COI 101 Presentation Summary
Florida Research Administration Conference 2018

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Types of Conflicts

• Individual
  o In the context of research, an individual conflict of interest exists when an investigator’s private interests may compromise, or have the appearance of compromising, an investigator’s professional judgment in the design, conduct or reporting of the research.

• Institutional
  o In the context of research, an institutional conflict of interest may exist when the institution or one of its senior officials has a financial interest related to research.

• Organizational
  o Government is typically concerned about three things: unequal access to information, biased ground rules and impaired objectivity.

Federal Regulation and Policy

• The U.S. Public Health Service

• National Science Foundation
  o Proposal and Award Policies and Procedures Guide, Chapter IX, A. Conflict of Interest Policies
  o https://www.nsf.gov/bfa/dias/policy/

• Other federal agencies
  o Incorporate a variety of COI terms in their solicitations and awards (e.g. DoE, NIJ)
  o Some agencies remain silent on scientific conflicts of interest

Key elements of the PHS and NSF COI policies:

• Individual financial conflicts of interest
• Disclosure required for actual financial interests (within specified timeframes)
• Disclosure prior to proposal submission and annually
• Investigators (“anyone responsible for design, conduct or reporting”) must disclose
• Specific thresholds for what is considered a Significant Financial Interest
• Reporting obligations to the sponsor (varies by sponsor)
- Subrecipient compliance
- Training requirements (PHS)
  - The Final Rule (PHS) requires Investigators to complete FCOI training every 4 years.
  - Institutional policies may include additional COI training requirements.
- Public accessibility (PHS)
- Retrospective review for non-compliance (PHS)

**State of Florida- Code of Ethics**

- Doing Business with One’s Agency [112.313(3)]
  - State employees are prohibited from purchasing, renting, or leasing realty, goods, or services for their state employer from a business entity in which the employee, spouse or child, is an officer, partner, director, or proprietor, or owns more than 5% interest.
  - State employees (acting in private capacity) are prohibited from renting, leasing, or selling any realty, goods, or services to their state employer.
- Conflicting Employment or Contractual Relationship [112.313(7)]
  - State employees are prohibited from holding any employment or contractual relationships with a business entities or agencies doing business with their public employer.
  - State employees are prohibited from holding any employment or having a contractual relationship which will create a continuing or frequently reoccurring conflict between their private interests and the performance of their agency duties or which will impede their full and faithful discharge of their agency duties.

- **EXEMPTIONS IF COI RELATED TO SPONSORED RESEARCH OR TECHNOLOGY TRANSFER** (must disclose and be approved by President & Board of Trustees)


**COI Management: Partners in Compliance**

- Institutions establish programs and policies to mitigate bias resulting from investigator COIs.
- Institutions vary on what is allowable according to their policies and procedures.
- COI offices work with a variety of other entities to ensure management plans are accurate and implemented:
  - Institutional Review Boards (ratify management plans, both internal and external)
  - Institutional Animal Care and Use Committee
  - Technology Transfer/Patents and Licensing
  - Sponsored Research
  - University Audit
  - University Compliance
  - Colleges and departments
  - Faculty Affairs
COI Committees

- Not a regulatory requirement but common practice
- Review and approve management plans (including inherent and additional controls)
- Provide guidance regarding COI policies/procedures
- COI Committees may permit variation from standard practices based on compelling circumstances
  - Many institutions use a rebuttable presumption for human subjects research

Elements of COI Management Plans

- Elements of a Management Plan:
  - Research summary
  - Investigator role(s)
  - Financial interest and/or intellectual property rights
  - Controls that reduce opportunities to introduce bias
  - Investigator adherence to the plan
  - Compliance monitoring
- Inherent controls:
  - Investigators blinded to treatment groups
  - Non-interested co-investigators conducting the research and/or data analysis
  - External, non-interested lab involved in sample and/or data analysis
  - Objective endpoints
- Additional controls:
  - Public disclosure in presentations and publications
  - Disclosure to human subjects research participants through informed consent
  - Safe harbor for students
  - Notification to research personnel on the study
  - Limited role for interested investigator (e.g. does not obtain consent or recruit)
  - External IRB review (for institutional conflicts)
  - Monitoring of research by an independent reviewer(s)
  - Reduction or elimination of SFI or severance of relationships
  - Restricting use of institutional equipment, facilities, services, personnel in outside activity

Management of Nepotism in Research

- Nepotism can create potential bias in research.
- Conflicts can be avoided with Co-PIs of equal status (i.e. no indirect or direct reporting relationships).
- Most institutions have processes for addressing nepotism in research, including approval by departments/colleges and documentation of mitigation strategies.
Commercialization

- Universities are becoming more engaged in licensing technologies and faculty spin-off companies (e.g. incubators)
- As university-held technologies are commercialized, COI programs must look at many aspects of the resulting relationships, particularly for SBIR/STTR recipients that make subawards to the university. Examples include:
  - Who is on each side of the agreement (and are there any prohibitions in the guidelines)?
  - Does anyone on the University research team have an interest (technology and/or ownership)?
  - Who is the SBIR/STTR PI and is there any connection to the University?
  - Who owns the technology and is there a license in place?
  - Does the university have an interest in the small business recipient?
  - What phase is the study (and is the study therefore exempt from the PHS regulation, i.e. Phase I)?
  - Are there sponsor restrictions on who can be paid via the subaward?

Subrecipients

- Subrecipients must be compliant with COI regulations of the prime sponsor.
- If the project is funded by PHS, NSF, or any other sponsor that has adopted federal financial requirements requiring disclosures from subrecipient investigators:
  - Subrecipient must have an active/enforced COI policy or agree to comply with the prime awardee institution’s COI policies and procedures.
    - Includes investigator disclosure, monitoring, training, and reporting as applicable.
  - PHS requires compliance with 42 CFR 50, Subpart F and 45 CFR 94 (The Final Rule)
    - FDP FCOI Clearinghouse: http://nrc59.nas.edu/pub/fcoi_list.cfm
  - NSF requires compliance with the provisions of NSF Proposal and Award Policies and Procedures Guide, Chapter IX, A. Conflict of Interest Policies.