

Financial Conflicts of Interest in Research



Introduction

The Texas A&M University System (system) recognizes its responsibilities to encourage interaction between its employees and the public and private sectors as an important component of its research activities.

The system is committed to conducting research in a manner consistent with the highest standards of integrity and ethics and ensuring that research activities are conducted in a manner free from bias resulting from financial conflict of interest.



COIs & FCOIs

A *conflict of interest* (COI) exists when there is a risk that personal bias will unduly influence one's actions or choices.

A *financial conflict of interest* (FCOI) exists when there is a risk that personal financial interests will unduly influence one's actions or choices.



Learning Objectives

- Recognize various forms of COIs in research.
- Describe federal regulations related to FCOI.
- Describe system policies related to FCOI.
- Identify **what** significant financial interests (SFIs) must be disclosed and **when**.
- Identify **who** is required to disclose SFIs.
- Identify **who** is responsible for reviewing disclosures and implementing the system's FCOI program.

This training will take about 30-45 minutes to complete. You must view every page and pass a 10-question mastery test to receive a completion.



FCOIs in Research

Examples of FCOIs in research may include:

- Owning stock in a pharmaceutical company who manufactures the drug that will be tested in a research project.
- Accepting travel or gifts from the manufacturer of a medical device that will be tested in a research project.
- Disclosure or use of confidential information or unpublished research results for personal financial gain.



FCOIs in the News

statesman.com

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Fracking researcher has ties to industry

By [Farzad Mashhood](#)

Published: 9:17 p.m. Monday, July 23, 2012

The lead author of a recent University of Texas study that suggested that hydraulic fracturing, commonly called fracking, does not contaminate groundwater is a paid board member and shareholder in a company that engages in the practice, a situation that critics are calling a conflict of interest and of which the researcher's supervisors were unaware.

"The report was presented as if it was an independent study of fracking when, in fact, the study was led by a gas industry insider," said Kevin Connor, the director of the nonprofit Public Accountability Initiative in Buffalo, N.Y., which reported the researcher's role Monday.

Charles "Chip" Groat, who led a study released in February by UT's Energy Institute, billed the university-funded report as an independent look at the process of shale gas harvesting, a controversial process that has increased in recent years.

Groat, who did not respond to messages from the American-Statesman, has been on Houston-based Plains Exploration & Production Co.'s board for several years. Groat was paid \$413,900 in cash and stock by the company in 2011, according to SFC filings reviewed by the Statesman more than twice his salary from the university and holds almost

UT researcher claims fracking not harmful to groundwater supplies, but receives \$430K—more than twice his university salary—for sitting on board of Natural Gas Company.

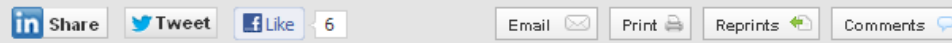


More FCOI News

M.D. Anderson chosen to lead clinical trials for new cancer drug, but M.D. Anderson CEO is one of drug company's founding officers.

Sponsored by:

HBJ Morning Call



★ Drug trial possibly a conflict of interest for M.D. Anderson

Houston Business Journal by Olivia Pulsinelli, Web producer

Date: Wednesday, July 18, 2012, 7:10am CDT - Last Modified: Wednesday, July 18, 2012, 4:57pm CDT



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If an upcoming drug trial were held at the [The University of Texas M.D. Anderson Cancer Center](#), it could be considered a conflict of interest for the institution, the *Houston Chronicle* reports.

Boston-based Aveo Oncology in May said M.D. Anderson would lead the testing of its new cancer drug, though no contract between the institution and the company

[Enlarge Image](#)



An upcoming drug trial could be considered a conflict of interest for The University of Texas M.D. Anderson Cancer Center.



PART I: Federal Regulations



Federal Regulations: Overview

The U.S. government has adopted many regulations that address COIs:

- National Science Foundation (NSF) – *Conflict of Interest Policy*, Grants Policy Manual Section 510 (NSF, 2010).
- Public Health Service (PHS) – 42 CFR, Part 50, Subpart F; 45 CFR, Part 94.
- U.S. Department of Health and Human Services (HHS) – *Common Rule*, 45 CFR 46, Subpart A.
- Food and Drug Administration (FDA) – 21 CFR 56.107(e); *Financial Disclosure by Clinical Investigators*, 21 CFR Part 54 *et seq.*
- U.S. Department of Agriculture (USDA) – *Animal Welfare Act*, 9 CFR, Ch. 1, Part 2, Subpart C, 2.31(d)(2)
- Secretary of Defense & NASA – FAR, Subpart 9.5.



Federal Regulations: FCOI

In 1995, the Office of Health & Human Services (HHS) and the Public Health Service (PHS) adopted regulations addressing FCOIs in federally-funded research.

In 2011, HHS revised these regulations and imposed new requirements for PHS-funded research.

Institutions who receive PHS funding are required to implement the revised regulations by August 24, 2012.

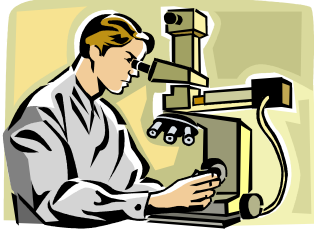


Significant Changes in 2011 Revisions

- Lowered *de minimis* threshold for Significant Financial Interest (SFI) disclosure from \$10,000 to \$5,000.
- Expanded:
 - SFIs required to be disclosed, and narrowed exclusions;
 - Reporting requirements to PHS when an FCOI is identified; and
 - Requirements for research conducted through subrecipients or subcontractors.
- Added:
 - New requirements for public accessibility;
 - Mandatory training requirements; and
 - Retrospective review and mitigation requirements.

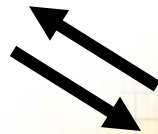


Federal Regulations: Framework



Investigator

- Disclosure of SFI
- Compliance with Institutional Policy



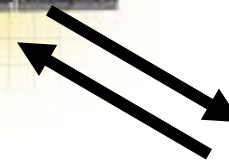
Institution



- Compliance with Regulations
- Reporting to NIH/NSF

- Institutional Policy Implementation
- Evaluation of SFI
- Identification of FCOI Management

NIH/NSF



Oversight

PHS regulation 42 CFR Part 50, Subpart F and 45 CFR Part 94



PART II: System Regulation 15.01.03



System Regulation 15.01.03

System Regulation 15.01.03, *Financial Conflicts of Interest in Research*, implements the 2011 revisions to federal regulations related to financial conflicts of interest.



Scope

Except as provided by federal law, this regulation applies broadly to **all** research or research activities regardless of funding source, as well as to research activities without external funding.

The system has chosen a broad application of this regulation to promote consistency and transparency across **all** research disciplines.



PART III: Who is Responsible? (Investigators and COI Officials)



Investigator

Each person who meets the definition of ***Investigator*** must comply with the training and disclosure requirements in System Regulation 15.01.03.

Investigator means 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 or research activities.



Who is an Investigator?

Examples of persons who meet the definition of ***Investigator*** might include:

- A principal investigator or PI
- A Co-PI
- A graduate student
- A post-doctoral researcher



Who is *not* an Investigator?

Examples of persons who do *not* meet the definition of ***Investigator*** include:

- A secretary or lab assistant who inputs research data or types a research report.
- An undergraduate student who writes a research paper for a class.
- An administrative assistant who tracks research expenditures.



COI Official

Each system member shall adopt a rule and designate a *COI Official*.



PART IV: What are the Investigator and COI Official Responsibilities?



Investigator Responsibilities



Investigator Responsibilities


Investigator responsibilities include:

1. Disclosing SFIs
2. Identifying and Managing FCOIs
3. Training



Financial Disclosure Statements

Investigators must submit a Financial Disclosure Statement to their system member's designated COI Official.



**Financial Disclosure Statement
as Required by System Regulation 15.01.03**

Name: Date:

College/Department: Title:

If statement is made on behalf of a Covered Family Member, use the following format for the "Title" field: "Covered Family Member, [spouse, son, (insert Investigator Name)]"

Do you have any Significant Financial Interests (SFIs) related to your institutional responsibilities as defined in System Regulation 15.01.03? Yes No

-If your answer is "NO," then sign the CERTIFICATION below and return this form to your COI Official.
-If your answer is "YES," then please complete the remainder of the form before signing and returning to your COI Official.

SFIs RELATED TO INSTITUTIONAL RESPONSIBILITIES (as defined in System Regulation 15.01.03)			
Source	Description (e.g., salary, royalty interest, sponsored travel)	Value (in whole \$)	Related to

If necessary, add pages.

RESEARCH OR RESEARCH ACTIVITY (as defined in System Regulation 15.01.03) Please fill out this portion if any SFI identified above is related to research or research activity.			
Project #	Project Title & Description	Funding Agency/Entity	Budget

If research is unfunded, use "N/A" for the "Funding Agency/Entity" field and "\$0" for "Budget" field. If necessary, add pages.

CERTIFICATION

I certify that the information provided in this form is true and correct to the best of my knowledge. I further certify that I have read System Regulation 15.01.03 *Financial Conflict of Interest in Research* and the applicable system member rule and that I am aware of and understand my responsibilities and applicable federal regulations and system policies regarding disclosure of Significant Financial Interests.

Signature: Date:

Instructions
Conflict of Interest Financial Disclosure Statement

- Complete the top portion of the form (Name, Date, College/Department and Title).
 - If the Financial Disclosure Statement is made on behalf of a Covered Family Member, use the following format for the "Title" field: "Covered Family Member, [spouse, son, daughter of (insert Investigator Name)]"
- If you DO NOT have any Significant Financial Interests (SFIs) related to your institutional responsibilities as defined in System Regulation 15.01.03, sign the certification portion of the Financial Disclosure Statement form and email the form to your COI Official.
- If you DO have any Significant Financial Interests (SFIs) related to your institutional responsibilities as defined in System Regulation 15.01.03, complete the sections titled SFIs Related to Institutional Responsibilities and Research or Research Activity. Sign the certification portion of the Financial Disclosure Statement form and email the form to your COI Official.

Financial Disclosure Statement Submission Requirements:
Investigators shall submit or update a Financial Disclosure Statement to the system member's COI Official:

- Within 30 days of the Investigator's initial employment date;
- Annually not later than August 31st;
- Within 30 days after acquiring a new SFI requiring disclosure; and
- For those Investigators participating in PHS-funded research, not later than the application date for PHS-funded research, except that an Investigator who will be participating in an ongoing PHS-funded research project must submit a Financial Disclosure Statement within 30 days of the Investigator's initial employment date.

Investigators shall also submit or update a separate Financial Disclosure Statement for each Covered Family Member within the time periods specified in section 4.3.

Definitions:
Covered Family Member includes an Investigator's spouse, dependent child, stepchild or other dependent, for purposes of determining federal income tax liability during the period covered by the financial disclosure statement, and a related or non-related, unmarried adult who resides in the same household as the Investigator and with whom the Investigator is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investments.

Institutional Responsibilities means an Investigator's professional responsibilities within the Investigator's field of discipline on behalf of a system member, including teaching, research, research consultation, professional practice, committee memberships, and service on panels such as an Institutional Review Board (IRB). This term includes consulting and other external employment approved under System Regulation 31.05.01 - *Faculty Consulting, Outside Professional Employment and Conflicts of Interest*. However, this term does not include external employment approved under System Regulation 31.05.02 - *External Employment*.

Investigator means 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 or Research Activities.

Research or Research Activities means any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research, scholarship (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). The term also includes educational activities funded by the National Science Foundation (NSF) or proposed for funding by NSF.



When is disclosure required?

Investigators must submit or update Financial Disclosure Statements:

- Within 30 days of initial employment;
- Annually, not later than August 31st;
- Within 30 days of acquiring a new SFI; and
- For Investigators participating in PHS-funded research, not later than the application date or within 30 days of initial employment, if participating in an ongoing PHS-funded project.



What is an SFI?

In simple terms, ***Significant Financial Interest (SFI)*** includes any financial interest received by an Investigator (or Covered Family Member) within the past 12 months that exceeds \$5,000 in value and reasonably appears to be related to the Investigator's Institutional Responsibilities.



Examples of SFIs

An SFI might include:

- Quarterly Stock Dividends or Royalties of \$1,300 received in each of the past four quarters.
- Consulting Fees of \$20,000 received over the past year.
- Salary compensation received for sitting on a corporate board of directors.
- Corporate sponsored or reimbursed travel in excess of \$5,000 during the past 12 months.

[Click here to review more examples of SFIs \(excerpted from System Regulation 15.01.03\).](#)



SFI Exclusions

The term “SFI” ***does not*** include:

- Salary paid by a system member.
- Income from mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these accounts.
- Income from a seminar sponsored by Yale University.
- Travel reimbursed or sponsored by the NSF.

Click here to review more examples of exclusions,
(excerpted from System Regulation 15.01.03).



Who is a Covered Family Member?

Covered Family Member includes an Investigator's spouse, dependent child, stepchild or other dependent, for purposes of determining federal income tax liability during the period covered by the Financial Disclosure Statement, and a related or non-related, unmarried adult who resides in the same household as the Investigator and with whom the Investigator is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage or investments.



What are my Institutional Responsibilities?

Institutional Responsibilities means an Investigator's professional responsibilities within the Investigator's field of discipline on behalf of a system member, including teaching, research, research consultation, professional practice, committee memberships, and service on panels such as an Institutional Review Board (IRB).

- This term includes consulting and other external employment approved under System Regulation 31.05.01, *Faculty Consulting, Outside Professional Employment and Conflicts of Interest*.
- However, this term does not include external employment approved under System Regulation 31.05.02, *External Employment*.



How do I know if an SFI is related to my Institutional Responsibilities?

Examples of SFIs that might be related to an Investigator's Institutional Responsibilities include:

- A Petroleum Engineering professor who is paid to serve on the board of an oil and gas company;
- A Finance professor who receives consulting fees from the banking industry;
- An Agriculture professor who serves as a paid expert witness for a fertilizer company; or
- A graduate student in Aerospace Engineering who accepts a paid internship with Lockheed Martin or Boeing.



Examples: When is an SFI *not* related to my Institutional Responsibilities?

Examples of SFIs that do *not* relate to an Investigator's Institutional Responsibilities may include:

- A Petroleum Engineering professor who owns stock in Home Depot valued at \$15,000;
- A Finance professor who receives income from a family cattle business; or
- A graduate student in Aerospace Engineering who also works as a real estate agent.



What if I am unsure about whether to disclose an SFI?

Investigators should err on the side of disclosure.

Investigators should ask the designated COI Official at their system member agency or institution if there is any question about whether to disclose an SFI.



Identifying and Managing FCOIs

Investigators must work with each member's designated COI Official to identify and manage FCOIs.

COI Officials may request Investigators to provide additional information regarding SFIs held by an Investigator or Covered Family Member.



Training

Federal law and System Regulation 15.01.03 require Investigators to take mandatory FCOI training to understand the reporting and disclosure obligations.



Responsibilities of the COI Official



Responsibilities of the COI Official

Responsibilities of the COI Official include:

1. Collecting and reviewing financial disclosure statements.
2. Identifying and managing FCOIs.
3. Reporting FCOIs to sponsors and administrators.
4. Maintaining publicly accessible policies and records to document compliance.
5. Enforcing the system's FCOI policies.



Financial Disclosure Statements

Each system member's COI Official must collect and review ***all*** financial disclosure statements submitted by Investigators.



Identifying & Managing FCOIs

An FCOI exists when the COI Official reasonably determines that an SFI held by an Investigator or a Covered Family Member could directly and significantly affect the design, conduct, or reporting of the Investigator's research.

If a COI Official determines that an FCOI exists, the COI Official shall notify the Investigator in writing and work with the Investigator to develop a Management Plan specifying the steps to be taken to manage, reduce or eliminate the FCOI.



What is a Management Plan?

A Management Plan includes the following key elements:

- The research affected by the FCOI, including, if available, the project number;
- The role and principal duties of the Investigator who has the FCOI;
- The conditions or restrictions to be implemented to manage, reduce or eliminate the FCOI;
- A statement explaining how the Management Plan will protect the research from bias resulting from the FCOI;
- Confirmation of the Investigator's agreement to abide by the Management Plan;
- A statement explaining how the Management Plan will be monitored to ensure compliance and who is responsible for monitoring compliance with the Management Plan; and
- Any other information as needed.

The Management Plan must be signed by the Investigator and the Investigator's supervisor, and be approved by the COI Official.



What conditions might be included in a Management Plan?

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate an Investigator's FCOI include, but are not limited to:

- Public disclosure of the FCOI;
- For research projects involving human subjects, disclosure of the FCOI to the participants;
- Appointment of an independent monitor who will take measures to protect the design, conduct, and reporting of research against bias resulting from the FCOI;
- Modification of the research plan or research activities;
- Requiring a change in personnel and/or responsibilities for all or a portion of the research activities;
- Disqualification of personnel from participation in that portion of the research activities that would be affected by the FCOI;
- Reduction or elimination of the SFI (e.g., sale of an equity interest); and
- Severance of relationships that create an FCOI.



Reporting Requirements

If a COI Official discovers an FCOI related to PHS-funded research that was not timely identified or managed, or if an Investigator fails to comply with a Management Plan, the COI Official shall:

- Complete a retrospective review;
- Implement any measures necessary to remediate noncompliance;
- Notify sponsors and the member's CEO as required by law or system regulation;
- Submit a Mitigation Report, if required by law or system regulation; and
- Update the system member's FCOI reports.



Public Accessibility

Each system member shall make its FCOI policy available on a publicly accessible website.

For each FCOI identified by a COI Official, the COI Official shall:

- Retain all information related to the FCOI in a central location; and
- Make this information available to the public, upon request, as required by state or federal law.



Recordkeeping

- **For sponsored research:** COI Officials shall maintain all records related to Investigators' Financial Disclosure Statements and any FCOI determinations and/or Management Plans for the longer of 3 years from the date of the last expenditure on the project, or as required by law.
- **For non-sponsored/unfunded research:** COI Officials shall keep all FCOI records for 3 years from the date the research ended, or as required by law.



Enforcement

- Apparent oversights or violations of the system regulation or applicable system member rules shall be brought to the attention of the Investigator, who will be given an opportunity to comply.
- Repeated or intentional violations may be reported to the funding agency and the CEO by the COI Official if not corrected.
- Sanctions may be imposed by the CEO or designee and may range from a letter of reprimand up to and including termination.



PART V: Other Conflicts in Research

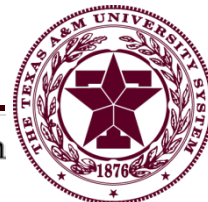


Conflicts of Commitment

Conflicts of commitment exist when an individual's job duties are impacted by engaging in other activities that may or may not be job related.

Examples include:

- An individual performing consulting work for a significant amount of the day rather than performing their institutional responsibilities.
- An individual performing work for an outside organization for a significant amount of the day rather than performing their institutional responsibilities.



Conflicts of Conscience

Conflicts of conscience can exist when an individual's personal beliefs might interfere with their ability to perform their job duties objectively.

Examples include:

- Serving on the institution's Animal Care and Use Committee (IACUC) and being an animal rights advocate.
- Collaborating on stem cell research while having personal or religious beliefs that may conflict with the research.

Conflicts of conscience are not regulated by federal regulations or by institutional policies. Individuals are responsible for maintaining awareness of and managing conflicts of conscience.



Resolving Conflicts of Commitment and Conscience

Steps to resolve conflicts of commitment and conscience:

1. Recognize that a conflict could exist;
2. Disclose potential conflicts; and
3. Develop a plan to manage the conflict or potentially decline participation in the activity that causes the conflict.



Institutional COIs

COIs can occur at the institutional level.

Examples of institutional COIs may include:

- An institution committed to a nicotine-free environment may be conflicted about accepting funding from a tobacco company, which intends to sponsor a study examining nicotine addiction.
- An institution may be conflicted about accepting a sponsored research project that examines topics that contradict the fundamental beliefs of those at the institution.



PART VI: Summary & Resources



Summary

- The U.S. government has adopted many regulations to address FCOIs in order to promote objectivity and transparency in research.
- The A&M System has adopted System Regulation 15.01.03, *Financial Conflict of Interest in Research*, to comply with federal law and to ensure that the research conducted by ***all*** system members remains free from bias resulting from FCOIs.



Resources

- 42 CFR Part 50 Subpart F (grants and cooperative agreements)
- 45 CFR Part 94 (contracts)
 - Initial Regulation effective 10-1-95
 - http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm
 - Revised Final Rule published on 8-25-11
 - <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
- *NIH FCOI Webinar for Grantees* (Nov. 30, 2011), available at <http://grants.nih.gov/grants/policy/coi/index.htm>
- Jodi R. Edelstein, *Surveying the Conflict of Interest Landscape: Research Universities*, NCURA MAGAZINE, May/June 2012, at 6.
- [System Regulation 15.01.03](#), *Financial Conflict of Interest in Research*

