** In the event that an investigator or a member of the investigator's immediate family (a spouse, sibling, child or household member related by blood or marriage) possesses a Significant Financial Interest such investigator shall immediately disclose the precise nature of the interest or involvement.
3. **Immediate Disclosure of related party transaction:** In the event that an investigator must consider or act upon a financial transaction on behalf of LTU which involves: a) a member of his or her family (a spouse, parent, sibling, child or any other person related by blood or marriage); or b) an organization with which the investigator is affiliated, such investigator shall immediately disclose the precise nature of the interest or involvement.
4. **Requirement to report Significant Financial Interest when engaged in U.S. Department of Health and Human Services funded research:** Pursuant to 42 CFR 50, Subpart F—Promoting Objectivity in Research, disclosure to the U.S. Department of Health and Human Services is required prior to the expenditure of its awarded funds and within 60 days of disclosure of a Significant Financial Interest. The Responsible Official will notify the sponsoring agency in these instances.

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### **Definitions:**

**Annual Report** - Process of yearly reporting of relationships and business affiliations that could reasonably result in the appearance of a financial conflict of interest involving LTU.

**Bias** - favor of or against one thing compared with another in a way considered to be unfair or not based on objective evidence.

**Financial Interest** – An item or position of monetary value, whether or not the value is readily ascertainable.

**Financial Conflict of Interest** – Financial interest that could reasonably appear to influence the design, conduct, or reporting of research. A financial conflict of interest exists when the LTU, through its

Responsible Official, reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the funded research.

**Institutional Review** – The monitoring process of issuing requests for annual disclosures, review of disclosures, administration of management oversight plans, and conduct of educational training and review of records to assure compliance with this policy.

**Investigator** – a person responsible for the design, conduct, or reporting of a research project.

**Management Plan** – A performance plan, subject to institutional oversight, to carry out the reduction or elimination of a Significant Financial Interest, to ensure to the extent possible, that the design, conduct or reporting of research will be free from bias. Whenever an LTU implements a Management Plan pursuant to this policy, LTU shall monitor compliance with the Management Plan on an ongoing basis until the completion of the research project.

**Research** – A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research, product development and testing.

**Responsible Official** – Sponsored Research and Institutional Grants' director is responsible to request, collect, review and monitor the status of annual and periodic disclosures, management plan actions, and continuing education in financial conflicts of interest.

**Significant Financial Interest (SFI) - *Significant financial interest* 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:

(i) With regard to any publicly traded entity, a Significant Financial Interest 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;

(ii) With regard to any non-publicly traded entity, a Significant Financial Interest 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); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact

monetary value may not be readily available), related to their institutional responsibilities, which will include, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

(3) The term Significant Financial Interest does not include: salary, royalties, or other remuneration paid by LTU if the PI is currently employed by LTU, including intellectual property rights and agreements to share in royalties; income from investment vehicles, such as mutual funds and retirement accounts, as long as the PI does not directly control the investment decisions; income from seminars, lectures, or teaching engagements paid 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, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for 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, or a research institute that is affiliated with an Institution of higher education.

**Significant Financial Interest Disclosure** – A written report of a Significant Financial Interest transmitted to the Responsible Official. Disclosures of financial interests and the LTU's review of, and response to, such disclosures shall be maintained for a period of least three years from disclosure or U.S. Department of Health and Human Services funded project end date, whichever is later.

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### **Reporting and Enforcement:**

LTU employees have an obligation to report concerns or suspected violations of this policy. Reports should be sent to [research@ltu.edu](mailto:research@ltu.edu).