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Policy Statement

Lehigh University (“the university/university”) is committed to conducting research and sponsored programs consistently with its academic mission, with the trust of its sponsors and the public, and in compliance with applicable federal and state laws, regulations, and policies regarding financial conflicts of interest. This commitment requires the university to identify and manage real or apparent financial conflicts of interests (fCOIs).

A financial conflict of interest (fCOI) exists when the university reasonably determines, pursuant to this policy, that an individual’s Significant Financial Interest is related to a University Research project or Sponsored Program and could directly and significantly affect the design, conduct, reporting or funding of the research or sponsored programs.

This policy establishes disclosure requirements that apply to Project Personnel. Project Personnel is defined as university personnel responsible for the design, conduct, or reporting of

- University Research, defined as any research activity supported by university funds regardless of source; and
- Sponsored Programs, defined as
 - programs funded by a sponsor through a grant, contract, or agreement with the university, including but not limited to research, education, testing, outreach, etc.; and
 - programs funded through Lehigh University’s internal grant programs administered through the office of the Vice Provost for Research, herein referred to as “VPR”.

Who Should Read This Policy


- All university faculty and staff who are responsible for the design, conduct, or reporting of University Research and/or Sponsored Programs.
- College deans, administrators, and department chairs.
- Trustees and Officers responsible for crafting and oversight of university policies on conflicts of interest.
- Members of the Conflict of Interest Review Committee (CIRC).

Conflicts of Interest Review Committee (CIRC)

The CIRC reviews disclosures made under this policy, in order to identify and/or confirm real or apparent financial conflicts of interest (fCOI) Related to University Research or Sponsored Programs, and addresses them in accordance with this policy and federal regulations. The CIRC promulgates binding fCOI Management Plans.

The CIRC is responsible for the following:

- Reviewing disclosures describing Significant Financial Interests (SFI) in external entities related to University Research and/or Sponsored Programs, and requesting additional material as needed;
- Identifying and/or confirming real or apparent fCOI;

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- Determining whether a project activity can proceed, and if so, constructing appropriate Management Plans, including working collaboratively with Project Personnel as necessary to arrive at practical and effective Management Plans;
- Reviewing allegations of noncompliance with this policy and/or with conditions imposed by established Management Plans, and;
- Monitoring compliance with Management Plans, judging the ongoing sufficiency of those plans, and making revisions accordingly.


The CIRC is a standing committee whose members are appointed by the Provost. The CIRC shall include, at a minimum, four faculty members, representing a variety of academic disciplines, and an administrator as voting members. Faculty members are expected to serve as members of the university community and not as advocates for specific academic units or constituencies. Non-members may be invited by the CIRC to participate in discussions but do not deliberate or vote. The committee may also include, in a non-voting status, university administrators, including representatives from the Office of Research Integrity (ORI), Office of Research and Sponsored Programs (ORSP), Internal Audit, and the Office of the General Counsel. Research Integrity staff serve as the CIRC administrator. CIRC members receive appropriate training and continuing education in the identification and management of fCOI, including related university policies and procedures and federal regulations.

Confidentiality

As far as is practicable and consistent with legal obligations, the university protects the confidentiality of fCOI information. Information and written materials are provided to CIRC members and to staff who are involved in the processing and review of disclosure information and the creation and implementation of Management Plans and to others on a need-to-know basis.

Who is Required to Make Disclosures

- Project Personnel, defined as any university faculty or staff member responsible for the purpose, design, conduct, or reporting of University Research and/or Sponsored Programs. Project Personnel includes all Senior and Key Personnel as defined below.
 - Design, conduct, or reporting of research is defined as oversight, decision-making, or participation in research that includes creating the structure, roles, and/or protocol of a research project; participating in the execution of the research roles and protocol; participating in the publication, presentation, or discussion of the research results.
 - Senior and Key Personnel is defined as the Project Director/Principal Investigator and any other person identified as Senior or Key Personnel by the institution in a grant application, project report, or any other report submitted to the sponsor, as well as any person identified by the sponsor as specifically stated in award documents. Senior and Key Personnel further include those identified on Public Health Service (PHS) awards or cooperative agreements issued on or after August 24, 2012, when travel is paid or reimbursed. PHS agencies include:

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- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of Global Affairs (OG)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Assistant Secretary for Planning and Evaluation
- Office of the Assistant Secretary for Preparedness and Response (ASPR)
- Office of Public Health and Science
- Substance Abuse and Mental Health Services Administration (SAMHSA)

When Disclosures Are Required

- Annually: All Project Personnel with an SFI in an External Entity that is Related to their University Research and/or Sponsored Programs.
- Event-based: All Project Personnel with an SFI in an External Entity that is Related to their University Research and/or Sponsored Program:
 - when taking on the role of Project Personnel for the first time, or after not having served as Project Personnel in the previous 12 months
 - no later than at the time of award of a Sponsored Program (internally or externally funded)
 - prior to engaging in the design, conduct, or reporting of University Research (not supported by a Sponsored Program)
 - with each Institutional Review Board (IRB) protocol application for research involving human participants
 - within 30 days of discovering or acquiring a new SFI.


Disclosure Requirements

Project Personnel must disclose:

- Every instance of an SFI in an External Entity that is Related to their University Research and/or Sponsored Programs
- All material changes affecting an existing Related SFI

Subject to the following definitions:

- Significant Financial Interests (SFI) include the following:
 - For a domestic or foreign publicly traded External Entity: an SFI exists if the sum of:


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- (a) the total value of any remuneration received by the Project Personnel and their Family from the External Entity in the twelve months preceding the disclosure **or** anticipated in the twelve months following the disclosure **and**
- (b) the value of any equity interest in the External Entity as of the date of disclosure exceeds \$5,000.

Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship). Equity interest includes any stock, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value.

- For a domestic or foreign non-publicly traded External Entity: an SFI exists if the value of any remuneration received by the Project Personnel and their Family from the External Entity in the twelve months preceding the disclosure or anticipated in the twelve months following the disclosure either:
 - (a) exceeds \$5,000, **or**
 - (b) the Project Personnel and/or their Family holds **any** equity interest (e.g., stock, stock option, or other ownership interest) **regardless** of its value.
- Project Personnel and/or their Family received income in the twelve months preceding the disclosure or anticipates receiving income in the twelve months following the disclosure related to intellectual property rights and interests (e.g., patents, patent applications, copyrights).
- Project Personnel (and not their Family) held a management position, such as a director, officer, partner, president, vice-president, or trustee, in any External Entity in the twelve months preceding the disclosure, or anticipates holding a management position in the twelve months following the disclosure.
- Project Personnel participated in, or receives support from, a Foreign Talent Recruitment Program, in the twelve months preceding the disclosure or anticipates doing so in the twelve months following the disclosure.


A Foreign Talent Recruitment Program (FTRP) is defined as 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.

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FTRPs do not include making scholarly presentations and publishing written materials regarding scientific information not otherwise controlled under U.S. law and participating in international conferences and research projects or other programs that involve open and reciprocal exchanges of scientific information.

- For PHS and Department of Energy (DOE) funded personnel only: any travel that is reimbursed, paid, or otherwise sponsored on the Project Personnel's (and not their Family's) behalf, related to the individual's Lehigh responsibilities that is not otherwise disclosed in current and pending or other support disclosures.
 - This excludes any travel that is reimbursed or sponsored by Lehigh University; a U.S. federal, state, or local government agency; a U.S. non-profit 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 in the U.S.
- Significant Financial Interests (SFI) **do not** include the following:
 - Salaries, royalties, or other remuneration paid by Lehigh to an individual, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights.
 - Income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control the investment decisions made in these vehicles.
 - Income from seminars, lectures, or teaching engagements sponsored by, or income from service on advisory committees or review panels for a U.S. federal, state, or local government agency; a non-profit U.S. 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 a non-profit U.S. institution of higher education as defined at 20 U.S.C. 1001(a).
 - Any paid-for or reimbursed travel determined by Lehigh to not constitute an SFI.
- Family is defined as Project Personnel's spouse, domestic partner, dependent children, and any persons residing in their household.
- External Entity is defined as any non-federal entity other than the university or its components.
- Related means that the planning, conduct, reporting, or administration of the Sponsored Program or University Research could affect the monetary value of a financial interest, have a financial impact on the External Entity, or affect the Project Personnel or their Family's ability to fulfill their obligations to the External Entity.

For each SFI, Project Personnel are required to make a reasonable, good faith determination as to whether the SFI is Related and thus requires disclosure.

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For paid, reimbursed, or sponsored travel for personnel on PHS or DOE awards, the details of the disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

Disclosure Review and Monitoring Requirements


- **Annual Disclosures:** all faculty members with conduct of research included within the scope of their appointments, and all staff engaged in the design, conduct, or reporting of University Research or Sponsored Programs must:
 - disclose SFIs in external entities that are Related to their research, and;
 - review this policy and affirm that they have read, understand, and agree to abide by it, and to submit a disclosure pursuant to this policy if applicable.

All Project Personnel must complete and submit their disclosures annually, by the deadlines established by the CIRC Administrator. Annual disclosures under this process satisfy this policy's requirement for annual disclosures during the period of a Sponsored Program award.

- **Sponsored Program Disclosures:** ORSP/VPR requires all Project Personnel to certify if they have any SFIs related to a Sponsored Program award.
- **Disclosures for University Research not supported by any sponsored program:** Project Personnel on University Research not supported by a sponsored program are responsible for notifying their Department Chair/direct supervisor only when they have determined that they have SFIs Related to the proposed research. The Department Chair/supervisor is then required to notify the CIRC Administrator. The CIRC Administrator coordinates directly with the Project Personnel to solicit a disclosure.
- **Disclosure for University Research Involving Human Participants:** All faculty and staff Project Personnel listed on IRB protocols are required to declare at the time they submit an application to the IRB if they have an SFI related to the proposed research. The requirement does not apply to undergraduate students, graduate students, and Ph.D. candidates listed on IRB protocol applications. The ORI coordinates with the CIRC Administrator as necessary to solicit a disclosure.
- **Amending Existing Disclosures for Material Changes in Circumstances:** Project Personnel must amend an appropriate disclosure(s) within 30 days of any material changes to their external SFIs related to their University Research and/or Sponsored Programs, including when new Project Personnel are added to a project.

When a disclosure certification in any of the instances above indicates a Related SFI, the disclosure certification is reviewed by the CIRC Administration and the assessment results in one of the following determinations:

- An SFI does not exist and no further review is required.

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- An SFI exists but does not present a real or apparent fCOI (e.g., because the SFI is unrelated to the Sponsored Program, University Research, and/or Human Subjects Research), and no further review is required.
- An SFI exists and poses a real or apparent fCOI. Commencement of the program is contingent upon development and CIRC approval of an appropriate Management Plan. The account/index is not established and funds are not expended until a Management Plan is approved by the CIRC, and if required, the sponsor notified.
- An SFI exists and poses a real or apparent fCOI that cannot be addressed through a Management Plan.

When review of a disclosure results in referral to CIRC for the development of a Management Plan, the Department Chair/supervisor and Project Personnel are notified that the Related research activity may not proceed until development and CIRC approval of an appropriate Management Plan. ORSP, in consultation with the CIRC Administrator, determines the need for sponsor notification and/or limitations on project activity pending CIRC determination. Sponsored Program accounts/indexes are not established, funds are not expended, and IRB review is not completed until any Related SFIs are reviewed, any required Management Plans have been implemented, and any required sponsor notification has occurred. .

Conflict Management Plan Development

When a preliminary determination is made to refer a disclosure for CIRC review, the CIRC Administrator works with the Project Personnel, in cooperation with their Department Chair/supervisor as necessary, to develop a Management Plan for the CIRC's review.


CIRC Review

The CIRC reviews the preliminary determinations of real or apparent fCOI and the resulting draft Management Plan. The CIRC votes to confirm that a real or apparent fCOI exists, and, if so, whether to approve the recommended Management Plan as presented or with modifications, or requests additional information as necessary. Based on the CIRC decisions, the CIRC Administrator will work together with the Project Personnel, in cooperation with their Department Chair/supervisor as necessary, to finalize the Management Plan.

Conflict Management

Management measures may, as appropriate, include, but are not limited to, the following:

- Disclosure of the SFI to human participants, fellow researchers, students involved in the research activity, journal publishers, and/or others.
- Project Personnel's 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.

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- Independent review of student research progress.
- Relationship management (spouse, partner, colleague, etc.)

The Management Plan will state who is responsible for overseeing the implementation of the plan, and for reporting on compliance at stated intervals to the CIRC. If the Management Plan prescribes monitoring of the activity, it will describe specifically how the monitoring shall be performed, who shall perform it, what records are to be kept, and what reports are made to the CIRC. When faculty Conflict of Interest Monitors are required, the Department Chair is typically asked to serve in this role. However, if the Chair has a relationship with the entity described in the Management Plan (for example, as a collaborator, advisor, or reviewer), then in consultation with the college leadership and the managed individual, the CIRC will identify another senior member of the faculty or staff, unaffiliated with the research and/or the external entity, to serve as the Conflict of Interest Monitor.

Additional Input on Management Plans


In making review and management decisions, the CIRC and CIRC Administrator may consult with others on an as-needed basis only, including campus administrative offices, General Counsel, as well as the Project Personnel (and/or their Family, if applicable) and Department Chairs, particularly when the Management Plan will likely require Department-level implementation and/or monitoring.

Management Plan Notification

The CIRC Administrator communicates the CIRC's decision and Management Plan to the Project Personnel and those responsible for implementation of the Management Plan. The approved Management Plan is incorporated into an agreement between the university and the Project Personnel that details the conditions or restrictions imposed on the Project Personnel in the conduct of the project. ORSP will notify sponsors of the existence of a managed conflict if the regulations of that agency or award so require. fCOIs must be satisfactorily managed, reduced, or eliminated in accordance with this policy and all required reports to the sponsor completed before any expenditures are charged to an award. ORSP will notify the sponsor if the university finds that it is unable to satisfactorily manage an fCOI. It will be the responsibility of the Project Personnel and any responsible department administrators to notify ORSP, VPR, or the CIRC Administrator any time the recommendations of the CIRC cannot be fulfilled. ORSP will notify the sponsor. For awards from DOE or HHS, ORSP will prepare a report that states that a conflict of interest exists and that the conflict has been resolved. The report will be submitted to the HHS awarding unit. No details concerning the nature of the conflict need to be provided. Any subsequent change in financial interests resulting in a conflict must be resolved and reported to the awarding unit within 60 days of identification.

Process for Appealing CIRC Decisions

After receiving a notification of the CIRC decision, Project Personnel must, within the timeframe required by the CIRC, acknowledge in writing agreement to comply with any required Management Plan or submit a written request for reconsideration to the CIRC, which has the authority to review and affirm the previous

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decision or amend the Management Plan. The CIRC will notify the Project Personnel and the responsible individual of the result of the appeal. Project Personnel who do not agree with the CIRC decision may submit a written request for reconsideration to the VPR, who may recommend to the CIRC that they alter or delete a requirement. The VPR may not alter or remove a requirement. In all cases, the VPR may add requirements to a Management Plan at his or her discretion. The CIRC issues a final binding decision.

Financial Conflict of Interest Reporting to Public Health Service Agencies and DOE


For Project Personnel funded under a PHS award or cooperative agreement awarded on or after August 24, 2012, and for DOE awards made on or after December 20, 2021 Lehigh will provide to the appropriate PHS agency an fCOI report regarding any Project Personnel's SFI found to be an fCOI as follows:

- Prior to the expenditure of funds
- During the period of award
- Within 60 days of new, or newly identified, fCOIs for existing Project Personnel
- Within 60 days of identification of Project Personnel newly participating in the project
- At the same time as when the grantee submits an annual progress report, including multi-year progress: report annually for the duration of the project period (including extensions with or without funds), addressing the status of the fCOI and any changes to the Management Plan.
- Following a retrospective review to update a previously submitted report, if appropriate.

All fCOI reports will include the following information:

- The project number
- The PD/PI or contact PD/PI if a multiple PD/PI model is used
- The name of the Project Personnel with the fCOI
- The name of the External Entity with which the Project Personnel has an SFI
- The nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
- The value of the Financial Interest (dollar ranges are permissible: \$0 - \$4,999; \$5,000 - \$9,999; \$10,000 - \$19,999; amounts between \$20,000 - \$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- A description of how the Financial Interest relates to the PHS-funded Research and why Lehigh determined that the Financial Interest conflicts with such Research
- A description of the key elements of the institution's Management Plan, including the following:
 - The role and principal duties of the conflicted Project Personnel in the Research project
 - The conditions of the Management Plan
 - How the Management Plan is designed to safeguard objectivity in the Research project
 - A confirmation of the Project Personnel's agreement to the Management Plan
 - How the Management Plan will be monitored to ensure Project Personnel compliance
 - Other information as needed

Noncompliance with Disclosure Requirements

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Project Personnel who have not completed annual disclosures within 30 calendar days of the established deadline will be prohibited from submitting Sponsored Program proposals. Existing awards for sponsored programs in which Project Personnel who have not completed annual disclosures within 60 calendar days of the established deadline will not be distributed. When Management Plans are required, Sponsored Program awards are not distributed until Management Plans are implemented.

Project Personnel who fail to disclose Significant Financial Interests related to University Research not supported by any sponsored program are subject to the Misconduct in Research inquiry/investigation process as detailed in the University’s Ethical Conduct in Academic Research, Scholarship, and Creative Activities policy.

IRB protocols will not be processed until all faculty and staff Project Personnel named on a protocol to the IRB have declared the existence of any project-specific, external financial interests. The IRB will not approve a protocol unless all fCOI related to the research have been resolved.

Failure to amend disclosures within 30 calendar days of any material changes to SFIs related to University Research and/or Sponsored Programs will result in the sanctions described above, depending on the specific circumstances.


Noncompliance with Terms of a Management Plan

The CIRC will review cases of failure by Project Personnel to sign off on a conflict Management Plan and to adhere to an approved Management Plan and determine whether or not they constitute non-compliance with this policy. Determination of non-compliance will be cause for one or more of the sanctions noted in Sanctions for Noncompliance, at the discretion of the VPR. In addition, where such failure is not remedied, the non-compliance may be reported to the pertinent sponsor, if applicable, and referred to the Provost and further to appropriate university review committees for further action. Any academic misconduct or termination proceedings will be conducted in accordance with the applicable university policies and codes.

Complaints alleging noncompliance with this policy and/or the conditions imposed by an established Management Plan are referred to the CIRC Administrator or the VPR. Although the procedures for handling a complaint will depend upon the particulars of the complaint, normally the CIRC will interview the individual reporting the allegation and the Project Personnel. If the complaint is not resolved or the violation or failure to comply remedied informally by the CIRC, then the matter will be referred to the Provost and subsequently to the appropriate university review committee for further action. If the violation results in a collateral proceeding under university policy regarding misconduct in science, then a decision on sanctions should be deferred until the misconduct in science process is completed.

Subrecipients

For subrecipients under a prime award, Lehigh will document in a written subrecipient agreement that the subrecipient certifies that it has its own fCOI policy compliant with 2 CFR 200.112 and 113 (Uniform

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Guidance), or alternatively: for PHS awards, 42 CFR Part 50 and 45 CFR Part 94; for DOE awards, the December 20, 2021 DOE Interim COI Policy (“sponsor regulations”). The subrecipient agreement will include time periods to meet the disclosure and/or fCOI reporting requirements of Lehigh to the sponsor. Lehigh will take reasonable measures to monitor the subrecipient’s compliance with any applicable fCOI regulations, Management Plans, and for reporting all identified fCOI to the appropriate agency as necessary. This may include periodic review of the fCOI policy, disclosure forms, Management Plans, and any other information deemed relevant to assessing the effectiveness of the subrecipient’s fCOI disclosure and management process.

Except under the special circumstances described below, organizations who do not have their own fCOI policy which complies with either the Uniform Guidance or the sponsor regulations, will be considered ineligible to be a subrecipient for awards until such time as they develop, adopt, and implement their policy and can demonstrate compliance with it in the conduct of the award.

Under special circumstances, subrecipients without their own fCOI policy may agree to comply with Lehigh’s policy only if all subrecipient Project Personnel disclose to Lehigh at proposal stage that they have no related Significant Financial Interests. In this situation, the subrecipient remains obligated to disclose annually and with material changes in circumstances.


Lehigh reserves the right to prohibit any subrecipient without their own fCOI policy which complies with either Uniform Guidance or the sponsor regulations from participating in a proposal or an award if Lehigh determines that the subrecipient and/or Lehigh is not able to adequately comply/monitor the subrecipients compliance with the Lehigh fCOI policy.

Record Retention

Records regarding the fCOI process will be maintained in accordance with university policy and sponsors’ requirements. Sponsored programs-related disclosure forms and records of actions taken to manage fCOI shall be securely maintained by ORSP or VPR for at least three years from the date that the final expenditure report is submitted to the sponsor, or from other dates specified in 45 CFR 74.53(b) and 92.42.(b), or 2. CFR 200.334 (DOE) 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 university fCOI policy and procedures. Federal sponsors have the right to review this material. Project Personnel will be informed of any request from a federal sponsor to release this information.

Retrospective Review, Mitigation Plans and Reporting to PHS Agencies and DOE

If the university identifies a new SFI that was not disclosed in a timely manner by the Project Personnel, or if the university had not previously reviewed the SFI, it must be disclosed, reviewed, and any necessary Management Plan must be reviewed, approved, and implemented within sixty days of identification of the

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SFI.

For Senior and Key Personnel funded under PHS grants or cooperative agreements issued on or after August 24, 2012 or DOE award on or after December 20, 2021: Whenever an fCOI is not identified or managed in a timely manner, including failure by the Project Personnel to disclose an SFI, failure by the institution to review or manage an fCOI, or noncompliance with the Management Plan, Lehigh will, within 120 days of the determination of noncompliance, complete a retrospective review of the Project Personnel's activities and the project to determine bias in the design, conduct or reporting of such research. The retrospective review will include the following:

- The project number
- The project title
- The PD/PI or contact PD/PI if a multiple PD/PI model is used
- The name of the Project Personnel with the fCOI
- The name of the entity with which the Project Personnel has an fCOI
- The reason(s) for the retrospective review
- The detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
- The findings and conclusions of the review

When bias is found, ORSP will notify the appropriate PHS agency promptly and submit a mitigation report with the following pieces of information required under the regulations:

- The key elements documented in the retrospective review
- A description of the impact of the bias on the research project
- A plan of action to eliminate or mitigate the effect of the bias


In any case in which the Department of Health and Human Services determines that a PHS agency-funded clinical research project with the purpose of evaluating the safety or efficacy of a drug, medical device, or treatment has been designed, conducted, or reported by Project Personnel with an fCOI that was not managed or reported by the university as required by PHS regulations, the university will require the Project Personnel to:

- Disclose the fCOI in each public presentation of the results of the research, and
- Request an addendum to previously published presentations.

Training

All Project Personnel: Must attest, as part of the annual report and any event-based disclosure, that they have reviewed this policy, and understand and agree to comply with the requirements outlined in this policy.

Project Personnel funded under PHS awards/cooperative agreements issued on or after August 24, 2012, and Project Personnel funded under Department of Energy (DOE) awards/cooperative agreements issued

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on or after December 20, 2021: In addition to the above, must complete training as designated by the ORSP AVP and must provide evidence of successful completion to ORSP prior to engaging in PHS-agency or DOE funded research and at least every four years, and immediately under the designated circumstances whenever:

- University fCOI policies change in a manner that affects the requirements for Project Personnel
- Project Personnel is newly appointed
- The university finds that the Project Personnel is not in compliance with university fCOI policies or an existing Management Plan

ORSP will not accept awards or approve charges for sponsored programs on which Project Personnel have not completed the required fCOI training within the past four years. ORSP notifies active Project Personnel on PHS-funded and DOE funded awards of their need to renew training in advance of the end of a four-year period.

For all Project Personnel funded under DOE awards/cooperative agreements issued on or after December 20, 2021: Must certify their disclosure is true, complete, and accurate as per the Department of Energy Interim Conflict of Interest Policy prior to engaging in DOE awards.

ORSP implements any additional agency-specific training requirements that may be issued by PHS or other agencies for those participating in programs funded by such agencies.

Audit


The CIRC Administrator is responsible for administering random audits of disclosures submitted pursuant to this policy.

Research Integrity and/or Internal Audit may conduct investigations of potential non-compliance with reporting requirements, Management Plans, or other policy-related issues, when necessary. Instances of non-compliance that require reporting to federal agencies, sponsors, and/or other regulatory bodies, will be determined by Research Integrity, Internal Audit, and/or the Office of the Vice Provost for Research, and acted on as required. The CIRC, Research Integrity, and/or Internal Audit may conduct audits of process and compliance reviews to identify needed improvements to the fCOI process.

Public Accessibility of a Conflict of Interest Related to Public Health Service-Funded or DOE-Funded Research

Applicable to Senior and Key Personnel on PHS-funded awards or cooperative agreements with issue dates on or after August 24, 2012, or DOE awards issued on or after December 20, 2021:


To ensure public accessibility, Research Integrity will provide a response within five business days of receiving a written request submitted according to the procedures outlined on Research Integrity's public website on fCOI, regarding information concerning any identified fCOIs that meet the following three criteria:

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- The SFI was disclosed and is still held by the Senior or Key Personnel for the PHS agency-funded or DOE-funded project identified by Lehigh in the grant application, progress report, or any other required report submitted to the NIH
- Lehigh determines that the SFI is related to the PHS agency-funded research
- Lehigh determines that the SFI is a fCOI


The information that Lehigh will make available via a written response will include the following:

- The Project Personnel's name
- The Project Personnel's title and role with respect to the research project
- The name of the entity in which the SFI is held
- The nature of the SFI
- The approximate dollar value of the SFI (dollar ranges are permissible: \$0 - \$4,999; \$5,000 - \$9,999; \$10,000 - \$19,999; amounts between \$20,000 - \$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value


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Summary of Revisions to this Policy

Effective Date	Revisions
21-Jan-2021	<ul style="list-style-type: none"> ● 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 is being revised to include it as a formal requirement. ● The IP-related income section of the definition of Significant Financial Interest was revised for clarity. ● The term “talent recruitment or development program based outside of the U.S.” was further defined, using an adaptation of NSF’s definition of “foreign government talent recruitment program”. ● The definition of the term “related” was further expanded to provide additional information. ● The requirement for the CIRC to be chaired by a faculty member appointed by the Provost was removed. ● The term “most recent disclosure on file” was replaced with “current disclosure on file”. ● References to “non-student PIs and co-PIs” were removed from the sections on disclosure requirements for IRB applications. Lehigh University IRB policy prohibits students from serving as PIs or co-PI, and this policy on 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. ● Minor edits were made throughout the document to apply consistent formatting.
27-Oct-2021	<ul style="list-style-type: none"> ● The timeline for receipt of income from IP rights and interests was expanded to include income 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 is being revised to include it as a formal requirement. ● A timeline of twelve months preceding the disclosure and anticipated in the twelve months following the disclosure was added to the management position section of the definition of Significant Financial Interest. ● The definition of a Significant Financial Interest pertaining to travel reimbursement for PHS funded investigators was revised for clarity. ● Minor edits were made throughout the document, including to definitions of Significant Financial Interests, to apply consistent formatting, and for clarity. ● The definition of a Foreign Talent Recruitment program was revised to more closely correspond to the definition provided by the Joint Committee on the Research Environment (JCORE) of the National Science and Technology Council (NSTC),

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	<p>Subcommittee on Research Security’s 2021 report, “Recommended Practices for Strengthening the Security and Integrity of America’s Science and Technology Research Enterprise”.</p>
19-Oct-2022	<ul style="list-style-type: none"> ● Language throughout the policy was edited for clarity, including the Management Position section of the definition of Significant Financial Interest. ● The definition of a Foreign Talent Recruitment program was revised to more closely correspond to the definition provided by the Guidance for Implementing National Security Presidential Memorandum 33 (nspm-33) on National Security Strategy for United States Government-Supported Research and Development. ● The description of Required Disclosures was edited throughout the policy to be more concise. ● Procedures pertaining to Project Personnel’s’ review of their current disclosures were removed from the Process for Sponsored Program-Specific Disclosure. ● Removed references to the University-Wide Conflict of Interest Survey, administered by the department of Internal Audit, as this survey has been combined with the Annual Disclosure of Financial Conflicts of Interest Related to Research and Sponsored Programs. ● Information previously contained under Conflict Management Plan Development is now integrated within the descriptions of Disclosure Processes and Retrospective Review processes. ● The CIRC Review and Conflict Management section has been updated to reflect that Conflict of Interest Monitors may not be required in every instance of conflict management. ● Audit procedures have been updated to reflect that the Conflict of Interest Survey administered by the department of Internal Audit has been combined with the Annual Disclosure of Financial Conflicts of Interest Related to Research and Sponsored Programs Process. ● Training procedures have been updated to include the requirements of the Department of Energy Interim Conflict of Interest Policy that went into effect on December 20, 2021.
20-Nov-2023	<ul style="list-style-type: none"> ● Additions were made throughout the policy to incorporate requirements established by the December 20, 2021 Department of Energy (DOE) Interim COI Policy. ● The policy was revised throughout to correspond to the Lehigh University Integrated Research Administration (LIRA) system processes. ● The term “direct administration” was removed. The functions are already encompassed in the “design, conduct, or reporting” definition and the PHS and DOE regulations do not specifically require inclusion of “direct administration”. ● The Subrecipients and Record Retention sections were moved.
12-Apr-2024	<ul style="list-style-type: none"> ● The term “Foreign Government-Sponsored Talent Recruitment Program” was replaced by “Foreign Talent Recruitment Program” as defined by the White

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	House Office of Science and Technology Policy. This term and definition has been and will continue to be adopted uniformly by federal research funding agencies.
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