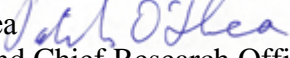




August 24, 2012

MEMORANDUM

TO: Vice Presidents, Deans, Directors, and Department Chairs

FROM: Patrick G. O'Shea 
Vice President and Chief Research Officer

SUBJECT: PHS FCOI Regulations

The Public Health Service (PHS) regulations governing Financial Conflict of Interest (FCOI) programs at institutions that accept PHS research funds have new requirements effective August 24, 2012. In order to ensure a continuous and seamless flow of proposal submissions and award acceptance, the University will be implementing Conflict of Interest (COI) Regulatory Compliance Guidelines for ensuring and reporting Objectivity in Research. The University's new Policy and Procedures on Financial Conflicts of Interest in PHS Funded Research (II-3.10(C)) will apply to all Investigators who are involved in the design, conduct or reporting of research with additional disclosure and training requirements for PHS funded investigators working on PHS-funded studies. Additional information on the regulations and PHS policy is available at: http://grants.nih.gov/grants/policy/coi/coi_faqs.htm.

PHS COI TRAINING: CITI PROGRAM

PHS recently issued updated conflict of interest regulations applicable to existing and new PHS-funded researchers. One of the key requirements in the updated regulations is that **all current PHS investigators who are responsible for “design, conduct or reporting” of research must undergo conflict of interest training initially, including a component describing the new regulations, and again at least every 4 years.**

The training link is www.citiprogram.org and individuals should register and enroll in the **Conflict of Interest Mini-Course.**

Principal Investigators, should note that they are responsible for verifying that all personnel who are responsible for “design, conduct or reporting” (typically “key personnel”) on PHS-funded projects have completed this training, including any key personnel added to any project after it was awarded.

PHS regulations require that in order for spending to continue on active awards, all training must be completed before the issuance date of the next Notice of Award for that project. To avoid interruption of projects, it is recommended that all key personnel on existing awards be trained on the new regulations as soon as possible.

PHS MANDATORY DISCLOSURE PRIOR TO PROPOSAL SUBMISSION: IRBNet – FCOI Module

Mandatory FCOI disclosures are now required prior to any PHS proposal submission. The IRBNet – FCOI Module provides a FCOI workspace, with functionality similar to our existing IRB and IACUC Modules. It allows for FCOI forms to be directly submitted for review, and allows the creation and tracking of FCOI management plans. This module allows for submission of Initial, Interim and annual disclosures. Once a disclosure is acknowledged, reminders will be sent to the project owner 60, 45, 30 and 15 days prior to the due date of the annual disclosure submission.

Investigators/key personnel are required to submit their disclosure via a Smart Form in IRBNet and link it to their created project. This project can be shared with all key personnel on the project so that they may complete their Smart Form disclosure. Once all disclosures are linked to the project and all key personnel electronically sign the project, the project owner can submit to the COI Administrator. The COI Administrator, in conjunction with the COI Committee Chair and members, will determine if no FCOI is present or if a disclosure requires full COI Committee review.

Additional guidance will be distributed directly to all investigators.

Please don't hesitate to contact the Compliance Office (ext. 54212) or your ORA Contract Administrator (ext. 56249) if you have any question about how the regulations apply to you.