U.S. Public Health Service Financial Conflict of Interest

The U.S. Public Health Service (PHS) amended its Financial Conflict of Interest (FCOI) Regulation effective August 24, 2012.

Additionally, ISU adopted a new Conflict of Interest and Commitment (COIC) Policy effective July 1, 2011. In order to fully comply with ISU’s new COIC policy and with PHS’s new regulation, ISU has incorporated changes to the Conflict of Interest and Commitment (COIC) Disclosure in Access Plus. If you currently receive funding from, plan to apply for funding from, or have your salary funded by a grant from any PHS agency, you must comply with the new FCOI Regulation. 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)
  - NIH Centers and Institutes
- Office of the Inspector General (OIG)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

PHS defines “Investigator” as 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.

- Investigator is broadly defined so that it may include P&S personnel, post-doctoral associates, and graduate students.

Changes to PHS FCOI Policy

The FCOI regulation, effective August 24, 2012, requires that all persons applying for, receiving, or being supported on PHS funds must be compliant with PHS rules on training, disclosure, and establishment of conflict of interest management plans prior to applying for or receiving the funds. Disclosures by persons applying for or receiving funding from any PHS agency will be evaluated by PHS rules regarding significant financial interests in non-university (non-ISU) entities. These rules are stricter than for other funding agencies and Iowa State University. In addition, the rules apply to current interests and interests in the 12 months preceding the disclosure, rather than interests that are anticipated in the future.

The major changes to the PHS Financial Conflict of Interest Policy include:

- Lower financial disclosure thresholds
- Increased transparency for travel reimbursement
- New conflict of interest training
- New public accessibility requirements
Lower Financial Thresholds

Investigators must disclose the following as a significant financial interest if applicable to the Investigator, the Investigator’s spouse (or domestic partner), or dependent children:

- The value of any remuneration received from any **publicly traded** entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure that, when aggregated, exceeds **$5,000**.
  - Please note that assets in or income from investment vehicles such as mutual funds and retirement accounts are not considered significant financial interests and do not need to be disclosed as long as you do not directly control the investment decisions made in these vehicles.
- The value of any remuneration received from any **non-publicly traded** entity in the twelve months preceding the disclosure that, when aggregated, exceeds **$5,000**, or any equity interest in non-publicly traded entities. Intellectual property rights and interests count toward the $5,000 received from the entity upon receipt of income related to such rights and interests.

Increased Transparency for Travel Reimbursement

*Any* reimbursed travel or sponsored travel related to Institutional responsibilities if paid directly on behalf of the Investigator (including purpose of trip, sponsor/organizer, destination, and duration) must be disclosed as a Significant Financial Interest.

Please note that you are not required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. For example, if travel is reimbursed or paid by ISU as part of a gift or sponsored project, it is not considered a significant financial interest and does not need to be disclosed.

Financial Conflict of Interest Training for PHS Investigators

Please note that effective August 24, 2012, each Investigator must complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under the following circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements;
- An Investigator is new to ISU; or
- ISU finds an Investigator noncompliant with ISU’s FCOI policy or management plan.

Public Accessibility Requirements

ISU must make certain information available concerning identified FCOIs held by senior/key personnel via a publicly accessible website or by a written response to any requestor within five business days of a request. PHS defines “senior/key personnel” as the project director or Principal Investigator and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution. At a minimum, ISU must provide the following information:
• Investigator’s name;
• Investigator’s title and role on the PHS research project;
• Name of the entity in which the significant financial interest is held; and
• Approximate dollar value of the significant financial interest.
  o These can be reported in a dollar range: $0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000–$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000; or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

**Contact for further information or assistance:** coi@iastate.edu