Financial Conflict of Interest Disclosure at USM:
Policy and Procedures
Office of Research Integrity
Read Before Proceeding

Only complete this course if you serve as an investigator on PHS grants (NIH) or other externally funded grants in which institution-specific FCOI training is required.

If you fall into one of the categories above, click the forward button.

Forward

If you do not fall into either of the categories listed above, click the Exit button below to close this course.

Exit
Course Completion Instructions

- Terms or websites in blue and underlined are clickable links.
- Please access each of these to review the content.
- Click the next button twice to move forward after a test question.
- Click the forward button to move to the next slide.
- Upon reaching the course completion slide, select the Exit button.
Course Purpose

The purpose of this course is to explain USM’s FCOI disclosure policy and procedures. All University constituents engaged in research, scholarship and creative activities are expected to understand the policy and to abide by it.

This course is required only of investigators on active Public Health Service (PHS) grants (PHS includes NIH, CDC, and several other federal agencies).
True/False

I acknowledge that I have received training regarding my organization’s policy, and I hereby certify that I have read, understood and will comply with the policy. I understand that a breach of my organization’s policy may result in discipline.

A) True
B) False
Introduction

Research and scholarly integrity requires objectivity, but objectivity can be threatened by various external influences.

- One potential concern is that investigators can have financial relationships that affect their impartiality.
- Also, the interests of funding sources sometimes conflict with the independence of judgment needed for quality research and scholarship.
Purpose of Policy

The University of Southern Mississippi’s financial conflict of interest (FCOI) disclosure policy is intended to prevent bias and the appearance of bias and to comply with requirements imposed by the Public Health Service\(^1\) and other external sponsors.

Objectives

By the end of this module, you will be able to:

- Define financial conflicts of interest, significant financial interests, and related terms.
- Describe your disclosure responsibilities under USM’s FCOI disclosure policy.
- Identify the three main aspects of USM’s disclosure process.
A conflict of interest (COI) is a situation in which someone’s personal interests conflict with her professional responsibilities.
Example 1:

- A court case in which one of the judge’s family members is on trial.

The judge’s professional responsibility to apply the law fairly could be undermined by her (presumed) desire to help a close relative.
Another Example

Example 2:

- A purchasing manager at a university has a financial interest in one of the firms submitting a bid for a valuable contract.

The duty to act in the best interests of the institution is potentially at odds with what may benefit the purchasing manager financially.
Putting COIs in Context

- Merely being in a conflict of interest situation does not imply wrongdoing.
  
  - COIs are common in professional life, since most people have numerous work-related responsibilities and personal interests.
  
  - People in conflicted situations are capable of making unbiased decisions, as might the judge and the purchasing manager in the scenarios just mentioned.
To say something is a conflict of interest is merely to say that given the situation, professional objectivity might be questioned or is particularly at risk.
In academic life, COIs take many forms.

- Some stem from personal relationships, such as if the chair of an academic department is in the same department as her spouse.
- Others involve financial interests, such as when a faculty member owns considerable stock in a company that sponsors her research.
- Additional examples can include copyrights or other intellectual property rights, consulting fees, sponsored travel, and other financial benefits or incentives.
- Federal policy defines “financial” broadly: “anything of monetary value received or held by an individual or family.”
Nevertheless, the concept of a COI is somewhat narrower than is sometimes implied.

- Broadly, virtually all academics have, in one way or another, an obligation to pursue the truth. Getting things right is what we aim at, whether we’re doing chemistry, nutrition science, or history.
- At the same time, academics typically have an interest in advancing their careers, getting promoted, being granted tenure, and so forth.
• “Getting things right” and doing what best serves career goals are not always the same thing. While in a broad and generic sense these two together produce a Conflict of Interest (COI), in the present context the term COI refers to specific situations and relationships that some academics have but that many or most others lack.
Other Types of Conflicts: Conflict of Obligation

A conflict of obligation (COO) is a situation in which two or more professional responsibilities conflict with each other. For example, a college promotion committee member has a COO when someone from her own department is up for tenure. Exercising impartial judgment on behalf of the college may be at odds with what most benefits the committee member’s department. COOs sometimes are called “two hats problems” after a famous remark made during last-minute deliberations about whether to launch the ill-fated Space Shuttle Challenger in 1986.¹

¹ The shuttle exploded because rubber O-Rings in the booster rockets were defective at low temperatures. NASA and manufacturer Morton Thiokol were both aware of this defect. During a last-minute conference, NASA pressured Morton Thiokol’s management to approve the planned Jan. 28, 1986 launch against the advice of the company’s engineers, who were concerned by unseasonably cold temperatures. At a key juncture in the deliberations, a senior Thiokol manager told Bob Land, Vice President of Engineering, to “take off his engineering hat and put on his management hat.” Tragically, Land relented. Roger Boisjoly. “The Challenger Disaster: Moral Responsibility and the Working Engineer,” in Ethical Issues in Engineering, ed. Deborah Johnson et al., (Prentice Hall, 1991), 6-14.
Other Types of Conflicts: Conflict of Conscience

A conflict of conscience (COC) is a situation in which professional responsibilities clash with moral convictions. A classic example occurs when pharmacists are asked to fill prescriptions for legal contraceptives which they personally oppose being used. COCs are rare in academia, since academic freedom typically allows an easy resolution to clashes between obligations and conscience.
Question - Suppose a USM faculty member has a son or daughter as a student in class. In terms of the definitions provided above, this situation represents which of the following:

- A) Financial Conflict of Interest
- B) Conflict of Obligation
- C) Conflict of Conscience
- D) Non-financial Conflict of Interest
Financial conflicts of interest (FCOI) occur when personal financial interests threaten professional responsibilities. Since 1995, the U.S. government has regulated FCOIs in federally funded academic research by requiring disclosure and institutional oversight. In large part, FCOI regulations are a response to changes in the way research is now funded. For example, over half of the financial support for academic biomedical experimentation currently comes from private industry rather than the government.¹ Also, the Bayh-Dole Act of 1980 and subsequent legislation allows institutions and academic researchers to have financial stakes in the results of government-funded research.

Real Life FCOI

A tragic example of an FCOI is the Jesse Gelsinger case. Gelsinger died in a gene therapy experiment conducted by James Wilson at the Univ. of Pennsylvania’s Institute for Human Gene Therapy. Jesse was not an ideal candidate for the treatment, and before attempting the risky procedure on him, Wilson’s team had not resolved problems evident in animal trials. Wilson had millions of dollars’ worth of shares in Genovo, a biotech firm that would have benefited from a successful outcome.¹

Responding to FCOIs at USM

- Both federal regulations and USM policy address FCOIs through a combination of institutional and individual responsibilities.
  - PHS regulations require the University to have a publicly accessible policy on financial conflicts of interest (USM’s FCOI Policy) and systems in place for FCOI disclosure, management and review.
- Southern Miss policy requires full-time faculty members and researchers to disclose Significant Financial Interests (SFIs) annually, and depending on the individual, further disclosure and training may be required as well.
Putting Disclosure into Perspective

- A key component of FCOI oversight involves individuals’ disclosure of certain kinds of financial interests to the institution.

- Disclosure facilitates review to determine whether further action is needed to protect research objectivity. To explain the disclosure aspect of Southern Miss’s FCOI policy, it is helpful to think in terms of its “how,” “who,” “what” and “when.”
How Are Financial Interests Disclosed?

Disclosures occur by means of electronic forms available from the Office of Research Integrity’s [FCOI web page](https://www.ori.od.nih.gov/). Click here.

- USM personnel log in using SOAR credentials.¹
- Those who answer “yes” to the first question also must complete an “Addendum” form linked from the FCOI web page.
- For most users, however, completing the form will consist of three simple check box responses, comparable to completing a monthly time and attendance report in SOAR.

¹ Depending on specific funding arrangements, certain non-USM investigators may need to use USM’s disclosure process as well. Non-USM personnel can log in using their names, email addresses and other contact information.
Who Must Complete Disclosure Forms?

- USM policy requires annual disclosure by all full-time USM faculty members and researchers:
  - whether or not they have the relevant financial interests; and
  - whether or not they are involved in sponsored research.

  For purposes of this policy, “full-time faculty” includes full-time instructors, assistant professors (including both clinical and research professors), associate professors, professors, research scientists and librarians.¹

¹ For the full listing of the relevant job titles and HR job codes, see the FAQ page on USM’s ORI FCOI page.
In addition, disclosure forms must be completed by all investigators working on projects sponsored by sources that require such disclosure.

“Investigators” are by federal definition all of those who participate in the design, conduct, and/or reporting of research.

Thus, non-USM consultants and collaborators, post-doctoral associates, students and staff might be investigators, depending on the project; and

Those who provide merely technical assistance are not investigators.
Specifics of Disclosures

- Sponsored projects that require disclosure by all investigators include those from various Public Health Service (PHS) agencies, such as the National Institutes of Health (NIH), the Centers for Disease Control (CDC), and the Food and Drug Administration (FDA).
- Principal Investigators, also referred to as “key personnel” in federal regulations, are responsible for ensuring that non-USM-faculty investigators complete disclosures when required.
- Federal regulations stipulate that grant funds cannot be expended until the required disclosures have been made.
What are the Significant Financial Interests?

Only “significant financial interests” (SFIs) must be reported. While “financial interests” are defined very broadly, only a subset of financial interests are considered “significant” and must be disclosed.
Types of SFIs

An SFI is a financial interest that is “reasonably related to the individual’s institutional obligations” and is of one of four kinds:

- Compensation from a publicly-traded company in the twelve months prior to disclosure, and/or equity ownership in that company at the time of disclosure, with an aggregate value of $5000 or more;
- Compensation from a non-publicly-traded company in the twelve months prior to disclosure with an aggregate value of $5000 or more, or any equity in a non-publicly traded company at the time of disclosure;
- Income received from intellectual property rights and interests, such as licensing fees from patents; or
- Sponsored travel not reimbursed by the government or academic institution.
Several kinds of financial interests are explicitly excluded and need not be disclosed such as the following:

- USM salary and wages;
- income from seminars;
- lectures, or teaching engagements paid for by a government agency; and
- payments for participation in governmental advisory panels or review committees.
The following are additional types of financial interests that are explicitly excluded from disclosure:

- income from investments in which the employees do not control the investment decisions (such as mutual funds); and
- income from the authorship of scholarly works.

Intellectual property rights derived from the authorship of teaching materials, however, must be disclosed.\(^1\)

When are SFIs Disclosed?

Disclosures must be completed annually in the fall, at the beginning of the academic year.

Additionally, updated disclosure forms must be completed within 30 days if:

a) The individual acquires or relinquishes an SFI; or
b) The individual becomes an investigator on a Public Health Service (PHS) grant project or application or that of another sponsor that requires disclosure.
Federal regulations and USM policy also mandate training in financial conflicts of interest when expected by sponsors. PHS grants require such training for investigators, for example.

Successfully completing this module satisfies USM’s FCOI training requirements.
Multiple Choice

Which of the following kinds of disclosures could apply to full-time faculty members?

- A) Updates when their SFIs change
- B) Annual
- C) Updates when they submit NIH grant proposals
- D) All

Incorrect - Click anywhere or press 'y' to continue.
Multiple Choice

In terms of FCOI policy, investigators are:

- A) Principal Investigators only
- B) All full-time faculty members
- C) All those who are responsible for the design, conduct, or reporting of externally funded projects
- D) All students involved in research

Incorrect - Click anywhere or press 'y' to continue.

Submit
Next
1. Suppose Antonio is a full-time USM faculty member, and in January he submits a new NIH grant proposal to USM’s Office of Research Administration as the Principal Investigator. Which of the following indicates what Antonio needs to do:

   a) Antonio need not complete any additional disclosure forms.
   b) Antonio needs to complete a disclosure form only if he did not complete one at the beginning of the year.
   c) Antonio needs to complete an updated disclosure form.

Click the forward arrow to see the correct answer.
Illustrative Example #1 - Explanation

1. Suppose Antonio is a full-time USM faculty member, and in January he submits a new NIH grant proposal to USM’s Office of Research Administration as the Principal Investigator. Which of the following indicates what Antonio needs to do:

   Please wait for correct answer to display below.

The correct answer is c). As a full-time faculty member, Antonio should have completed a disclosure form at the beginning of the school year. As an investigator on a newly submitted PHS grant proposal, an update is also required.
2. Suppose LaKeisha is an adjunct USM instructor who has recently become an investigator on a sponsored grant project conducted at Southern Miss. Which of the following indicates what LaKeisha needs to do:

a) LaKeisha need not complete a disclosure form.
b) LaKeisha needs only to complete an annual disclosure in the Fall.
c) LaKeisha needs to complete an updated annual disclosure.

Click the forward button to view the correct answer.
2. Suppose LaKeisha is an adjunct USM instructor who has recently become an investigator on a sponsored grant project conducted at Southern Miss. Which of the following indicates what LaKeisha needs to do:

Please wait for correct answer to display below.

The correct answer in this case depends on sponsor requirements. USM disclosure forms must be completed only by those who are either full-time USM faculty members, researchers, or when required by research sponsors. Sponsors may also request that disclosures be made directly to them.
In addition to disclosure, there are two further aspects to USM’s FCOI policy.

The two additional aspects of USM’s FCOI policy are review and management.
• When faculty and non-faculty investigators report significant financial interests, their disclosures must be reviewed confidentially by the Vice President for Research.

  ▪ The key issue in the review process is determining whether or not an SFI constitutes a financial conflict of interest (FCOI).
**Definition:** A FCOI is an SFI that compromises or might reasonably appear to compromise fulfillment of an individual’s institutional obligations.

**Identifying a Financial Conflict of Interest:** In making this determination, the VP typically asks for input from an ad hoc conflict of interest review committee (COIRC) which includes the chair of the individual’s department and the dean of his or her college.
Management

- Determining how best to manage an FCOI requires examining the specifics of the situation.

- Possible management options: further disclosure, divestiture, recusal, partitioning of responsibilities, or outside monitoring.
Resolution Plans

- Resolution plans are agreements about how best to manage an FCOI:
  - must be mutually acceptable to the VP for Research and investigators alike; and
  - usually involve the COIRC in an advisory capacity.
Summary

Financial Conflicts of Interest have become a familiar aspect of academic life. In and of themselves, they are not unethical, but institutional oversight of them is both appropriate and required by federal regulations.

At USM, FCOI policy has three components:

- Disclosure - all USM faculty members must complete disclosure forms annually, and additional disclosure requirements may also pertain. When expected by sponsors, investigators need to receive FCOI training;
- Review; and
- Management.
Multiple Choice

As defined above, significant financial interests include:

- A) USM salaries
- B) royalties from teaching materials
- C) government reimbursements for serving on a federal review panel
- D) mutual fund investments
Multiple Choice

Question 6 of 7

According to University policy, disclosures must be done:

- A) by all staff members
- B) only by those working on sponsored projects
- C) by all graduate students
- D) by all full-time faculty members and select others

Incorrect - Click anywhere or press 'y' to continue.

Submit  Next
Multiple Choice

Determining whether or not an FCOI exists is the responsibility of:

- A) COIRC alone
- B) VP for Research, with advice from COIRC
- C) Director of the Office of Research Integrity
- D) Principal Investigator
• NIH on [Financial Conflict of Interest] includes links to guide notices, FAQs, and a training module.

Course Completion

Thank you for completing this course.

Should you have any questions or concerns, please contact Samuel Bruton, Director of the Office of Research Integrity, at samuel.bruton@usm.edu.

Click the PDF image below to access a pdf copy of this course.

Click the Exit button to complete the course.