

## University of Tennessee Institute of Agriculture Financial Conflict of Interest Guide

### NEW PHS REQUIREMENTS

In 2011, the Public Health Service (PHS) released revised financial conflict of interest (FCOI) regulations (42 CFR 50) that apply to any institution receiving funds from a PHS sponsor either directly or as a subcontract. Institutions **applying for or receiving funding** from any PHS entity must revise their institutional FCOI policy to be in full compliance with all of the regulations by August 24, 2012.

#### PHS agencies include:

- 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) – Including NIH Centers and Institutes
- Office of the Inspector General (OIG)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

The University of Tennessee has been working on the revisions to the Conflict of Interest (COI) policy to ensure compliance with the PHS regulations. This policy will have an institutional-wide impact. A copy of the policy is available at: <http://www.tennessee.edu/disclosure>.

#### Major changes include:

**Lower Financial Disclosure Threshold:** The minimum threshold for reporting a Significant Financial Interest (SFI) will be lowered from \$10,000 to \$5,000

**Financial Interest Disclosure Form for PHS Investigators:** Effective with proposals submitted on or after August 24, 2012, a Financial Interest Disclosure Form must be submitted and evaluated for FCOI prior to the submission of a proposal to a PHS agency. Print, sign and submit the completed form to your dept/unit head. The dept/unit head will forward the form to the appropriate dean's office. A link to the form for PHS Investigators is available at the bottom of the COI Policy, <http://www.tennessee.edu/disclosure>.

**In order to be compliant, the CVM research office and UTIA Office of Sponsored Programs will not be able to submit the proposal if the requirements have not been met.**

### NEW PHS REQUIREMENTS

#### Disclosure of all Externally-funded Travel Reimbursements:

PHS-funded investigators must disclose *all* travel reimbursements that are either sponsored by (that is paid by an outside entity directly to the investigator) or reimbursed directly to the investigator from an outside entity for travel that occurs after August 24, 2012, with some exceptions. Exceptions include: travel reimbursements from an institution of higher education, a federal/state/local government, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education. A link to the Disclosure Form for Reimbursed and Sponsored Travel for PHS Investigators is available at the bottom of the COI Policy, <http://www.tennessee.edu/disclosure>.

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**Mandatory FCOI Training Requirements:** Only for Investigators engaged in Public Health Service (PHS) funded research.

- All PHS-funded “investigators” must complete online FCOI training prior to the expenditure of funds on any newly-funded projects, including noncompeting continuation awards.
- This applies to all PHS-sponsored research awards received as of August 24, 2012.
- Training must be completed at least every four years.
- Current PHS awards are not subject to these new requirements until the noncompeting continuation award. However, we encourage investigators to take the training now to fulfill this mandatory requirement.
- The term “investigator” means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by the PHS, or proposed for such funding. Therefore, the regulations can apply to collaborators, consultants, post-doctoral fellows, graduate students, and others. The regulations apply either at the awardee institution or at the subrecipient organization, if the individual meets the definition of “investigator.”
- Online training is available for UTIA personnel using the CITI COI Module that can be found at: <https://www.citiprogram.org/>. If you are a new user you will need to register with CITI first. Contact [JaneBurns@utk.edu](mailto:JaneBurns@utk.edu) if you need assistance.

### **FCOI Information Made Accessible to the Public:**

The new regulations require public transparency of investigators’ FCOI management plans either by publicly-accessible website or by a written response within five business days to a request for an institution’s financial conflict of interest policy. This includes providing certain information regarding any key personnel whose significant financial interests are related to PHS-funded research.

### **Subrecipients:**

At time of Proposal: The “Subrecipient Commitment Form” must be completed by each subrecipient organization. Subrecipients must certify that they have a PHS FCOI compliant policy and declare any conflicts of interest. If Subrecipient does not have a policy, they must certify that they will follow UT’s policy. The Subrecipient Commitment Form can be found at: <http://agriculture.tennessee.edu/sponsoredprograms/contractsSubcontracts.asp>

At time of Award: Subaward will not be issued until the FCOI requirements have been met, which includes any disclosures of FCOI and mandatory training.

**Additional information on PHS FCOI can be found on the following site:**

<http://grants.nih.gov/grants/policy/coi/>.