

TU Conflict of Interest Policy, LKSOM Conflict of Interest Policy & PHS Conflict of Interest Regulation

Temple University Training

This training is in relation to the federal regulations 42 CFR Part 50 Subpart F & 45 CFR Part 94 which are incorporated into Temple University Policy Number 02.52.12



The LKSOM Disclosure Process

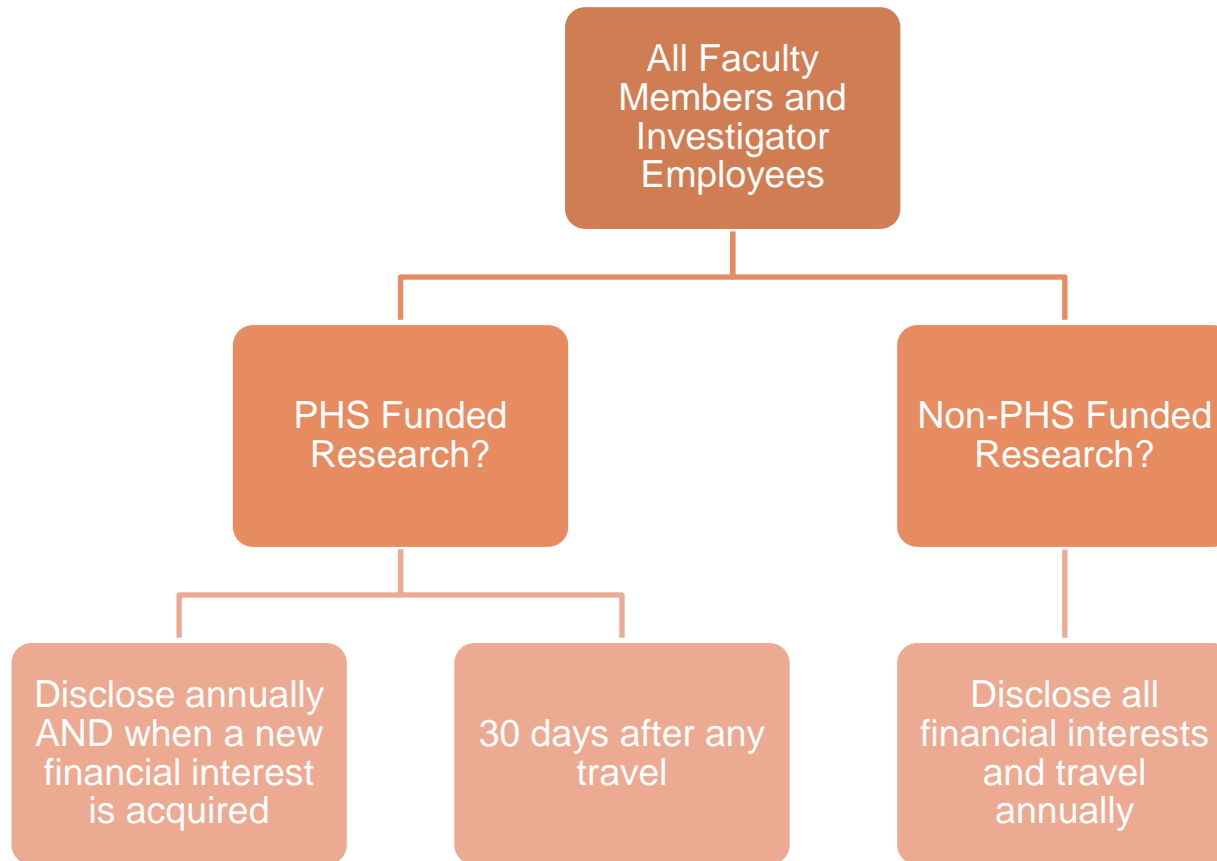


Who should complete a disclosure?

- Every faculty member at LKSOM regardless of whether or not they are participating in funded research
- Employees who meet the definition of investigator and are participating in sponsored research at least annually during the award period
- Graduate students, residents and postdoctoral fellows who meet the definition of investigator on sponsored research



When do I complete a disclosure?



What am I required to disclose?

- All financial interests related to your institutional responsibilities acquired by you and your immediate family
 - The COI Office will determine if they are significant when evaluating your disclosure
- All travel related to your Institutional responsibilities
- Spousal and familial relationships with other Temple University employees



Examples of Significant Financial Interests (SFI)

- Consulting fees, honoraria, or gifts > \$5,000
- Ownership, equity interests or options > \$5,000 in a publicly traded company
- Equity interests of any amount in a non-publicly traded company
- Any Intellectual Property Rights, regardless of value, upon receipt of income related to such rights and interests



Travel is an SFI

- Must disclose all travel related to your Institutional responsibilities including: days away for meetings, conferences, education, consulting, etc.
- You must disclose any reimbursed or sponsored travel (i.e., paid on your behalf, not reimbursed directly so you do not know the exact value) related to your Institutional responsibilities
- The travel disclosure requirement applies to any spouses and dependent children traveling with you



Travel Exclusions from SFI

All Travel must be disclosed but not all travel considered an SFI

- Excluded travel is paid by: Institutions of higher learning, academic teaching hospitals, medical center, research foundations associated with the above
- Also excluded – travel paid by Federal, state or local government
- It is the sponsor of the travel that causes the travel to be reported – not the purpose of the travel. If Merck pays for you to travel to give a CME talk, it is a reportable SFI



What is a considered a Financial Conflict of Interest (FCOI)?

An SFI that could directly and significantly affect the design, conduct, or reporting of PHS funded research

E.g.:

1. An investigator received \$18,000.00 in consulting fees from a company sponsoring a clinical trial they are working on
1. A PI on a project has equity in the privately held company whose technology is being tested on human subjects at Temple
2. An investigator's spouse works at a company and has personally developed the technology used on a device being implanted in patients as part of a study



When do you need a Management Plan?



Management plan may be as simple as a disclosure to third parties:

Disclose FCOI in all publications, lab staff, talks

More complicated situations can require independent data monitor or addition of unconflicted PI's, etc.

FCOI's must be managed prior to the expenditure of funds



How does the COI office use my disclosure?

Annual or updated disclosure Received and Reviewed by COI Office

- The COI Office reviews all disclosures when submitted through eRA
- Compared with current funded projects to assure no financial conflicts of interest exist
- Mark disclosure as reviewed or follow up for management of financial conflict of interest

At time of grant submission

- COI Office reviews investigators listed on grant submissions
- All investigators COI disclosures are reviewed for conflicts of interest
- No grants are allowed to be submitted with out disclosures on file for all responsible persons

At Notice of Award or Continuation

- COI office requests a final list of investigators on the project
- COI office reviews all investigator disclosures for significant financial interests
- If there is a significant financial interest related to research, COI office determines if is it a Financial Conflict of Interest and may require a management plan which will be reported to the funding agency as well as be made publically available upon request



The COI Disclosure Bottom Line

- Monies funding the project cannot be spent until it has been certified that all investigators' disclosures have been reviewed, and where applicable, a management plan is in place related to the funded project
- Without COI review and certification no new FOAPAL will be issued



Agencies Using the PHS FCOI Regulation

- **Public Health Service (PHS) Agencies:** Office of Global Affairs (OG); Office of the Assistant Secretary for Health (OASH); Administration for Children and Families (ACF); Office of the Assistant Secretary for Preparedness and Response (ASPR); Agency for Health Care Research & 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); Substance Abuse and Mental Health Services Administration (SAMHSA)

Non-PHS Agencies: Alliance for Lupus Research (ALR); Alpha-1 Foundation; American Asthma Foundation; American Cancer Society (ACS); American Heart Association (AHA); American Lung Association (ALA); Arthritis Foundation (AF); CurePSP; Juvenile Diabetes Research Foundation (JDRF); Lupus Foundation of America (LFA); Patient-Centered Outcomes Research Institute (PCORI); Susan G. Komen for the Cure



TU and LKSOM Conflict of Interest Policy Review



Full Text of the TU and LKSOM COI Policies may be found at:
<http://research.temple.edu/conflict-interest-program>



TU Conflict of Interest Policy

- LKSOM disclosure form addresses the TU Conflict of Interest Policy by asking about:
 - Employees or employees relatives as officers, directors, trustees etc. or is a person involved in a transaction involving the University
 - Employees whose independent judgment might appear to be impaired by an existing or potential financial interest
 - Employees who supervise or participate in decisions that affect a relative of the employee



TU Conflict of Interest Contd.

If a conflict or appearance of a conflict is disclosed, then the employee:

1. Must make full disclosure to the employee's supervisor
2. Refrain from acting until the employee has received written approval from University Counsel that the action is appropriate
3. The LKSOM COI office will coordinate communication between the employee and University Counsel's office



LKSOM COI Policy

The LKSOM COI Policy covers

- A. Gifts to employees
- B. Gifts to LKSOM
- C. Site Access by manufacturer representatives
- D. Participation in Industry Sponsored Programs
- E. Faculty Consulting and research relationships
- F. Faculty Expert Witness Services
- G. Ghost Writing Services
- H. Purchasing Decisions
- I. Financial Conflicts of Interest in Research



LKSOM COI Policy

The next few slides will cover the most frequently asked questions by Faculty Members about the LKSOM COI Policy

- No Gifts Policy
- Site Access by Manufacturer Representatives
- Participation in Industry Sponsored Programs
- Faculty consulting and research relationships
- **For more information, please see the LKSOM COI Policy**



LKSOM COI Policy

All employees subject to our
Strict **No Gifts** Policy

Gifts include but are not limited to:

- Supplies
- Books
- Equipment
- Food & Beverage
- Travel (there are exceptions for consulting relationships)
- Hospitality in the form of tickets to events
- Payment or reimbursement of expenses for attending a meeting or other event at which the employee is not a speaker or presenter
- Industry marketing materials such as pens, paper pads, bags, USB drives, etc.



LKSOM COI Policy

Site Access by Manufacturer Representatives Policy:

- Must be by appointment only
- Must be away from patient care areas
- Industry representatives may not bring food or beverage on to campus or pay for any food or beverage that is intended for consumption by employees
- **For more information, please see the LKSOM COI Policy**



LKSOM COI Policy

Participation in industry-sponsored programs :

- No Restaurant Talks: no compensated presentations (honorarium, food, lodging, etc.) for non-CME events directed at health care professionals
- No Speakers Bureaus: no compensation for membership speakers bureau, speakers list, or for attending an industry event at which he/she is not a speaker.
- No finders fees for referring or recruiting prospective subjects in clinical research
- **For more information, please see the LKSOM COI Policy**



LKSOM COI Policy

Faculty consulting and research relationships:

- May engage in consulting relationships provided that they are fully disclosed to department chairperson, section chief etc. for prior approval.
- Consulting agreement must also contain LKSOM's IP Rider
- COI Office will not review individual consulting agreements, but will answer your questions as needed
- **For more information, please see the LKSOM COI Policy**



Subrecipient Requirements

- If Temple is issuing a subaward, we must have in our written agreement terms that establish whether the grantees or grantors COI policy will apply. The language must include time periods to meet SFI disclosure, if applicable, and FCOI reporting requirements
- Subrecipient Institutions who rely on their own FCOI policy must report identified FCOIs to Temple University with sufficient time to allow us to report the FCOI to the PHS/NIH Awarding Component



Public Accessibility of FCOIs

- Prior to expenditure of funds, the regulation requires we make certain information concerning FCOIs held by senior/key personnel publicly accessible via a Web site or provide written response within five business days of a request

Temple will NOT post FCOI's on website but will respond as required by the regulation to written requests



Conflict of Interest Module

To update your disclosure, please login to eRA@TU portal: https://era.temple.edu/tu_login/login.asp using your accessnet ID and TUsecure password (same as your TU mail login)



Information/Resources

- For more information, please contact:
 - Adam Nester, JD, MS (adam.nester@temple.edu)
LKSOM Office: 215-707-1986 (ext. 2-1986)
- <http://research.temple.edu/research-compliance/conflict-interest>
- OER FCOI Web Site
- <http://grants.nih.gov/grants/policy/coi/>

