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## Policy Statement

Lehigh University (“the university/university”) is committed to conduct of research and sponsored programs in a manner that is consistent with its academic mission, maintains the trust of its sponsors and the public, and promotes compliance with applicable federal and state laws, regulations, and policies regarding financial conflicts of interest. These commitments require the university to identify and manage any 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 or Sponsored Program and could directly and significantly affect the design, conduct, or reporting 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, reporting, or direct administration 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 President and Associate Provost for Research and Graduate Studies, herein referred to as “VPR”.

## Entities Affected By This Policy/Who Should Read This Policy


- All university faculty and staff responsible for the design, conduct, reporting, or direct administration 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 has authority for reviewing disclosures made under this policy, in order to identify and/or confirm real or apparent financial conflicts of interest (fCOI) Related to Research, and address them in accordance with this policy and federal regulations. The CIRC has the authority to promulgate binding fCOI Management Plans.

The CIRC is responsible for the following:

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

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- 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. The CIRC is chaired by a voting member appointed by the Provost. 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 Research Integrity, Office of Research and Sponsored Programs (ORSP), Internal Audit, and the Office of the General Counsel. Research Integrity provides staff to 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

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

### Who is Required to Make Appropriate Disclosures

- Project Personnel, defined as any university faculty or staff member responsible for the design, conduct, reporting, or direct administration 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.
  - Direct administration of research is defined as oversight or decision-making impacting research, such as selection of vendors, determining the allocation of funds, negotiating budgets, deliverables, or other terms with sponsors, protocol review and approval, or managing resulting intellectual property.
  - 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:
    - Agency for Healthcare Research and Quality (AHRQ)

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- 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 Must Be Made

- Annually: All Project Personnel having an SFI in external entities that are related to the University Research and/or Sponsored Program and which may, per this policy, present a real or apparent fCOI.
- Event-based: All Project Personnel having an SFI in external entities that are related to the University Research and/or Sponsored Program and which may, per this policy, present a real or apparent fCOI:
  - when taking on the role of Project Personnel for the first time, or after not having served in such a role in the previous 12 months
  - with each submission for a Sponsored Program (internally or externally funded)
  - prior to engaging in the design, conduct, reporting, or direct administration of University Research (not supported by a Sponsored Program)
  - with each Institutional Review Board (IRB) protocol application for research involving human participants
  - when they have material changes to their circumstances affecting existing disclosures


### What Must Be Disclosed

Project Personnel must disclose:

- Every instance of an SFI in an external entity that is related to a person's role as Project Personnel on University Research and/or Sponsored Programs
- All material changes in the existence of SFI


Subject to the following definitions:

- Significant Financial Interests (SFI) include the following:
  - With regard to a publicly traded external entity, an SFI exists if the sum of (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 and (b) the value of any equity interest in the external entity as of the date of disclosure exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not

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otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); and equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

- With regard to any 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, when aggregated, (a) exceeds \$5,000, or (b) when the Project Personnel and/or their family holds any equity interest (e.g., stock, stock option, or other ownership interest) regardless of its value.
- Intellectual property rights and interests (e.g., patents, patent applications, copyrights) of the Project Personnel and/or their family, assigned to or to be assigned to a party other than the University, upon receipt of income related to such rights and interests.
- A management position in any entity, such as a director, officer, partner, president, vice-president, or trustee, held by the Project Personnel (and not their family) in any entity.
- As required by the federal regulations and only for Project Personnel on PHS funded awards or cooperative agreements issued on or after August 24, 2012, any travel that is reimbursed or paid on the Project Personnel's (and not their family's) behalf, related to the individual's Lehigh responsibilities, and determined by Lehigh to constitute or contribute to an SFI. 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.
- Participation by the Project Personnel and/or their family in or support from a talent recruitment or development program based outside of 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 entity other than the university or its components.
- Related means that the Project Personnel's SFI (and/or those of their family) reasonably appear to be related to the research or sponsored program.

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Disclosure of SFIs and reporting of material changes to existing circumstances must be made using disclosure forms and systems provided by the university, as described in the following sections below. For each such external relationship or financial interest, personnel must provide all of the information required in the appropriate disclosure form. For paid or reimbursed travel for Senior and Key Personnel on PHS 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.

### Annual Disclosure Process

- **Disclosure made to:** the CIRC Administrator
- **Related policy:** this policy
- **Required Disclosure:** All faculty members and staff engaged in the design, conduct, reporting, or direct administration of University Research or Sponsored Programs must disclose SFIs in external entities that are related to their research and may thus present a real or apparent financial conflict of interest pursuant to this policy. The CIRC administrator is responsible for the annual distribution of this policy to all university faculty members and any staff who have identified themselves, through the annual University Conflict of Interest disclosures made to Internal Audit, as engaged in University Research or Sponsored Programs in the 12 months prior to the date of the disclosure. Each individual is required to review the policy affirm that they have read, understand, and agree to abide by it, and to submit a disclosure pursuant to this policy if applicable.
- **Assessment of Disclosure:** The CIRC Administrator retains record of all disclosures made during the annual solicitation, and a record of all faculty and staff that have indicated they have no related SFIs to disclose. This record becomes the Project Personnel's "most recent disclosure on file". During the year following the annual disclosure, when Project Personnel are included on an application for a Sponsored Program, their "most recent disclosure on file" is presented to them and they are required to either affirm that they have no changes, or submit an updated disclosure. When an updated disclosure is made during this process, it becomes the "most recent disclosure on file".
- **Timing of Disclosure:** 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 an award (for Sponsored Programs).

### Process for Sponsored Program-Specific Disclosure

- **Disclosure made to:** ORSP (external sponsors) or VPR (internal funding)
- **Related policy:** this policy
- **Required Disclosure:** All Project Personnel on a proposal must certify if they have any SFIs related to the proposed Sponsored Program that may present a real or apparent fCOI pursuant to this policy.
- **Assessment of Disclosure:** ORSP solicits disclosures from all Project Personnel immediately following submission of the Intent to Submit to ORSP. As described in the Annual Disclosure Process section above, Project Personnel are presented with their "most recent disclosure on file"

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and they are required to either affirm that they have no changes, or submit an updated disclosure. When an updated disclosure is made during this process, it becomes the “most recent disclosure on file”. Proposals are not submitted to sponsors unless all Project Personnel have submitted completed disclosures to ORSP. Completed disclosures are internal documents and are not submitted to the sponsor with the proposal.


The ORSP Contracts and Grants Specialist (CGS) assigned to the proposal conducts an initial assessment of disclosures. If they confirm that all answers on a disclosure are “no”, no further review is required, and the disclosure is filed with the proposal file. If any answers are “yes”, the CGS refers the disclosure for Executive-Level Assessment by the Assistant Vice President of ORSP or their designee. The Executive-Level Assessment makes one of the following determinations for each disclosure:

- An SFI does not exist and no further review is required. The disclosure is filed with the proposal file.
- An SFI exists but does not present a real or apparent fCOI (e.g. because the SFI is unrelated to the Sponsored Program), and no further review is required. The disclosure is filed with the proposal file.
- An SFI exists and poses a real or apparent fCOI. The disclosure is filed and ORSP tracks that, if funding is offered, commencement of the program is contingent upon development and CIRC approval of an appropriate Management Plan. The procedure for review and resolution of the conflict will be initiated only after an award has been received from the sponsor. If a proposal is not funded, no further action is necessary.
- An SFI exists and poses a real or apparent fCOI that is not amenable to being addressed through a Management Plan. The proposal is withdrawn.

For internal grant programs, VPR does not solicit disclosures from Project Personnel unless funding is offered. A research account is not established unless and until all Project Personnel have submitted disclosures, disclosures have been reviewed by the VPR, and/or any required Management Plans have been approved by the CIRC.

The VPR administrative staff conducts an initial assessment of disclosures. If they confirm that all answers on a disclosure are “no”, no further review is required, and the disclosure is filed with the proposal file. If any answers are affirmative, the VPR administrative staff refers the disclosure for Executive-Level Assessment by the VPR. The VPR conducts the assessment and makes one of the following for each disclosure:


- An SFI does not exist and no further review is required. The disclosure is filed with the proposal file.
- An SFI exists but does not present a real or apparent fCOI (e.g. because the SFI is unrelated to the Sponsored Program), and no further review is required. The disclosure is filed with the proposal file.
- An SFI exists and poses a real or apparent fCOI. The research account is not established unless and until the CIRC reviews and approves an appropriate Management Plan.

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- An SFI exists and poses a real or apparent fCOI that is not amenable to being addressed through a Management Plan. The offer of funding is withdrawn.
- **Timing of Disclosure:** ORSP solicits disclosures from all Project Personnel immediately following submission of the Intent to Submit to ORSP. Proposals are not submitted to sponsors unless all Project Personnel have submitted completed disclosures to ORSP. For internal grant programs, VPR does not solicit disclosures from Project Personnel unless funding is offered. In either case, resulting awards are distributed only after any SFIs related to the program have been reviewed and any Management Plan has been implemented. All financial disclosures must be updated by Project Personnel during the period of the award as new reportable SFIs are obtained or Project Personnel are added to a sponsored program (see the “Process for Amending Existing Disclosures for Material Changes in Circumstances” section below).

#### Process for disclosures for University Research not supported by any sponsored program

- **Disclosure made to:** the CIRC Administrator via the Project Personnel’s Department Chair or direct supervisor.
- **Related policy:** this policy
- **Required Disclosure:** University faculty and staff (Project Personnel) who wish to engage in the design, conduct, reporting, or direct administration of University Research not supported by a sponsored program (and therefore not covered by any sponsored program-specific disclosure) are subject to this policy and must notify their Department Chair/direct supervisor only when they have determined that they have SFIs related to the proposed research that may present a real or apparent fCOI and require disclosure pursuant to this policy. The Department Chair/supervisor is then required to notify the CIRC Administrator. The CIRC Administrator coordinates directly with the Project Personnel to complete the process for disclosures related to University Research not supported by any sponsored program.
- **Assessment of Disclosure:** The CIRC Administrator conducts an initial assessment of disclosures for completeness and refers the disclosure for Executive-Level Assessment by the VPR. The VPR conducts the assessment and makes one of the following for each disclosure:
  - An SFI does not exist and no further review is required. The disclosure is filed with CIRC records and the Department Chair/supervisor and the Project Personnel is notified that no further action is required.
  - An SFI exists but does not present a real or apparent fCOI (e.g. because the SFI is unrelated to the research), and no further review is required. The disclosure is filed with CIRC records and the Department Chair/supervisor and the Project Personnel is notified that no further action is required.
  - An SFI exists and poses a real or apparent fCOI. The Department Chair/supervisor, Project Personnel, and CIRC Chair are notified that the research activity may not proceed unless and until the CIRC reviews and approves an appropriate Management Plan.
  - An SFI exists and poses a real or apparent fCOI that is not amenable to being addressed through a Management Plan. The Department Chair/supervisor, Project Personnel, and CIRC Chair are notified.

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- **Timing of Disclosure:** disclosures are required prior to engaging in the design, conduct, reporting, or direct administration of University Research. Project Personnel may not engage in University Research until disclosures are received, assessed, and a final determination is issued.


### Process for IRB Protocol Application-Specific Disclosure for University Research Involving Human Participants

- **Disclosure made to:** Research Integrity via a protocol application to the Institutional Review Board (IRB).
- **Related policy:** IRB Conflict of Interest policy; this policy.
- **Required Disclosure:** Non-student PIs and co-investigators for IRB protocols are required to declare at the time they submit an application to the IRB if they have any relationship or equity interest with any institutions or sponsors related to the proposed research that may present or appear to present a conflict of interest with regard to the outcome of the proposed research, and if yes, whether or not the conflict has already been disclosed pursuant to this policy.
- **Assessment of Disclosure:** If Project Personnel on an IRB protocol application disclose SFIs related to the project the Research Integrity staff informs the CIRC Administrator. If the Project Personnel have indicated on their application that their SFIs have already been disclosed pursuant to this policy, the CIRC Administrator confirms that the research disclosure on file includes information regarding the involvement of human subjects. If it does not, or if the Project Personnel have indicated on their application that they have not yet disclosed their SFIs, the CIRC Administrator works with the Project Personnel to amend the disclosure/complete a new disclosure. Disclosures are assessed by the Director of Research Policy and Compliance, per the Executive Level Assessment process as described in the above Assessment of Sponsored Project-Specific Disclosures section of this policy.
- **Timing of Disclosure:** The disclosure question on the IRB application must be answered on a protocol application to the IRB. Any disclosed SFIs related to the project must be assessed and any required Management Plans implemented, and reviewed and approved by both the CIRC and the IRB, prior to protocol approval. All disclosures must be updated by Project Personnel during the entire period they are engaged in University Research Involving Human Participants, both annually and as new reportable SFIs are obtained or Project Personnel are added to the University Research program (see the “Process for Amending Existing Disclosures for Material Changes in Circumstances” section below).

### Process for Amending Existing Disclosures for Material Changes in Circumstances

- **Disclosure made to:** the Project Personnel’s Department Chair, ORSP, VPR, and/or the IRB via the CIRC Administrator.
- **Related policy:** this policy and the IRB Conflict of Interest policy.
- **Required Disclosure:** All 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. Individuals are responsible for notifying the CIRC administrator directly. The CIRC administrator coordinates directly with the Project Personnel to complete the process for updating the appropriate



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disclosure(s) and also notifies, depending on which type of disclosure needs amending, the Project Personnel's Department Chair/supervisor, ORSP, VPR, and/or the IRB.

- **Assessment of Amended Disclosure:** The process for assessing amended disclosures is the same as described above for each type of disclosure (Annual Disclosures, Sponsored Program-Specific Disclosures, disclosures for University Research not supported by any sponsored program, and IRB Protocol-Specific Disclosures).
- **Timing of Disclosure:** within 30 days of any material changes to their external Financial Interests Related to their Lehigh responsibilities and/or research.


### Conflict Management Plan Development

When review of a Sponsored Program-Based Disclosure results in referral to the CIRC for the development of a Management Plan, the CIRC is not engaged unless and until funding is offered. For new awards, 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. For any existing award on which Project Personnel have submitted an annual disclosure or a disclosure related to a material change in circumstance that results in referral to the CIRC for the development of a Management Plan, ORSP, in consultation with the CIRC administrator, determines the need for sponsor notification and/or limitations on project activity pending CIRC determination. When review of a disclosure related to University Research not supported by any sponsored program results in referral to CIRC for the development of a Management Plan, the Department Chair/supervisor, individual Project Personnel, and CIRC Chair are notified that the research activity may not proceed unless and until the CIRC reviews and approves an appropriate Management Plan. When review of an IRB Protocol-Specific Disclosure for Research Involving Human Participants disclosure results in referral to the CIRC, the resulting Management Plan must be reviewed and approved by both the CIRC and the IRB, and the IRB will not approve the protocol application until the CIRC's review of the Management Plan is complete. The IRB has the authority to recommend, as a condition of protocol approval, adding human participant protection measures to an approved Management Plan, but does not have the authority to delete other items approved by the CIRC. 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 SFI.

When a preliminary determination is made to refer a disclosure for CIRC review, the office/individual making the determination (per the "When/To Whom Disclosures Are Made and How Disclosures Are Assessed" section above) notifies the CIRC Administrator and forwards the disclosure and any supporting documentation. 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 and Conflict Management

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

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Project Personnel, in cooperation with their Department Chair/supervisor as necessary, to finalize the Management Plan.

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.
- 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. Typically, the Department Chair is asked to serve as the Conflict of Interest Monitor for any Management Plan involving individuals in their department. If, however, 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 may call upon 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 communicates the CIRC decision and Management Plan to the Project Personnel via the CIRC Administrator, 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 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.

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### 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 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

For Project Personnel funded under a PHS award or cooperative agreement awarded on or after August 24, 2012, 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

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## Sanctions and Mitigation Plans for Noncompliance

- **Annual Disclosures:**  
Project Personnel who have not completed annual disclosures within 30 calendar days of the deadline established by the CIRC Administrator will not be able to submit sponsored program proposals, or will be removed from the proposal before it is submitted, to ORSP/VPR. Any existing awards for sponsored programs in which Project Personnel who have not completed annual disclosures within 60 calendar days of the deadline established by the CIRC Administrator will not be distributed by ORSP/VPR.
- **Disclosures for University Research not supported by any sponsored program:**  
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.
- **Sponsored Program-Specific Disclosures:**  
At a minimum, (1) Project Personnel who have not completed their proposal-specific declaration will not be able to submit the proposal or must be removed from the proposal before it is submitted, and (2) any awards for sponsored programs in which these Project Personnel are participating will not be distributed by ORSP/VPR until any required Management Plans have been implemented.
- **IRB Protocol Application-Specific Disclosures for Research Involving Human Subjects:**  
IRB protocols will not be processed until all non-student PIs and co-PIs 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.
- **Amending Existing Disclosures for Material Changes in Circumstances:**  
All Project Personnel are required, by this policy, to amend an appropriate disclosure(s) within 30 calendar days of any material changes to their SFIs related to their University Research and/or Sponsored Program. Failure to provide such amended disclosures will result in the sanctions described in the applicable "sanctions for noncompliance" section for each type of disclosure as listed above.
- **Management Plans:**  
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.

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Complaints alleging noncompliance with this policy and/or the conditions imposed by an established Management Plan are referred to the Chair of the CIRC 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.

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

For Senior and Key Personnel funded under PHS grants or cooperative agreements issued on or after August 24, 2012: 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

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For 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.

For Project Personnel funded under PHS awards/cooperative agreements issued on or after August 24, 2012: In addition to the above, must complete training in the PHS rules as designated by the ORSP AVP and must provide evidence of successful completion to the ORSP prior to engaging in PHS-agency 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 submit proposals, 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 awards of their need to renew training in advance of the end of a four-year period.

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 to verify that annual disclosures made to Internal Audit pursuant the University Conflict of Interest policy correspond to both annual disclosures pursuant to this policy and to individual Sponsored Program-Specific disclosures. When discrepancies are identified, the CIRC Administrator and ORSP/VPR work together with the Project Personnel to facilitate their review of the Financial Conflict of Interest Related to Research and Sponsored Programs policy and to update their sponsored program-specific disclosure as necessary, or to contact Internal Audit to update their disclosure pursuant to the University Conflict of Interest policy as necessary.

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 Research**

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

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

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website on fCOI, regarding information concerning any identified fCOIs that meet the following three criteria:

- The SFI was disclosed and is still held by the Senior or Key Personnel for the PHS agency-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


### Sub-Recipients

For sub-recipients under a prime award, Lehigh will document in a written sub-recipient agreement that the sub-recipient certifies that it has its own fCOI policy compliant with 2 CFR 200.112 and 113 (Uniform Guidance), and for PHS awards, 42 CFR Part 50 and 45 CFR Part 94, as appropriate. The sub-recipient 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 sub-recipient'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 sub-recipient'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 Uniform Guidance or the PHS regulations as appropriate, will be considered ineligible to be a sub-recipient 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, sub-recipients without their own fCOI policy may agree to comply with Lehigh's policy only if all sub-recipient Project Personnel disclose to Lehigh at proposal stage that they have no related Significant Financial Interests. In this situation, the sub-recipient remains obligated to disclose annually and with material changes in circumstances, as described in the Annual Disclosures and Amending Existing Disclosures for Material Changes in Circumstances sections above.

Lehigh reserves the right to prohibit any sub-recipient 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

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determines that the sub-recipient and/or Lehigh is not able to adequately comply/monitor the sub-recipients 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), 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.