



## SPONSORED RESEARCH-CONFLICT OF INTEREST POLICY

### PURPOSE

Long Island University (LIU) is committed to maintaining a research environment that promotes high quality research and academic productivity and attention to the highest ethical standards for research. This commitment includes compliance with regulatory requirements set forth by the Public Health Service (PHS), the National Science Foundation (NSF), and other sponsors and regulatory and ethical bodies. Grants, contracts, and gifts from public and private sources provide significant support for these endeavors. In pursuing any teaching, research or public service effort, the LIU community must meet the highest ethical standards and operate in accordance with the mandates of the funding entities. **To this end, LIU investigators must acknowledge their legal obligation to disclose any private interest or commitment that may impact the integrity of their LIU responsibilities.**

The purpose of this policy is to educate individuals about situations that generate research-related financial conflicts of interest (FCOI), and to provide means for faculty, staff, students, and the University to identify, manage, reduce, and/or eliminate actual or potential conflicts of interest.

Financial Conflicts of Interest (FCOI) typically arise when an investigator's personal interests (outside consultancies, financial investments, or economic interests) might interfere with any of their LIU obligations. Conflicts can compromise, or be perceived to compromise, academic independence, research integrity or LIU's mission. The potential for conflicts of interest may develop as a result of specific projects undertaken by investigators from the nature of their responsibilities within and outside LIU, or through the financial or economic interests that the investigator or the investigator's immediate family hold. Situations requiring disclosure include, but may not be limited to, those described in the **Required Disclosures** section of this policy.

### STATEMENT OF POLICY

This policy sets forth requirements and guidelines for the disclosure of outside interests by LIU investigators who engage in research or scholarship funded by internal or external sources; the review of these disclosures by LIU; and the identification, reporting and management of conflicts of interest. The policy applies to all forms of internal and external support for LIU programs, projects, activities, and services, whether solicited or unsolicited, including gifts and donations that support the efforts of specific individuals.

This policy applies to all personnel involved in designing, conducting, or reporting research. Principal Investigators, co-investigators, and key personnel listed on a proposal always meet this threshold. Other positions (for example: study coordinators, statisticians, and non-paid personnel) may also meet this threshold based on their role in the research. This policy also applies to all employees directly involved in the approval of research proposals and/or the post-award administration of grants (for example: Office of Sponsored Projects and Grants management personnel).

### PROCEDURES

## Completion of FCOI Certification

All individuals meeting the definition of Investigator or as otherwise defined in this policy must certify their knowledge of and compliance with this policy by completing the FCOI Certification annually at the start of each Fiscal Year (FY), which for LIU is **September 1**.

Certifications and associated disclosures must also be actively updated:

- At the time of submission for new funding.
- If unrelated to proposals for funding, at the time of submission of human or animal protocols if financial relationships related to the research exist.
- Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

## Required Disclosures

All significant financial interests held by investigators and their immediate family members must be disclosed. A **Significant Financial Interest (SFI)** is a financial interest that falls into one of the following categories and is reasonably related to any of an investigator's institutional duties:

- Remuneration in excess of \$5,000 from a publicly traded entity during the preceding 12 months. 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 (stock, stock options, or other ownership interest) in a publicly traded company valued in excess of \$5,000 at the time of certification.
- Any combination of the above two items (equity and income) that exceeds \$5,000 during the preceding 12 months.
- Any amount of equity (stock, stock options, or other ownership interest) in a non-publicly traded entity, including a start-up company.
- Remuneration that exceeds \$5,000 from a non-publicly traded entity in the past 12 months.
- Intellectual property rights and interests (e.g., patents and copyrights), upon receipt of such income related to such rights and interests (royalties). Income related to intellectual property rights in excess of \$5,000 paid by any source other than the Investigator's current Institution.
- Reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator so that the exact monetary value may not be known by the investigator), related to the investigator's institutional responsibilities, in an amount or estimated amount in excess of \$500. Excluded from this requirement is travel that is 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, or a research institute that is affiliated with an institution of higher education.

Other examples of potential conflicts requiring disclosure include situations where:

- The design, conduct or reporting of the research, educational or public service project could directly affect the financial interests of the investigator.
- An investigator has an external obligation to an individual or organization that provides support for LIU research, educational or public service effort.
- An investigator has an external obligation to or engagement with an individual or organization which LIU supports through a financial arrangement.

- Consulting arrangements exist between an investigator and a business enterprise licensed to commercialize technologies developed by the investigator.
- An investigator has significant financial interests in a business enterprise that supports or is supported by the investigator's research.
- An investigator holds a position as consultant, officer, director, trustee, or owner of an external business enterprise that supports or is supported by the investigator's research.
- An investigator has significant financial interests in a business enterprise that owns or has applied for the patent, manufacturing or marketing rights to a drug, device or procedure that is a subject of, or may reasonably result from, the investigator's research.

All disclosed significant financial interests that have a potential relationship to the discloser's engagement in research on behalf of LIU are reviewed by the Executive Director of the Office of Sponsored Programs to determine if these interests conflict, or appear to conflict, with the research.

**The following DO NOT require disclosure:**

- Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution.
- Income from seminars, lectures, teaching engagements or travel sponsored by a federal, state, or local government agency, or an Institution of higher education within the United States defined as an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- 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.
- Income from service on advisory committees or review panels for a federal, state, or local government agency or Institution of higher education within the United States defined as an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights.

**A disclosure MUST include:**

- The investigator's current or pending relationship with the outside enterprise or entity in which a significant financial interest exists.
- The relationship of the research to the enterprise or entity.
- The means by which the investigator proposes to address actual or potential conflicts of interest that arise from their (or immediate family members') dual University and enterprise or entity roles.
- The dollar amount of the financial interest in specified ranges.

All investigator certifications and associated disclosures updates are submitted through the COI module of the OSP Portal.

**DEFINITIONS**

For the purposes of this policy, the terms below have the following definitions:

1. **Certification/Disclosure Process:** All individuals who meet the definition of Investigator as defined above must provide certification of their knowledge of and compliance with this policy on an annual basis. The certification process involves either a certification that no significant financial interests exist, or the disclosure of existing significant financial interests to the Institution. In addition to the annual requirement, the acquisition or discovery of new financial interests requires disclosure within 30 days. All disclosures are reviewed by the OSP Executive Director and Research Compliance Director.
2. **Designated Official:** The individual at the Institution responsible for the solicitation and review of disclosures of significant financial interests from each Investigator who is participating in, or is planning to participate in, research. The Designated Official for the LIU is the Executive Director of the Office of Sponsored Projects (ED). The ED is also responsible for developing Management Plans that specify the actions that have been and shall be taken to manage Conflict of Interest.
3. **Financial Conflict of Interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of research. Similarly, if a significant financial interest could reasonably appear to be affected by the research, or the interest is in entities whose financial interests would reasonably appear to be affected by the research, review and elimination or management of the conflict is required.
4. **Institutional Responsibilities:** Investigators' professional responsibilities on behalf of the Institution including, but not limited to, activities such as research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards and other Boards.
5. **Investigator:** Refers to the Principal, Co-Principal, and all other key person(s) who are responsible for the design, conduct or reporting of an LIU program, project, activity, or service described in any application made through LIU for funding or any grant award. *This includes the Project Director or Principal Investigator, and any other persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding. In addition, any research team member who indicates a financial interest related to the submission of a human or animal research protocol will be asked to complete a certification.* This policy, therefore, can apply to collaborators, consultants, post-doctoral fellows, graduate students, and others who meet the threshold for responsibility. "Investigator" shall include the investigator's spouse and dependent children.
6. **Research:** An activity is considered research if it meets the definition of research provided by the agency funding the project, or any agencies that oversee the project. If unfunded or not otherwise defined, the following definitions apply:
  - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.
  - Systematic study directed toward fuller scientific knowledge or understanding of the subject studied. Research is classified as either basic or applied according to the objectives of the sponsoring agency.

7. **Significant Financial Interest (SFI):** Anything of monetary value, whether the value is readily ascertainable, that 1) is related to the Investigator's professional responsibilities on behalf of the Institution; and 2) belongs to the Investigator or the Investigator's spouse or dependent children.
8. **Significant Obligations:** Include any paid or unpaid position held as an officer, trustee, director, employee, or consultant of any entity, whether for profit or not-for-profit, that could be directly or indirectly affected by the funded work.

**POLICY TYPE: ACADEMIC AFFAIRS**