



Sponsored Research Financial Conflict of Interest (FCOI) Training Module

MAY 2022

Learning Objectives

When you have completed this training module, you will understand:

- The federal FCOI requirements fulfilled by the college's FCOI policy;
- Who is subject to sponsored research FCOI requirements;
- What is meant by the term **“Significant Financial Interest” (SFI)**;
- Where and when SFIs must be disclosed;
- How SFIs are reviewed at the college;
- What is meant by the term **“Financial Conflict of Interest “ (FCOI)**;
- How FCOIs are managed at the college;
- How FCOIs may be reported to sponsors and to the public;
- Implications for noncompliance with FCOI requirements

Why Do We Care about FCOI?

- FCOI training and reporting is required by law;
- The risk of an individual's external financial interests resulting in bias or compromise – or have the appearance of biasing or compromising – an individual's judgment, objectivity, or decision-making with respect to research design, conduct, or reporting can endanger objectivity in research, data integrity, and the welfare and safety of participants;

Conflicts of Interest in Research

- Common sources for FCOIs: invention licensing, faculty start-up companies, consulting relationships.
- Considerations of personal financial gain must not influence the decisions or actions of individuals in carrying out their college responsibilities. The perception that such incentives might harm research objectivity or the protection of human subjects, students or others whose work depends on the direction of the Project Director is enough to mandate that such conflicts be identified, and then managed, reduced or eliminated.

College Compliance

As a condition of federal funding, the college has established procedures that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from Project Director Financial Conflicts of Interest (FCOIs). The college:

- Maintains a current, documented, and enforced COI policy;
- Educates Project Directors in this policy;
- Facilitates compliance with initial and ongoing FCOI disclosure;
- Identifies and manages FCOIs;
- Requires subrecipients and collaborators to adhere to FCOI policy;
- Meets sponsor reporting requirements.

FCOI Policy Summary

- Project Directors must disclose all SFIs related to their institutional responsibilities (not just outside interests they judge to relate to particular research activity) on an ongoing basis;
- The college determines whether an SFI could be an FCOI for each sponsored activity in which the Project Director is involved;
- The college must eliminate, reduce, or manage FCOIs, and meet sponsor reporting requirements;

Please review SCCC's Research Financial Conflict of Interest Policy, available here:

<https://www.sunysuffolk.edu/legalaffairs/documents/research-conflict-of-interest.pdf>

Sponsors Requiring FCOI Policy

All PHS Agencies:	Other Federal	Private	
AHRQ, ATSDR	NSF	American Heart Assoc.	PCORI
ASPR, CDC		American Cancer Soc.	Susan G. Komen Fdn.
FDA		Alliance for Lupus Res.	
HRSA		Arthritis Fdn.	
IHS		American Lung Assoc.	
NIH		CA Breast Cancer Res.	
OG, OASH		Cure PSP	
SAMHSA		JDRF	
USDA		Lupus Fdn. of America	

Who is Subject to FCOI Policy

Any person, regardless of title or position, who is responsible for the design, conduct or reporting of research. This always includes:

- Project Director / Principal Investigator;
- Anyone named as Key Personnel.

This may also include:

- Outside collaborators (e.g., subrecipient Investigators, consultants) who satisfy the definition of being responsible for the design, conduct, or reporting of the research;
- Any other faculty, staff, or technicians who satisfy the definition of being responsible for the design, conduct, or reporting of the research.

What Must Be Disclosed?

Significant Financial Interests related to a Project Director's (or a Project Director's immediate family) institutional responsibilities.

Immediate family members include: spouse, dependent children, and/or domestic or civil union partner.

University Responsibilities refer to an Project Director 's professional responsibilities performed on behalf of the college, which may include activities such as:

- Developing and managing programs or research;
- Teaching and advising;
- Institutional committee memberships and other service;
- Service on institutional panels.

What Must Be Disclosed?

Type of Significant Financial Interest (SFI):	Thresholds:
Compensation and/or other payments for service	> \$5,000 per any entity every 12 months
Equity interests in a publicly-traded entity	> \$5,000 per any entity every 12 months
Equity or other ownership interests in a non-publicly-traded entity	\$0 value, 1 share, any other ownership interest (i.e., ANY and ALL equity interests in non-publicly traded entities)
Intellectual property (IP) rights and interests upon receipt of income related to such rights and interests (e.g., royalties)	> \$5,000 per any entity every 12 months
Sponsored or reimbursed travel	> \$5,000 per any entity every 12 months

What Need Not Be Disclosed?

Type of SFI:	DO NOT DISCLOSE:
General	Anything (compensation, equity, royalties, or travel) that does not exceed \$5,000 per entity in 12 months.
Compensation and/or other payments for service	Compensation for lectures, seminars, teaching engagements, or service on committees or panels relating to government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education, and/or compensation received from or through SCCC funds.
Equity interests	Personal retirement accounts, mutual funds (403b,IRA, etc.).
Intellectual property (IP) rights	Unlicensed IP that does not generate income.
Sponsored or reimbursed travel	Travel administered through SCCC funds or sponsored by a government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an Institution of higher education.

When Must You Disclose?

Before engaging in research proposed to or funded by sponsors:

- A Sponsored Research FCOI Disclosure must be on file with OGD from everyone subject to disclosure before the proposal is submitted.

Within 30 days of receiving or becoming aware of a new SFI:

- SFIs must be disclosed within 30 days of acquisition; Do NOT wait until annual disclosure time to update your disclosure with new SFIs.

At least annually:

- If you have no new SFIs to disclose between annual FCOI disclosure cycles, the annual FCOI disclosure is sufficient. You must complete a FCOI disclosure annually, even if acknowledging no change.

How are Disclosures Reviewed?

Office of Grants Development performs an initial review, subject to the college's FCOI requirements.

A Significant Financial Interest (SFI) is any financial interest meeting the definition that is ***related*** to your college responsibilities and needs to be disclosed.

A Financial Conflict of Interest (FCOI) is an SFI that could ***directly and significantly*** affect the design, conduct or reporting of specific sponsored research activity.

What Happens If a FCOI is Identified?

When a potential FCOI is identified, OGD work with the Project Director to reduce, manage, or eliminate it. Examples of management strategies include:

- Disclosure in publications;
- Disclosure to colleagues and collaborators;
- Disclosure to IRB and to research subjects;
- Reduced role in project;
- Independent data review and/or monitoring.

OGD reports the FCOI to the sponsor as required. OGD notifies Project Directors prior to such reporting.

Certain FCOI information relative to PHS-funded research must be made available to the public upon request. Such information is provided through the Legal Affairs Office. Project Directors are notified prior to provision of such information.

What is FCOI Policy Noncompliance?

Noncompliance includes failure to identify, review, or manage FCOIs as required by college policy. The following are examples of noncompliance:

- Failure to disclose information as required by college policy;
- Failure to submit an updated disclosure within 30 days of acquiring a new SFI;
- Submission of an incomplete, erroneous, or misleading disclosure;
- Failure to comply with FCOI management plan strategies;

Instances of non-compliance will be reviewed and disciplinary action taken, if needed, in accordance with applicable college policies and procedures.

For PHS-funded research, noncompliance may result in the need to perform a retrospective review of the research project to determine whether any research conducted during the time period of the noncompliance was biased in design, conduct, or reporting.

Federal FCOI Training

Please complete the National Institutes of Health FCOI training activity located at the following link:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Once you have completed the online-tutorial, print the ***Certificate of Completion*** located at the end of the tutorial, sign and date it, and return it to the Office of Grants Development in partial fulfillment of your FCOI training requirement.

Attestation

I have read and understand the material in this Sponsored Research Financial Conflict of Interest (FCOI) Training Module.

Signature:	
Name:	
Date:	
Sponsored Program:	

Instructions: Please print this page, sign, date, and indicate the name of the sponsored program you direct. Please return the signed attestation to the Office of Grants Development in partial fulfillment of your FCOI training requirement.

Further Information

- (<http://grants.nih.gov/grants/guide/notice-files/not95-179.html>) *Promoting Objectivity in Research*, 42 CFR Part 50, 45 CFR Part 94 *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors* – Public Health Service (PHS) Rules
- (http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510) *Conflict of Interest* – National Science Foundation (NSF) Rules
- (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=54>) 21 CFR 54 – FDA regulation for financial disclosure by clinical investigators
- (http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf) *COI Final Rule* issued August 25, 2011
- (http://grants.nih.gov/grants/policy/coi/summary_of_major_changes.doc) *Summary of Major Changes to COI Policy*

Acknowledgements

This training module borrows heavily from training materials available on the web, including “Research Conflict of Interests Training: PHS Final Rule and VCU Policy”, Virginia Commonwealth University, 2013 and 2016 (http://www.research.vcu.edu/coi/coi_training.pdf); “Sponsored Research Conflict of Interest (COI) Training Module”, Northwestern University, 2014 (http://www.northwestern.edu/coi/training/COI_Training_Module.pdf); and “Financial Conflict of Interest Training”, Vanderbilt University, 2012 (<http://www.vanderbilt.edu/compliance/includes/COITrainingPHSInvestigators.pdf>).