

FCOIs in 2013

A Primer (and more) on PHS FCOI Regulations

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Comparison: PHS funded Investigators

1995 REGULATION

- Threshold for Significant Financial Interests: \$10K
- Investigators Disclose: only interests related to a specific PHS-funded research activity
- Travel Activities: no reporting requirement
- Training: no requirement

2011 REGULATION

- Threshold for Significant Financial Interests: **\$5K**
- Investigators Disclose: **all interests** related to Institutional Responsibilities
- Travel Activities: **report all sponsored travel**
- Training: Investigators must **complete training** prior to engaging in PHS funded research

Comparison: PHS funded Institutions

1995 REGULATION

- Maintain consistent policy
- Designate an Institutional Official
- Require Investigator reporting prior to proposal of SFIs the Investigator determines are related to the research

2011 REGULATION

- Maintain consistent policy and make publicly available
- **Train** Investigators
- **Sub-recipient Monitoring**
- **External Investigators**
- Designate an Institutional Official
- Require Investigator reporting prior to proposal **of SFIs related to his/her Institutional Responsibilities**

Comparison: PHS funded Institutions

1995 REGULATION

- Provide guidelines for Institutional Official to identify conflicts
- Manage conflicts
- Report FCOIs to PHS prior to expending funds

2011 REGULATION

- Provide guidelines for Institutional Official to **determine if Investigator SFIs are Financial Conflicts of Interest (FCOIs)**
- Manage FCOIs, **including a management plan.**
- Report FCOIs to PHS prior to expending funds (initial and **continuing**)

Comparison: PHS funded Institutions

1995 REGULATION

- Recordkeeping
- Enforcement
- Certify Compliance to PHS

2011 REGULATION

- Recordkeeping
- Enforcement
- Certify Compliance to PHS
- **Public Accessibility**: web posting of Investigator FCOIs, or respond to written requests
- **Retrospective Review** when non-compliance is identified
- **Mitigation Plan** when bias is identified

Investigator Responsibilities

- Complete Conflict of Interest Training.
- Update an Disclosure Form within thirty (30) days of acquiring a new or changed outside interest.
- Ensure that a current Disclosure Form is on file by updating within twelve (12) months from the previous submission.
- Disclose sponsored travel exceeding \$5,000, including reimbursed travel, no later than thirty (30) days after the travel occurred.
- Notify the COI Office before new Investigators begin work on a PHS-funded project.
- Comply with any management plan as necessary.

Institutional Responsibilities

- Train Investigators
- Identify Investigators
- Subrecipient Monitoring
- External Investigators
- FCOI Determination
- FCOI Management Plans
- Ongoing Monitoring

Train Investigators

- Online training built in-house
- Prompt at proposal
- Required prior to expenditure of funds

Identify Investigators

- PI must fill out an Investigator Form prior to proposal identifying all Investigators
- “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.”

Additional Guidance:

- Roles of those involved
- Degree of independence
- Scope of Work
- Effort of project/paid on project

Subrecipient Monitoring

- FDP Clearinghouse
- Subrecipient Commitment Form
 - Certifies that a subrecipient has compliant policy OR
 - Gives notice that subrecipient does not have compliant policy
- Subrecipients who have no policy
 - Provide FDP Model
 - Obtain approval to subsume

External Investigators

i.e. external collaborators/consultants

- No subcontract with Investigator's Institution
- Obtain permission to subsume
- Obtain outside disclosure form (FDP template) and certificate of University of Missouri training

COI Overview

34,748 Students
4,347 Academic Staff
12,534 Administrative Staff

- One System with four campuses
 - Policy at system level
 - Directive to develop campus procedure
- Annual Disclosure
 - \$0 threshold
- Designated Official: Deputy Chancellor
- Conflict of Interest Committee
 - 13 voting members meet monthly
 - 3 member Small Group meets weekly
- Conflict of Interest Office
 - ~2 full FTE (just hired one more)

FCOI Determination

Step One: COI Office

- ◉ Notification of award from OSPA
 - Notice of Award
 - Request for Pre Award Account
 - Continuation Application of Annual Progress Report
- ◉ COI Office review of project
 - Identify Investigators with outside interests
 - Preliminary assessment of SFI
 - If SFI, review scope of work
 - If needed, contact Investigator to ask specific questions and gather more information

FCOI Determination

Step Two: Committee Review

SFI REVIEW: Is there an SFI?

Is the financial interest related to the investigator's institutional responsibilities?

AND

*the Investigator
(including spouse and children)*

(1) received remuneration from the entity in past 12 months that exceeds \$5,000 when aggregated, OR

(2) holds equity interest in a non-publically traded entity, OR

(3) receives or has received income related to IP rights?

Has sponsored travel occurred?

Faculty: teaching, research, and service in field of expertise

Not an SFI/Not Sponsored Travel:

- Salary, royalties, and other remuneration from MU
- Mutual funds and retirement accounts not in the Investigator's control
- Remuneration or travel reimbursed or sponsored by:
 - Federal, state, or local government agency
 - Institution of higher education
 - Academic teaching hospital
 - Medical center
 - Research institute affiliated with an Institution of higher education

FCOI Determination

Step Two: Committee Review

RELATEDNESS REVIEW: Is the SFI related to the investigator's research?

Could the SFI be affected by the PHS-funded research?

OR

Is the SFI in an entity whose financial interest could be affected by the research?

Consult factors for further guidance in determination.

Yes

FCOI REVIEW: Is the SFI an FCOI?

Could the SFI directly and significantly affect the design, conduct, or reporting of the PHS-funded research?

Consult factors for further guidance in determination.

Yes

Management Plan – Report – Enforce

FCOI Determination

Step Two: Committee Review

RELATEDNESS factors that may be taken into consideration:

- What is the nature of the relationship the Investigator has with the entity?
- How closely involved is the Investigator with the entity in which he/she holds an SFI?
- Is the Investigator's SFI in the position to make decisions on behalf of the entity?
- Where the SFI is also a sponsor of the research, is the SFI an invention?
- Where the SFI is also a sponsor of the research, what amount of royalties resulting from the SFI has been received and is expected by the Investigator?
- Is the goal of the research to evaluate an invention linked to the SFI?
- What is the Investigator's role in the design, conduct, and reporting of the research?

FCOI factors that may be taken into consideration:

- Is the Investigator's ongoing role necessary to continue advancing the research?
- What is the value of the SFI in relation to the size and value of the entity?
- Does the entity in which the Investigator holds an SFI fund any research in the Investigator's lab?
- Is the research basic or applied?
- To what degree is there replication and verification of the research?
- How likely is the research to result in immediate commercialization or clinical application?
- Does the research involve human subjects?
- If so, are there double blind conditions?
- If so, is there involvement of a data safety monitoring board?
- Are other scientific groups independently pursuing similar questions?
- Is sufficient external review of the research available to mitigate undue bias?

FCOI Determination

Step Three: Management Plans

- Create a management plan for the company, starting with a standard template with the following conditions:
 - Reporting and General Conduct, Use of MU Resources, Personnel, Grants and Contracts, Other University Offices and Committees, Research Integrity, Intellectual Property, Review and Recordkeeping, Appendixes
- Create Project Specific FCOI Reports and Plans

Ongoing Monitoring

- Campus-wide Oversight Committee
- Management plans are created with the COI Office, Faculty Member, Representative, Department Chair, and Dean.
- All management plans are audited by the COI Office with Oversight Review at least annually.

Case Studies

Case studies will be provided for each topic. We will explore if time allows based on audience interest.

- Train Investigators
- Identify Investigators
- Subrecipient Monitoring
- External Investigators
- FCOI Determination
- FCOI Management Plans
- Ongoing Monitoring

Questions

Thank You!