fCOI Related to Research and Sponsored Programs
January 2020 Policy Update
Policy Effective Jan. 1, 2020
Major changes include:

1. Simplified requirements: two separate policies (one for PHS and one for non-PHS) will be replaced by one policy that applies regardless of sponsor.

2. The policy also applies to “University Research”: any research activity supported by university funds, regardless of source.

3. Dollar value threshold for disclosure is lowered from $10k to $5k.
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 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 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 has intellectual property rights and interests assigned to party other than Lehigh.

• 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 a talent recruitment or development program based outside of the U.S.
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?

• January through spring 2020 – disclosures will be collected by ORSP or VPR for all Sponsored Programs. The disclosures will be collected using a Google form.

• Beginning in spring 2020 – all annual disclosures and disclosures for Sponsored Programs and University Research will be submitted through an e-system.

• 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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