MAJOR CHANGES TO THE PHS FCOI REGULATIONS

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

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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.

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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.

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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

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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.

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
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

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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

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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.

Disclosure

- Investigators must disclose SFIs that are related to an investigator’s institutional responsibilities.
Travel Disclosure Requirements

- Mandatory Information
  - Purpose of trip
  - Identity of Sponsor/Organizer
  - Destination
  - Duration

- Optional Information
  - Approximate monetary value

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
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

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

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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

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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

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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

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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

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