

Long Island University
Investigator Financial Conflict of Interest
Disclosure Policy

Issued by: Office of Vice President for Academic Affairs

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Background

Long Island University is committed to promoting high quality research and academic productivity. 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 University community must meet the highest ethical standards and operate in accordance with the mandates of the funding entities. To this end, University investigators must acknowledge their legal obligation to disclose any private interest or commitment that may impact the integrity of their University responsibilities.

I. Statement of Policy

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

II. Definitions

1. Conflicts of Interest

typically arise when an investigator's personal interests (outside consultancies, financial investments or economic interests) might interfere with any of his/her University obligations. Conflicts can compromise, or be perceived to compromise, academic independence, research integrity or the University'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 the University, or from of the financial or economic interests that the investigator or his/her immediate family hold.

A conflict can result when:

- 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 a University research, educational or public service effort.
- An investigator has an external obligation to or engagement with an individual or organization which the University 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.

2. Investigator

means the principal, co-principal and all other key person(s) who are responsible for the design, conduct or reporting of a University program,

project, activity or service described in any application made through the University for funding or any grant award. "Investigator" shall include the investigator's spouse and dependent children.

3. Vice President for Academic Affairs (VPAA)

shall include his/her appointed designee(s) and any conflict of interest review committee.

4. Significant Financial Interest

means anything of monetary value that reasonably would appear to be directly or indirectly affected by or related to the investigator's University responsibilities, including but not limited to: salary or other payments for services (consulting fees, paid authorship, honoraria); equity interests (stocks, stock options or other ownership interests); intellectual property rights (patents, copyrights, royalties) and third-party reimbursement for any travel related in any way to the investigator's University responsibilities. Examples also include income received for investment in or services rendered as an employee, consultant, officer or board member in:

- the entity to which the application will be submitted.
- any entity that owns or has applied for patent, manufacturing or marketing rights to products or procedures involved in, or that may reasonably result from, the work described in the application.
- any entity known by the investigator to own or have applied for such rights in any product that can reasonably be expected to compete with the product or procedure that predictably will result from the work described in the application.
- any entity that may be a sub-recipient of funding resulting from the application.
- any entity in which the value of investigator's aggregate financial interests exceeds \$5,000 or represents more than a 5% ownership interest.

- any entity for/from which the investigator consults/receives other remuneration, where the value is greater than \$5,000 annually.

5. Exclusions:

- salary, royalties or other remuneration paid to an investigator by the University.
- income from seminars, lectures, or teaching engagements sponsored by non-funding third party public or nonprofit entities.
- income from service on advisory committees or review panels for non-funding third party public or nonprofit entities.
- financial interests in non-funding third party business enterprises or entities if the value of such interests do not exceed \$5,000 and investigator's aggregate ownership interest does not exceed more than 5% for any one enterprise or entity.
- consulting or other remuneration from any non-funding third party business enterprise or entity if the cumulative value thereof does not exceed \$5,000 annually.

6. 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.

III. Review of Disclosures

1. The University's Conflict of Interest Declaration (CID) and Investigator Disclosure Form (IDF) serve as the investigator's mechanism for disclosing significant financial interests and obligations. The current versions of the CID and IDF forms are available from the Office of Sponsored Research.

2. Each investigator must complete and append a signed CID to the Research Proposal/Award Processing Form.
3. Submission of grant proposals to the sponsor will be delayed if CIDs for each key person named on the proposal are not provided. The investigator's Chair and Dean (or designee) shall review and sign each CID and Research Proposal/Award Processing Form. If the Chair or Dean determines that the CID is missing or incomplete, then the principal investigator must take appropriate corrective action.
 - a. For any CID 'yes' response, the investigator must file an IDF with the VPAA within 7 business days of submission of the CID.
 - b. 'No' CID responses may be accepted or questioned by the Chair or Dean. If accepted, no further action is required. If clarification is sought, the Chair or Dean must file a request within 7 business days with the VPAA, who shall either request that the investigator file an IDF within 7 business days, or determine that no further action is required.
 - c. If a Chair or Dean is the investigator on a grant application or otherwise has a conflict of interest, the Assistant Vice President for Sponsored Research shall assume that individual's CID review responsibilities.

Complete and endorsed CIDs shall be forwarded by the Dean with the Research Proposal/Award Processing Form to the Office of Sponsored Research for review, approval and appropriate processing.

4. Steps 2 and 3 must be followed each time a grant application is made. If a proposal is not required for funding, Steps 2 and 3 must be followed before the investigator establishes an account.
5. The investigator shall ensure CIDs and IDFs are updated and kept current during the proposal and award period, and whenever significant financial interests or obligations change.

6. At the outset of every case considered by the VPAA, he/she shall invite the investigator to comment on each matter under consideration. If human subject research is involved, the VPAA shall also advise and consult with the IRB Administrator. The VPAA shall determine:
 - a. Whether the disclosure is of a significant financial interest that could directly and significantly affect the design, conduct or reporting of the funded research, and if so:
 - b. Whether the conflict can be managed, and if so:
 - c. What conditions or restrictions should be imposed to manage, reduce or eliminate the conflict.
7. The VPAA's recommendations shall be conveyed in writing to the investigator, with copies to the Chair and Dean. The VPAA and investigator may meet to draft a management plan, at either party's request. The investigator's written commitment to comply with the conflict management plan shall be required before the grant proposal will be processed or an award accepted.
8. The investigator's Chair/Dean shall be responsible for monitoring compliance with the management plan, and shall report on a semi-annual basis to the VPAA about plan compliance.

IV. Maintenance and Reporting Obligations

1. The University Office of Sponsored Research is the repository for all original IDFs and all correspondence related thereto.
2. Every grant or award received from an external source, whether solicited or not, must be accompanied by completed CIDs for all key persons and, where conflicts are declared, IDFs reviewed by the VPAA and a management plan, if appropriate.
3. The review of financial disclosure forms requires the exercise of utmost discretion by all participants. To the maximum extent permitted by federal regulation, this process shall be confidential.

4. The University shall maintain all disclosures and records of actions taken to resolve actual or potential conflicts of interest for at least three (3) years after the termination or completion of the award to which they relate, or the resolution of any audit.
5. The VPAA shall report to the appropriate funding agency:
 - a. Any instance in which the University is unable to satisfactorily manage an actual or potential conflict of interest.
 - b. Any instance where an investigator fails to comply and the specific corrective measures taken by the University.
 - c. Before receipt of any Public Health Service award, a completed Financial Conflict of Interest Report.

V. Management Plans

The following conditions or restrictions should be considered when developing a management plan for actual or potential conflicts of interest:

1. Public disclosure of significant financial interests.
2. Monitoring of research by independent reviewers.
3. Modification of the research plan.
4. Investigator's disqualification from participation in that portion of the research or scholarly activity that is or would be affected by his/her significant financial interests.
5. Divestiture of significant financial interests.
6. Severance of relationships that create the actual or potential conflict.
7. Removal of investigator as Principal Investigator or Project Director.

8. Remedies specific to the conduct of research involving human subjects, such as the removal of ability to recruit or consent research subjects.

If the University is unable to resolve a real or potential conflict of interest or the appearance of same, the grant or funding sponsorship opportunity shall be declined.

VI. Appeal

If an investigator does not agree with the management plan recommended by the VPAA, he/she shall transmit comments to the VPAA within ten working days from receipt of the recommendation. The VPAA shall review the case, may seek the advice of impartial experts and shall discuss the matter with the investigator. A final decision shall issue within thirty working days of issuance of the initial recommendation. If a management plan is mandatory, program or project grants or awards may not be accepted by the University or investigator until the plan is in place.

VII. Compliance

1. If an investigator fails to comply with this Financial Disclosure Policy or a mandatory conflict management plan, the VPAA shall:
 - a. report promptly in writing to the President and initiate appropriate disciplinary proceedings against the investigator, including but not limited to changes related to the University's scholarly misconduct policies.
 - b. if the research project involves human subjects, request the IRB Administrator to initiate an investigation into matters of subject safety and welfare and potential regulatory violations.
 - c. initiate procedures associated with other relevant University policies, as appropriate.
2. The initiation of proceedings and imposition of sanctions against an investigator shall be consistent with relevant University Human Resources policies and applicable collective bargaining agreements.

3. On completion of disciplinary proceedings, if federal funds are involved, the President shall report to the appropriate federal agency as required by law, and to other affected parties as necessary.

VIII. Training and Education

The University Office of Sponsored Research shall ensure all affected University members (research program and department chairs, faculty, students and staff) receive training on this Financial Conflict of Interest policy and compliance therewith, on a recurrent basis. Each unit, program and department head shall make its members aware of this policy, and shall provide a copy to every new member as soon as possible after they join the University. It remains the obligation of each University investigator to familiarize him/herself with the procedures and obligations set forth herein.