

<b>Policy Title:</b> Financial Conflicts of Interest Related to Research and Sponsored Programs <b>Responsible Office:</b> Office of Research Integrity	
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### Who Should Read This Policy

- All university faculty and staff, regardless of title or position, responsible for the design, conduct or reporting of Lehigh University research or sponsored programs.
- College deans, associate deans, administrators, and department chairs.
- Staff in research administration roles.
- Trustees and Officers responsible for crafting and oversight of other university policies on conflicts of interest.
- Members of the Conflict of Interest Review Committee (CIRC).

### Introduction

Lehigh University recognizes that financial conflicts of interest may exist in an academic research environment. The university's commitment to unbiased design, conduct, and reporting of research requires the university to identify and manage real or apparent related Financial Conflicts of Interest (fCOI). This policy facilitates compliance with all applicable laws related to fCOIs in research. The university provides corresponding administrative processes and guidelines to enable the university and its investigators to meet their obligations under these laws.

### Policy Statement

This policy applies to all Investigators participating in or planning to participate in Lehigh University research and sponsored programs. It outlines the investigator disclosure requirements that enable the university to identify, manage, and report fCOIs related to university research and sponsored programs.

### Disclosure Submission and Review Procedures

Investigators are required to submit disclosures:

- Annually,
- no later than at the time of award setup for research or sponsored programs, and
- within 30 days of discovering or acquiring a new Significant Financial Interest (SFI).

Investigators must amend disclosures within 30 days of any material changes in circumstances affecting an existing SFI.

The Office of Research Integrity is designated to solicit and review related disclosures for determination of an fCOI. An Investigator may be involved in making the determination of whether a Significant Financial Interest (SFI) is Related to their research or sponsored programs. See the Definitions section below for a full definition of Related. The university offers detailed guidance for determining if an SFI is Related.

Prior to the expenditure of funds on a sponsored program, the Office of Research Integrity:

- reviews all Investigators' disclosures,
- makes a reasonable determination as to whether a disclosed SFI could directly and significantly affect the design, conduct, or reporting of the sponsored program (i.e. an fCOI exists), and
- in consultation with the Vice Provost for Research (VPR), the Conflict of Interest Review Committee (CIRC), and others as needed, determine whether the fCOI is manageable and a Management Plan is required in order for the research activity to proceed. See Appendix A – Conflict Management for details on that process.

### **Significant Financial Interests**

Anything that meets the following definition of a Significant Financial Interest (SFI) is required to be disclosed per the processes outlined above:

- 1) For a domestic or foreign publicly traded External Entity:
  - a) The total value of any Remuneration received by the Investigator or their Immediate Family in the twelve months preceding the disclosure and
  - b) The value of any Equity Interest in the entity as of the date of disclosure that together exceeds \$5,000.
- 2) For a domestic or foreign non-publicly traded External Entity:
  - a) The total value of any Remuneration received by the Investigator or their Immediate Family in the twelve months preceding that exceeds \$5,000 or
  - b) The Investigator or their Immediate Family holds any Equity Interest, regardless of its value.
- 3) Intellectual Property Income: Upon its receipt, any income received by the Investigator or their Immediate Family related to intellectual property rights and interests, except when that income is paid by Lehigh University to the Investigator or their Immediate Family.
- 4) Management Positions: Any management position held by the Investigator, such as director, officer, partner, president, vice-president, or trustee, in any External Entity in the twelve months preceding the disclosure.
- 5) Foreign Talent Recruitment Programs: Participation in or support received by the Investigator from a Foreign Talent Recruitment Program in the twelve months preceding the disclosure.
- 6) Travel Expenses: Any travel that is reimbursed, paid, or otherwise sponsored on the Investigator's behalf, related to the Investigator's university responsibilities, that is not

otherwise disclosed in current and pending or other support disclosures (see exception below).

The following are **not** SFIs:

- 1) Travel reimbursed or sponsored by:
  - a) the university,
  - b) a U.S. federal, state, or local government agency,
  - c) a U.S. non-profit institution of higher education as defined at 20 U.S.C. 1001(a), or
  - d) an academic teaching hospital, medical center, or research institute affiliated with an institution of higher education in the U.S.
- 2) Salaries, royalties, or other Remuneration paid by the university to the Investigator, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights.
- 3) Income from investment vehicles, e.g., mutual funds and retirement accounts, provided the Investigator does not directly control the investment decisions made in these vehicles.
- 4) Income from:
  - a) a U.S. federal, state, or local government agency,
  - b) a non-profit U.S. institution of higher education as defined at 20 U.S.C. 1001(a), or
  - c) an academic teaching hospital, medical center, or research institute affiliated with an institution of higher education in the U.S.

In exchange for:

  - a) seminars, teaching lectures, or teaching engagements, or
  - b) service on advisory committees or review panels

**Definitions**

<b>Equity Interest</b>	Stock, stock options, or other ownership interests. The value of equity in publicly-traded entities is determined through reference to public prices or other reasonable measures of fair market value.
<b>External Entity</b>	Any non-federal entity other than Lehigh University or its components.
<b>Financial Conflict of Interest (fCOI)</b>	An fCOI exists when the university reasonably determines that an Investigator’s Significant Financial Interest (SFI) is Related to university research or sponsored programs and could directly and significantly affect its design, conduct, or reporting.
<b>Foreign Talent Recruitment Program</b>	Any program, position, or activity that includes compensation in the form of cash, in-kind compensation, including research funding, promised future compensation, complimentary foreign travel, things of non de minimis value, honorific titles, career advancement opportunities, or other types of remuneration or consideration directly provided by a foreign country at any level (national, provincial, or local) or their designee, or an entity based in, funded by, or affiliated with a foreign country, whether or not directly sponsored by the

	foreign country, to an individual, whether directly or indirectly stated in the arrangement, contract, or other documentation at issue.
<b>Immediate Family</b>	The Investigator’s spouse, domestic partner, dependent children, and any persons residing in their household.
<b>Investigator</b>	Lehigh University personnel, regardless of title or position, responsible for the design, conduct or reporting of Lehigh University research or sponsored programs. This includes the project director or principal investigator, and any other senior/key personnel identified in a grant application, progress report, or any other report related to university research or sponsored programs.
<b>Management Plan</b>	A binding agreement between the university and the conflicted investigator that details the conditions or restrictions imposed on the conflicted investigator in the conduct of subject research.
<b>Related</b>	A Significant Financial Interest (SFI) is <b>Related</b> when a reasonable person could determine that the SFI: <ul style="list-style-type: none"> <li>• could be affected by the Lehigh research,</li> <li>• is in an entity whose financial interest could be affected by the research, or</li> </ul> could directly and significantly affect the design, conduct or reporting of the Lehigh research.
<b>Remuneration</b>	Salary and any payment for services not otherwise identified as salary. E.g. consulting fees, honoraria, paid authorship.
<b>Sponsored Program</b>	<ul style="list-style-type: none"> <li>• Programs funded by an external sponsor through a grant, contract, or agreement with the university, including but not limited to research, education, testing, and outreach.</li> <li>• Programs funded through Lehigh University’s internal grants program administered through the office of the Vice Provost for Research (VPR).</li> </ul>

**Appendices**

Additional detailed policy information on the following is included in the attached appendices:

Appendix A	Conflict Management
Appendix B	Subrecipient Requirements
Appendix C	Sponsor Reporting Requirements
Appendix D	Enforcement Mechanisms, Remedies, and Noncompliance
Appendix E	Training Requirements
Appendix F	Maintenance of Records
Appendix G	Public Accessibility

**Contacts**

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## **References**

CFR Title 2 – Grants and Agreements, Subtitle A – OMB Guidance for Federal Financial Assistance, Chapter II – OMB Guidance, Part 200 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, Subpart B – General Provisions, [§200.112 Conflict of interest](#).

CFR Title 42 – Public Health, Chapter I – Public Health Service, Department of Health and Human Services, Subchapter D - Grants, Part 50 – Policies of General Applicability, Subpart F – [Promoting Objectivity in Research](#)

[Department of Energy Interim Conflict of Interest Policy](#). December 20, 2021.

National Science Foundation. Proposal and Award Policies and Procedures Guide (PAPPG). Effective May 20, 2024. NSF 24-1. OMB Control Number 3145-0058. Part II: Award, Administration, and Monitoring of NSF Assistance Award. Chapter IX – Recipient Standards. A – [Conflict of Interest Policies](#).

## **Appendix A**

### **Conflict Management**

When a Management Plan is required, the Office of Research Integrity:

- Notifies the Investigator and their Department Chair/supervisor that the Related research cannot proceed until a Management Plan is approved by the CIRC,
- Works with the Office of Research and Sponsored Programs (ORSP) to determine if there are any sponsor notification requirements,
- Works with the conflicted investigator to develop a Management Plan, and
- Coordinates CIRC review of the Management Plan.

The CIRC reviews the recommended Management Plan and:

- votes whether to approve the recommended Management Plan as presented or with modifications, or
- requests additional information, including as-needed from campus administrative offices, General Counsel, and Department Chairs.

Based on the CIRC's review, the Office of Research Integrity works with the conflicted investigator, and their Department Chair/supervisor as necessary, to finalize the Management Plan, and to promulgate binding Management Plans once final. Compliance with the Management Plan is monitored on an ongoing basis until the conflict is eliminated.

Until required Management Plans are approved by the CIRC:

- ORSP does not establish accounts/indexes
- Funds are not expended
- IRB review is not completed

A conflicted investigator may appeal CIRC decisions by promptly submitting a written request for reconsideration. The CIRC has the authority to review and affirm their previous decision or to amend the Management Plan. As an ex-officio member of the CIRC, the VPR (or designee) may recommend that the CIRC alter or remove a requirement, but cannot require the CIRC to do so. In all cases, the VPR may add requirements to a Management Plan at his or her discretion. The Office of Research Integrity promptly informs the conflicted investigator of the results of the appeal.

## **Appendix B**

### **Subrecipient Requirements**

For subrecipients under a prime award to Lehigh University, the university will document in a written subrecipient agreement that:

- Certifies that the subrecipient has its own fCOI policy compliant with:
  - 2 CFR 200.112 and 113 (Uniform Guidance), or alternatively:
    - For PHS awards: 42 CFR Part 50 and 45 CFR part 94
    - For DOE awards: the December 20, 2021 Department of Energy Interim Conflict of Interest Policy
    - For NSF awards: Proposal and Award Policies and Procedures Guide (PAPPG) (NSF 24-1) Part II: Chapter IX.A
- Includes time periods to meet the disclosure and/or fCOI reporting requirements of Lehigh University to a sponsor.

Except under the special circumstances described below, subrecipients that do not have their own compliant fCOI policy are considered ineligible to be subrecipients for awards until they develop and implement a compliant policy.

Under special circumstances, subrecipients without their own compliant fCOI policy may agree to comply with Lehigh University's policy only if all subrecipient personnel disclose to Lehigh University at the proposal stage that they have no Related SFIs. In this situation:

- the subrecipient remains obligated to disclose annually,
- if the subrecipient discovers or acquires a new Related SFI during the course of the award, the subrecipient must notify the university as soon as possible, and within 30 days of discovering or acquiring the new SFI, and
- the university retains the right to modify or end the subaward agreement.

**Appendix C**  
**Sponsor Reporting Requirements**

The university provides initial and ongoing fCOI reports:

- To PHS as required pursuant to 42 CFR §50.604-606
- To DOE as required pursuant to Section V(b) of the December 20, 2021 Department of Energy Interim Conflict of Interest Policy
- To NSF as required pursuant to the applicable Proposal & Award Policies & Procedures Guide (PAPPG)



**Appendix D**  
**Enforcement Mechanisms, Remedies, and Noncompliance**

Investigators who have not completed required disclosures prior to deadlines established by the university are prohibited from submitting new sponsored program proposals. Existing awards for sponsored programs involving a noncompliant Investigator will not be distributed.

Investigators subject to a Management Plan are responsible for complying with the terms and conditions set forth in the Management Plan. Failures to adhere to the terms and conditions of a Management Plan are referred to the CIRC for determination if the failure constitutes noncompliance with this policy. A determination of noncompliance will be cause for appropriate sanctions, at the discretion of the CIRC. Where such a failure is not remedied, the noncompliance may be reported to the pertinent sponsor and referred to the Provost and further to appropriate university review committees for further action. Any academic misconduct or termination proceedings are conducted in accordance with applicable university policies.

If the university identifies an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the university during an ongoing sponsored program, the Office of Research Integrity shall, within 60 days:

- Review the SFI
- Determine whether it is related to the Investigator's active sponsored programs, and
- Determine whether an fCOI exists

If this review identifies an fCOI, the Office of Research Integrity will work with the conflicted Investigator to implement, on at least an interim basis, a Management Plan that specifies the actions that have been, and will be, taken to manage the fCOI going forward.

When the university identifies an fCOI that was not identified or managed in a timely manner, the university shall, within 120 days of the determination of noncompliance, complete a retrospective review of the conflicted Investigator's activities and the subject PHS-funded research project(s) to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research. The PHS sponsor will be promptly notified if bias is found and a required Mitigation report submitted, in accordance with to PHS 42 CFR §50.605(a)(3)(iii).

The university complies with the additional requirements pursuant to PHS 42 CFR §50.605(b) regarding unmanaged or unreported fCOIs in PHS-sponsored clinical research designed to evaluate the safety or efficacy of a drug, medical device, or treatment.

Allegations of noncompliance with this policy or with the terms and conditions of a Management Plan are referred to the Office of Research Integrity. If the allegation is not resolved the matter is referred further to the Provost, and if necessary, subsequently to the

appropriate university review committee for further action. If such an allegation results in a collateral proceeding under the university research misconduct policy, a decision on sanctions pursuant to this policy will be deferred until the university research conduct process is complete.

## **Appendix E**

### **Training Requirements**

Annually, and at award setup for each sponsored program award, the university informs each Investigator of:

- This policy
- The Investigator's disclosure responsibilities, and
- The applicable federal regulations

Investigators funded by PHS awards issued or DOE awards issued on or after December 20, 2021 must also complete training as designated by the Office of Research and Sponsored Programs (ORSP) and provide evidence of successful completion to ORSP:

- Prior to engaging in subject awards and thereafter at least every four years,
- At the direction of the Office of Research Integrity, when this policy changes in a manner that affects Investigator requirements,
- When Investigators are newly appointed to a subject award, or
- If the university finds that the Investigator is noncompliant with this policy or the terms and conditions of a Management Plan.

**Appendix F**  
**Maintenance of Records**

All fCOI-related records are maintained in accordance with university policy and sponsors' requirements. Disclosures and records of actions taken to manage fCOIs are securely maintained by the Office of Research and Sponsored Programs (ORSP) and the Office of Research Integrity for at least three years from the date that the final expenditure report is submitted to the sponsor, or from the dates specified in the applicable regulation, including from the date of the resolution of any government action involving those records, whichever is longer.

The university will exert reasonable efforts to keep all transactions related to disclosures secure. The information supplied will be released internally only to the extent necessary to comply with this policy.

Federal sponsors have the right to review fCOI-related records. The university will inform Investigators of any request from a federal sponsor to release these records.

**Appendix G**  
**Public Accessibility**

This policy is posted on Lehigh University's website.

Information concerning identified fCOIs held by senior/key personnel (defined by applicable federal regulations) on federally sponsored awards will be made available prior to the expenditure of funds as follows:

- Within 5 calendar days of a written request
- Including the minimum elements as provided in the applicable regulation
- Including current information that has been updated at least annually and within sixty days of a newly identified fCOI
- Remaining available for three years from the date the information was most recently updated