

## MAJOR CHANGES TO THE PHS FCOI REGULATIONS

- Lower Financial Threshold
- Investigator Disclosure Requirements
- Investigator Training
- Public Accessibility

IOWA STATE UNIVERSITY

Brooke Langlitz, JD  
Export Control Officer &  
Conflict of Interest Administrator

## Revised FCOI Regulations

- Implementation required by **August 24, 2012.**
- Applies to each Notice of Award issued subsequent to compliance dates of final rule.
- Applies to the Public Health Service of the U.S. Department of Health and Human Services and any component (organizational unit) of the PHS, including NIH.

IOWA STATE UNIVERSITY

## Financial Conflict of Interest (FCOI)

- A significant financial interest held by an Investigator that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

IOWA STATE UNIVERSITY

## Significant Financial Interest

- A Significant Financial Interest (SFI) is
  - A financial interest
  - Of the Investigator, his/her spouse, and dependent children
  - In the 12 months preceding the disclosure
  - Reasonably appears to be related to the Investigator's institutional responsibilities

IOWA STATE UNIVERSITY

## Significant Financial Interest

- SFI is a financial interest consisting of:
  - Salary and payment for services + equity interest + intellectual property income > \$5,000
  - For non-publicly traded entities, any equity interest is considered an SFI.

IOWA STATE UNIVERSITY

## Significant Financial Interest - Travel

- Investigators must disclose **any** reimbursed or sponsored travel that reasonably appears to be related to their institutional responsibilities
  - Exception: Travel reimbursed by a
    - U.S. Federal, state, or local government agency
    - U.S. Institution of higher education
      - Affiliated academic teaching hospital, medical center or research institute

IOWA STATE UNIVERSITY

## Exclusions from SFI

- Do not include in the calculation of SFI:
  - Salary, royalties, or other remuneration paid by the Investigator's current Institution
  - IP income received from Investigator's current Institution
  - Income from investment vehicles, such as mutual funds and retirement accounts, if Investigator does not directly control investment decisions

IOWA STATE UNIVERSITY

## Exclusions from SFI

- When paid by a U.S. federal, state, or local government agency, U.S. Institution of higher education, academic teaching hospital, medical center or affiliated research institute:
  - Income from seminars, lectures, or teaching engagements
  - Income from service on advisory committees or review panels

IOWA STATE UNIVERSITY



## Investigator

- Investigator: 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, which may include, for example, collaborators or consultants.

IOWA STATE UNIVERSITY

## Disclosure

- Investigators must disclose SFIs that are related to an Investigator's **institutional** responsibilities.

IOWA STATE UNIVERSITY

## Travel Disclosure Requirements

- Mandatory Information
  - Purpose of trip
  - Identity of Sponsor/Organizer
  - Destination
  - Duration
- Optional Information
  - Approximate monetary value

IOWA STATE UNIVERSITY

## Ensuring Investigators' Disclosure

- Institutions must establish a process to require each Investigator to disclose SFIs
  - No later than at the time of application for PHS-funded research
  - At least annually during the period of the award
  - Within 30 days of discovering or acquiring a new SFI

IOWA STATE UNIVERSITY

## After Disclosure

- Institutions are responsible to determine whether an SFI relates to PHS-funded research and whether it is an FCOI.
  - An FCOI exists when an SFI could be affected by the PHS-funded research

IOWA STATE UNIVERSITY

## Training Requirement

- Investigator must complete training before engaging in PHS-funded research
- Each Investigator must complete training regarding:
  - Institution's policy on FCOI
  - Investigator's responsibility to disclose SFI
  - PHS regulations

IOWA STATE UNIVERSITY

## On-going Training

- After initial training, PHS-supported Investigators must complete FCOI training
  - At least every four years
  - Immediately, if:
    - Institution revises FCOI policy that affects requirements of Investigators
    - Investigator is new to an Institution
    - Investigator is not in compliance with the policy or management plan.

IOWA STATE UNIVERSITY

## Subrecipient Agreements

- Establish via a written agreement whether the subrecipient will follow the FCOI policy of the awardee Institution or that of the subrecipient.
- Awardee Institutions are responsible for monitoring subrecipient's compliance with the FCOI regulation, management plans, and for reporting FCOIs through eRA Commons.

IOWA STATE UNIVERSITY



## Subrecipient Policy

- If Subrecipient policy applies:
  - Obtain certification from subrecipient that its FCOI policy complies with the regulation
  - Include in the written agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the awardee Institution to report identified FCOIs to PHS Awarding Component as required by the regulation

IOWA STATE UNIVERSITY

## Awardee Policy

- If the Awardee Institution's policy applies
  - Include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee Institution to identify, manage and report identified FCOIs to PHS Awarding Component.
  - Training of subrecipient Investigators
    - Through CITI

IOWA STATE UNIVERSITY

## Public Accessibility of FCOIs

- Certain information concerning FCOIs held by senior/key personnel must be made publicly available **prior to the expenditure of funds.**
  - Written response to any requestor within five business days of a request.
    - Investigator's name
    - Investigator's title and role with respect to the research project
    - Name of the entity in which the SFI is held
    - Nature of the SFI
    - Approximate dollar value of SFI

IOWA STATE UNIVERSITY

## Conclusion & Questions

- The definition of Significant Financial Interest is fundamental to understanding the new FCOI regulations
- ISU cannot allow expenditures on PHS awards unless all Investigators have:
  - completed an annual disclosure of SFI;
  - completed training; and
  - implemented a Management Plan if an FCOI exists

IOWA STATE UNIVERSITY