



# **fCOI Related to Research and Sponsored Programs Policy Effective 22-Jan-2021**

# Policy Effective Jan. 22, 2021

## Changes include:

1. The timeline for receipt of income from publicly traded and non-publicly traded entities was expanded to include remuneration anticipated in the twelve months following the disclosure, in addition to the existing timeline of twelve months prior to the disclosure. This is the standard that has been applied in practice and the policy was revised to include it as a formal requirement.

# Policy Effective Jan. 22, 2021

## Changes include:

2. The IP-related income section of the definition of Significant Financial Interest was revised for clarity.
3. The term “foreign talent recruitment program” was further defined, using an adaptation of NSF’s definition of “foreign government talent recruitment program”

# **Policy Effective Jan. 22, 2021**

## **Changes include:**

4. The definition of the term “related” was further expanded to provide additional information.
5. The requirement for the CIRC to be chaired by a faculty member appointed by the Provost was removed.
6. The term “most recent disclosure on file” was replaced with “current disclosure on file”.

# **Policy Effective Jan. 22, 2021**

## **Changes include:**

7. References to “non-student PIs and co-PIs” were removed from the section on disclosure requirements for IRB applications. Lehigh University IRB policy prohibits students from serving as PI or co-PI, and this policy on Financial Conflicts of Interest Related to Research and Sponsored Programs applies to Lehigh University faculty and staff. This policy does not apply to Lehigh University students.

# **The purpose of the policy is to identify and manage Financial Conflicts of Interest (fCOIs)**

An fCOI exists when a Significant Financial Interest (SFI) is related to and could directly and significantly affect the design, conduct, or reporting of the research or sponsored programs.

# Who must disclose related SFIs?

“Project Personnel” – any university faculty or staff member responsible for the design, conduct, reporting, or direct administration of University Research and/or Sponsored Programs

# Project Personnel (cont.)

“Design, conduct, or reporting of research” is oversight, decision-making, or participation in research.

Includes:

- Creating structure, roles, and/or protocols.
- Participating in execution of research roles and protocols.
- Participating in publication, presentation, or discussion of research results.



# Project Personnel (cont.)

“Direct administration of research” is oversight or decision-making impacting research.

Includes:

- Selection of vendors.
- Determining allocation of funds.
- Negotiating budgets, deliverables, or terms with sponsors.
- Protocol review and approval.
- Managing resulting intellectual property.

# Project Personnel (cont.)

Includes Senior and Key Personnel:

Project Director/PI and any other person identified as such by Lehigh in the grant application, project report, or any other report submitted to the sponsor, plus anyone identified by the sponsor in award documents.

# What are Project Personnel required to disclose?

Significant Financial Interests (SFI) in an External Entity, Related to the research, held by the Project Personnel or their Family.

- “Family” – spouse, domestic partner, dependent children, and any person residing in the household.
- “External Entity” – any entity other than Lehigh or its components.
- “Related” – the SFI reasonably appears to be related to the research or sponsored program.

# What are Significant Financial Interests (SFIs)?

For a Publicly traded External Entity, SFI exists when:

- Total of compensation paid to the Project Personnel or their family in 12 preceding months or anticipated in the upcoming 12 months PLUS any equity interest totals more than \$5,000.
  - Compensation including salary, consulting fees, honoraria, paid authorship.
  - Equity interests including stock, stock option, ownership interest – value determined by public prices or other reasonable measures of fair market value.

# What are SFIs? (cont.)

For a Non-publicly traded External Entity, SFI exists when:

- Total of compensation paid to the Project Personnel or their family in 12 preceding months or anticipated in the upcoming 12 months is more than \$5,000
- OR**
- Project Personnel or their family holds ANY equity interest, regardless of value.

# What are SFIs? (cont.)

The Project Personnel or their family's receipt of income in the 12 months preceding the disclosure related to intellectual property rights or interests.

- Patents, patent application, copyrights, etc.

# What are SFIs? (cont.)

The Project Personnel has a management position in an external entity – director, officer, partner, vice-president, trustee, etc.

- Does not apply to positions held by family.

# What are SFIs? (cont.)

For PHS-funded Project Personnel only: travel reimbursed on the Project Personnel's behalf, related to their Lehigh responsibilities, and determined by Lehigh to be an SFI.

- Does not apply to family.
- There are specific exceptions for U.S. government, U.S. higher ed/academic medical center, research institute, etc.



# What are SFIs? (cont.)

Participation by the Project Personnel or their family in foreign talent recruitment program – an entity based outside of the U.S. that provides direct compensation to individuals in exchange for the agreement to transfer knowledge, expertise, or other intellectual assets to the foreign entity. Direct compensation includes money, research funding provided other than through Lehigh, access to research facilities or other in-kind support, real or honorific titles, career advancement opportunities, promised future compensation, or other types of remuneration/consideration.

# SFIs Do Not Include:

1. Compensation paid by Lehigh, including royalties related to intellectual property rights assigned to Lehigh.
2. Income from investment vehicles where the individual does not directly control investment decisions (e.g. mutual funds, retirement accounts).
3. Income from seminars, lectures, teaching engagements sponsored by U.S. government, U.S. higher ed/academic medical center, research institute, etc.
4. Any paid or reimbursed travel determined by Lehigh not to constitute an SFI.

# When are disclosures required?

1. Annually
2. Event based:
  - With each submission for a Sponsored Program (internally funded through VPR or externally funded through ORSP)
  - Prior to engaging in University Research (i.e. not supported by a Sponsored Program)
  - Serving as Project Personnel for the first time, or after not having served in past 12 months
  - With each Institutional Review Board (IRB) application (abbreviated disclosure)
  - Within 30 days of any material changes to circumstances affecting existing disclosures

# How are disclosures made?

- Sponsored Program – disclosures will be collected by ORSP or VPR for all Sponsored Programs. The disclosures will be collected using a Google form.
- Annual disclosure – solicited by Research Integrity each January beginning in 2021.
- For University Research (i.e. research supported by University funds, not through VPR or ORSP) – faculty/staff engaged in University Research are required to notify their Department Chair/direct supervisor if they have a Related SFI to disclose. Department Chairs/direct supervisors are responsible for notifying Research Integrity in order to initiate the disclosure process.

# Managing fCOIs

When an SFI exits and presents a real or apparent Financial Conflict of Interest (fCOI):

- Management Plan is developed and approved by Conflict of Interest Review Committee (CIRC).
  - For Sponsored Programs: this is completed prior to the establishment of a research account/index and is not done unless and until funding is offered.
  - For University Research: this must be completed prior to Project Personnel engaging in the design, conduct, or reporting, or direct administration of the research.

# Examples of fCOI Management Measures

- Disclosure of the SFI to human participants, fellow researchers, students involved in the research activity, journal publishers, and/or others.
- Disqualification from participation in specific parts of the projects.
- Modification, divestiture, or severance of the SFI.
- Modification of the research plan (including the assignment of responsibilities).
- Monitoring of the research by a Conflict of Interest Monitor.
- Independent review of student research progress.
- Relationship management (spouse, partner, colleague, etc.)

# Questions?

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