

Compliance Update

September 4, 2012

- Grants/Contracts Submission
- FCOI Update

james.trempe@utoledo.edu



Grants/Contracts Submission

All grant and contract proposals must be developed, negotiated and submitted by the departments of Research and Sponsored Programs or Technology Transfer.

Grants/Contracts Submission

- **Budget issues**
 - Indirect Costs/Facility and Administrative Costs/Overhead
 - Fringe Benefit Rates, Tuition, etc.
 - Extra Compensation (Federal Guidelines, UT CBA)
- **Contract Issues**
 - Federal – negotiated by RSP
 - Corporate-negotiated by Tech Transfer
 - Governing Law, Indemnification, IP, Publication, etc.
- **Compliance Issues**
 - IRB, IACUC, Export Control, COI, etc.
- **Delegation of Signatory Authority for Documents that Bind the University (3364-40-08)**

“But this is not a research grant!”

“Yes but it is a sponsored program.”

FCOI Update

New Federal Regulations:

42 CFR Parts 50 and 94

“Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors; Final Rule”

August 24, 2012

COI at UT

- 3364-25-50 Conflict of Interest
- **3364-70-01 Financial Conflict of Interest for Sponsored Programs**
- 3364-81-12-206-04 Conflict of Interest and Disclosure (CME)
- 3364-81-01-004-01 Individual Conflict Interest in Education and Clinical Care (COM)
- 3364-01-06 Conflict of Interest for Members of the Board of Trustees

42 CFR Parts 50 and 94

- Institutions define whether FCOI exists
- De minimis threshold of \$5,000 for disclosure, payments and/or equity interests
- Investigator's "Institutional Responsibilities"
- Requires public disclosure
- Must create a management plan for all identified FCOI s and report details of plan to HHS prior to expenditure
- FCOI training required for investigators submitting PHS proposals
- SBIR/STTR Phase II applicants/awardees (Phase I SBIR/STTRs are exempt)

42 CFR Parts 50 and 94

- **A *Financial Conflict of Interest (FCOI)* exists when the Institution' designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of HHS funded research.**

“Significant Financial Interest”

- exists at a monetary threshold of \$5,000, of the aggregated amount of any remuneration received from the entity in the 12 months preceding disclosure:
- 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 option, or other ownership interest,

“Significant Financial Interest”

DOES NOT include:

- Income from seminars, lectures or committees or review panels for public or nonprofit entities
- Publication - Scholarly communications in the form of books, movies, television productions, *etc.*
- Clinical Practice
- Professional Service – External activities that reflect normal and expected public service activities of faculty
- Ownership or income from mutual funds or retirement funds not managed by the individual are not considered a financial interest and not subject to disclosure.

Disclosure Requirements

Who must disclose:

- All Investigators (including students or other trainees) listed by name on the proposal, regardless of role.
- Any Investigator, regardless of institutional status or affiliation, not named on the proposal but whom the PI knows or suspects will be involved in the design, conduct, or reporting aspects of the sponsored program, including persons who are sub-grantees, contractors, collaborators or consultants.
- All Investigators, regardless of institutional status or affiliation added to the program team after the proposal is submitted.

Disclosure Requirements

When to disclose:

- no later than the time of application for funded research,
- annually, during the period of the award,
- within thirty days of discovering or acquiring (through purchase, marriage or inheritance) a new significant financial interest.

<https://coi.utoledo.edu/>



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UT THE UNIVERSITY OF TOLEDO

University of Toledo - Conflict of Interest Disclosures

This website provides a means for the University of Toledo to comply with federal regulations regarding the disclosure of potential conflicts of interest by its researchers. A conflict of interest occurs when a personal, professional or financial relationship compromises a researcher's objectivity, judgment, integrity or ability to perform research-related or institutional responsibilities.

Only those who are responsible for the design, conduct, or reporting of research supported or proposed for support by any sponsor via a grant or Sponsored Program agreement are required to file a financial disclosure.

For detailed instructions on working through this web site please consult the [Conflict of Interest Tutorial](#).

Researchers affiliated with a Public Health Service-sponsored proposal (e.g. NIH, AHRQ, HRSA) are required to undertake training in financial conflict of interest at the Collaborative Institutional Training Initiative site: [CITI Training for Financial Conflict of Interest](#). Training must be re-taken every four years for these researchers. However, the University of Toledo strongly recommends that all researchers undertake training as a proactive and anticipatory measure. To access the CITI training click on the link above, log in and fill out the registration. At your Main Menu page, click on the "Add a course or update learner group" link to access the training.

Authorization Required:

Here are a few things you should know before logging in:

1. You must enter a valid UTAD username and password

Login	
User Name:	<input type="text"/>