

Conflict of Interest Policy – Texas Lutheran University

Background

To promote objectivity in the conduct of sponsored projects and remain in compliance with federal, state and additional external sponsor requirements, Texas Lutheran University (TLU) has a responsibility to manage conflicts of interest that arise during the period of performance for externally funded research.

Guidelines regarding conflict of interest disclosure and management vary from sponsor to sponsor. As a result of amended regulations from the Department of Health and Human Services implemented August 25, 2011, the most stringent requirements are for those seeking funding from U.S. Public Health Service (PHS) entities. The guidelines below reflect TLU's policy and procedures for disclosure and management of financial conflicts of interest, and are compliant with the requirements set forth in the 2011 Revised Conflict of Interest Regulation.

Reference:

2 CFR 200 (Uniform Guidance)

42 CFR 50 Subpart F

45 CFR 94

NIH FCOI Tutorial: <https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Applicability

Conflict of Interest (CoI) disclosure applies to all TLU employees who are responsible for the design, conduct, or reporting of research programs funded by external sponsors.

Subgrantees may follow their own policy and procedure provided their institution has a written and enforced policy that meets the federal and state requirements for disclosure of significant financial interests.

Definitions

Conflict of Interest (CoI) – for the purposes of this policy, CoI means a Significant Financial Interest that the Institutional Official reasonably determines could directly and significantly affect the design, conduct, or reporting of externally funded research.

Investigator – means any employee of TLU, regardless of title or position, who is responsible for the design, conduct or reporting of research and educational activities funded by an external sponsor or proposed for such funding, which may include collaborators and consultants. (Typical roles are PD/PI, Co-I, and Senior/Key Personnel as noted in a proposed or approved grant budget, though other roles may be applicable.)

Financial Interest – means anything of monetary value, whether or not the value is readily ascertainable.

Note: Financial Interest does NOT include:

- *Salary, royalties, or other remuneration from TLU, including intellectual property rights assigned to TLU and agreements to share royalties related to such rights*
- *Income from the authorship of academic or scholarly work*
- *Income from seminars, lectures or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. Institutions of Higher Education (IHE's), research institutes affiliated with IHE's, academic teaching hospitals, and medical centers OR*

- *Equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.*

Institutional Official – means the individual within TLU designated as responsible for collection and review of disclosures and Significant Financial Interests including those of the Investigator’s or Grants-related Administrator’s family related to their Institutional Responsibilities. For the purpose of Conflict of Interest evaluation and reporting, TLU’s Institutional Official is designated as the Vice President of Finance and Administration.

Institutional Responsibilities – mean a TLU employee’s professional responsibilities on behalf of TLU and as defined by TLU, including but not limited to activities such as teaching, professional practice, institutional committee memberships, service on panels such as the Institutional Review Board, and research or research consultation.

Significant Financial Interest (SFI) – means a financial interest consisting of one or more of the following interests of the Investigator/Grants-related Administrator (and those of the spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:

- With regard to any publicly traded entity the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of date of disclosure, when aggregated, exceeds \$5,000.
- With regard to any non-publicly traded entity, the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest.
- Intellectual property rights and interests upon receipt of income related to such rights and interests.
- Investigators must disclose any reimbursed or sponsored travel (paid on behalf of the investigator and not reimbursed so that the exact monetary value may not readily be available) related to their institutional responsibilities, unless the travel is reimbursed or sponsored by a Federal, state, or local government agency, an IHE, an academic teaching hospital, medical center or research institute affiliated with an IHE.

CoI Disclosure Requirements

TLU requires all Investigators to disclose/report Significant Financial Interests (SFI) as follows:

- At least annually
- No later than at the time of application for external funding if the Key/Senior (or equivalent role) individual has not previously disclosed
- Within 30 days of discovering or acquiring a new SFI
- Prior to conducting research with a PHS entity, should it be determined no previous disclosure is on file.

Processes for Disclosure

Annually –

- 1.) At the beginning of each Academic Year, the Grant Analyst will provide a CoI Disclosure form to all Investigators and Grant Administrators.
- 2.) Investigators will use the form to disclose any Significant Financial Interests (as described under “Definitions”), including interests of their spouse and dependent children that would reasonably appear to affect or be affected by their research or institutional responsibilities.

- 3.) Investigators who have no SFIs as defined above, must complete and submit a signed CoI Disclosure form indicating such.

At time of Proposal Application –

- 1.) If a proposal application includes an Investigator who has not previously completed a CoI Disclosure at TLU, the Director of Corporate and Foundation Relations, as part of the proposal submission process, shall request completion of the CoI Disclosure form.
- 2.) The CoI Disclosure form must be completed by the Investigator prior to the application being submitted.

Upon Discovering a new SFI –

- 1.) Any Investigator who acquires or discovers an SFI during the course of the year after regular annual disclosure, is required to complete a new CoI Disclosure form within 30 days of acquisition.
- 2.) The CoI form must be submitted to either the Grant Analyst or Institutional Official for tracking and review purposes. Best practice is to submit to the Grant Analyst for tracking purposes, who will then route the form to the Institutional Official for review.

Prior to Conducting Research with a PHS entity –

- 1.) Should an Investigator receive an award from a PHS entity, the Grant Analyst will check records to determine if the Investigator has disclosed within the past 12 months.
- 2.) If no CoI Disclosure is on file from within the previous 12 months, the Investigator must complete and return the form prior to conducting any research activities.

Investigator Responsibilities

Through the implementation of this policy by TLU, Investigators are responsible for complying with the guidelines set forth, completing CoI training when required, and for disclosing required information to TLU as described. Every Investigator has an obligation to become familiar with, and abide by this policy.

If a situation arises raising questions regarding conflict of interest, the Investigator should discuss it with the Institutional Official.

Lead Roles: Principal Investigator/Project Director Responsibilities

Investigators who are fulfilling the role of Principal Investigator (PI), Project Director (PD), Co-Investigator, or roles with equivalent responsibility to the overall project, have a responsibility to notify Grants-related Administrators of any other individuals working in support of their project who should disclose potential CoI's. TLU considers the Principal/Primary Investigator to have the most complete understanding of team member roles and responsibilities as they relate to the externally funded research, and be able to determine if/when an individual should be required to disclose.

Administration Roles & Responsibilities

Grant Analyst

- Distributes and collects disclosure forms annually
- Maintains CoI disclosure records
- Routes disclosure forms to Institutional Official for review/approval
- Notifies sponsor and Submits CoI management plans if applicable.

Director of Finance and Corporate Relations

- Asks new Investigators if they have disclosed CoIs to TLU within the past 12 months prior to submitting proposal applications
- Confirms date of last disclosure with Grant Analyst prior to submitting proposal applications
- Provides form to Investigators who need to disclose at time of proposal

Institutional Official

- Reviews and approves disclosure forms
- Determines if a Conflict of Interest exists
- Works with the Investigator to develop a management plan if a CoI exists
- Reviews CoI management plans to monitor conduct and compliance

CoI Disclosure Evaluation & Management Process

Evaluation

CoI Disclosure forms and any accompanying documentation will be collected by the Grants Analyst for tracking purposes. The Grants Analyst will track the date of receipt and submit the forms to the Institutional Official for review and evaluation if an SFI is disclosed. The Controller will review and approve the Institutional Official's disclosure form.

Management:

If a conflict of interest is present, the Institutional Official must work with the Investigator to develop a written management plan to address it. The plan may be developed in consultation with the Vice President of Academic Affairs if necessary, and may include reducing or eliminating the financial CoI if possible, prior to any research being conducted. The Institutional Official will implement the written plan. The affected Investigator must acknowledge agreement by signing the plan.

Research activities for PHS funded projects may not begin until the management strategy is finalized and signed by both the Institutional Official and Investigator. All CoIs must be disclosed to the sponsoring agency along with the management plan for review and approval prior to expensing any funds from the grant in question.

Upon implementation of the management strategy, the Institutional Official will periodically review the ongoing activity to monitor conduct and compliance.

Non-compliance:

In the event a CoI is not identified or managed in a timely manner, or if upon evaluation of the management strategy for an identified CoI the Investigator is deemed non-compliant, the Institutional Official shall complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of the research. The retroactive review should take place within 120 days of discovery of non-compliance, or discovery of a previously unidentified CoI. If bias is determined, a report will be filed with the sponsor to describe the impact of the bias, and a plan of action for eliminating the effect and bias moving forward.

Investigators who knowingly do not abide by the disclosure requirements outlined in this policy may be subject to reprimand or disciplinary action.

Records Retention

Completed and approved CoI Disclosure forms will be retained for three years. For instances in which a conflict of interest is disclosed, the disclosure form along with management plan will be retained for a minimum period of 3 years from the date the final expenditure report is submitted to the sponsor, unless sponsor terms and conditions require a longer period of retention.

Public Accessibility

Policy – TLU’s Conflict of Interest Policy will be made available to the public through the publicly-accessible sections of the online portal.

Conflicts of Interest - Consistent with requirements of the PHS regulation, prior to the expenditure of funds under a PHS-funded research project, TLU will ensure public accessibility of information about any Significant Financial Interest to the requestor within 5 business days of the request, if it meets the following criteria:

- The significant financial interest was disclosed and is still held by the senior/key personnel
- TLU determines that a significant financial interest is related to the PHS-funded research; and
- TLU determines the significant financial interest is a financial conflict of interest

The information made available to the public will meet the requirements as outlined in the PHS conflict of interest regulation.

Training

Any Investigator engaging in PHS-funded research is required to take CoI training prior to conducting research related to the PHS-funded project. PHS-funded Investigators must also refresh CoI training every 4 years, or immediately if found to be non-compliant with TLU’s CoI policy or a CoI management plan.

TLU utilizes the free CoI tutorial provided by National Institutes of Health (NIH) for training purposes. In addition to reviewing TLU’s policy – PHS Investigators, regardless of which PHS entity is funding their project, must provide assurance they have completed the NIH tutorial by sending a copy of the Certificate of Completion to the Grant Analyst. The tutorial consists of 22 slides, and can be completed using a standard internet browser.

Link to NIH tutorial: <https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Other Investigators (non-PHS funded) are not required to complete the NIH tutorial, but are encouraged to do so.

Proof of completion of other CoI training courses may be accepted in lieu of the NIH tutorial such as Collaborative Institutional Training Initiative (CITI).

List of PHS Entities

Below is a list of PHS entities using the PHS FCOI Regulations per the Federal Demonstration Partnership website. Institutions are encouraged to independently verify the inclusion of PHS regulations in their award terms from these agencies.

(updated 7/17/2017)

1. Administration for Children and Families (ACF)
2. Administration for Community Living (ACL)
3. Agency for Healthcare Research and Quality (AHRQ)
4. Agency for Toxic Substances and Disease Registry (ATSDR)
5. Centers for Disease Control and Prevention (CDC)
6. Food and Drug Administration (FDA)
7. Health Resources and Services Administration (HRSA)
8. Indian Health Service (IHS)
9. National Institutes of Health (NIH)
10. Office of Global Affairs (OG)
11. Office of the Assistant Secretary for Health (OASH)
12. Office of the Assistant Secretary for Planning and Evaluation
13. Office of the Assistant Secretary for Preparedness and Response (ASPR)
14. Office of Public Health and Science
15. Substance Abuse and Mental Health Services Administration (SAMHSA)

Though these are not PHS entities, the following agencies have been reported to include the same FCOI regulations in their award terms:

(updated 3/10/2015)

1. Alliance for Lupus Research (ALR)
2. Alpha-1 Foundation
3. American Asthma Foundation
4. American Cancer Society (ACS)
5. American Heart Association (AHA)
6. American Lung Association (ALA)
7. Arthritis Foundation (AF)
8. CurePSP
9. Juvenile Diabetes Research Foundation (JDRF)
10. Lupus Foundation of America (LFA)
11. Patient-Centered Outcomes Research Institute (PCORI)
12. Susan G. Komen for the Cure