

15.01.03 Financial Conflicts of Interest in Sponsored Research

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Regulation Summary

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. The system adopts this regulation to promote objectivity in research and to ensure that the research activities conducted by each member are free from bias resulting from financial conflicts of interest (FCOI).

This regulation implements federal law and regulations adopted by the Public Health Service (PHS) of the U.S. Department of Health and Human Services and the National Science Foundation (NSF) to address when a significant financial interest (SFI) reasonably appears to affect or bias the design, conduct or reporting of research.

Definitions

[Click to view Definitions.](#)

Regulation

1. PURPOSE AND BACKGROUND

This regulation defines the general procedures required for members to identify, manage and report financial conflicts of interest in research. The purpose of this regulation is to protect the credibility and integrity of system researchers and staff, as well as member universities and agencies themselves, so the public trust and confidence in their research activities are maintained. To that end, this regulation adopts standards for the disclosure, management and reporting of FCOI beyond those required by federal law.

Members have a responsibility to identify and manage, reduce or eliminate conflicts of interest that may arise due to financial or other personal interests of an investigator. Therefore, the system requires investigators to disclose financial interests related to their institutional responsibilities.

2. APPLICABILITY

Except as otherwise provided by federal law, this regulation applies broadly to all externally sponsored research or research activities regardless of the funding source.

In addition to the issues addressed in this regulation, there may be ethical considerations that are distinct and separate from FCOI questions. See, e.g., System Policy 07.01, *Ethics*; System Policy 31.05, *External Employment and Expert Witness*; System Regulation 31.05.01, *Faculty Consulting and External Professional Employment*; and System Regulation 31.05.02, *External Employment*.

3. CONFLICT OF INTEREST OFFICIAL

Each member's chief executive officer (CEO) must appoint a conflict of interest official (COI Official) who will be responsible for implementing this regulation. The COI Official must perform the duties assigned by this regulation and any other duties as assigned by the CEO.

4. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

4.1. Each investigator, as defined below, must submit or update a Financial Disclosure Statement as required in Section 4.2 of this regulation that:

- (a) Identifies all research or research activities in which the investigator is engaged at the time the Financial Disclosure Statement is submitted; and
- (b) Discloses the following information for each SFI held by the investigator or a covered family member, as defined below, that is reasonably related to the investigator's institutional responsibilities:
 - (1) The total amount of salary or other payments received in the preceding 12 months, in rounded, whole dollar amounts;
 - (2) A description and the value of any equity interest (e.g., stock, stock options, or other ownership interest or entitlement to such an interest) in rounded, whole dollar amounts by reference to public prices or other reasonable measures of fair market value;
 - (3) A description and the value of any intellectual property or royalty interests in rounded, whole dollar amounts;
 - (4) The source of the SFI, including the source's name and principal address; and
 - (5) For each occurrence of reimbursed or sponsored travel, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration of the trip. Each member, at its discretion, may require an investigator to disclose additional information in order to determine whether the travel at issue constitutes an FCOI.

4.2 Investigators must submit or update a Financial Disclosure Statement to the member's COI Official:

- (a) Within 30 days of the investigator's initial employment date;

- (b) Annually, not later than August 31st;
- (c) Within 30 days after acquiring a new SFI requiring disclosure; and
- (d) 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.

4.3 Investigators must also submit or update a separate Financial Disclosure Statement for each covered family member within the time periods specified in Section 4.2.

4.4 Investigators must submit the required Financial Disclosure Statement(s) online via Maestro.

4.5 An investigator or covered family member must provide any additional documentation related to the SFIs disclosed on a Financial Disclosure Statement upon request of a member's COI Official.

5. REVIEW OF FINANCIAL DISCLOSURE STATEMENTS

5.1 Each member's COI Official must review the Financial Disclosure Statement(s) submitted by each investigator at that member and determine:

- (a) Whether an SFI is related to research in which an investigator is participating; and
- (b) Whether an FCOI exists.

5.2 A COI Official may request additional information about an investigator's Financial Disclosure Statement to determine if an FCOI exists.

5.3 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.

6. CERTIFICATION AND REPORTING

6.1 Federal regulations require members to include specific certifications and agreements regarding this regulation and FCOI in each application for funding submitted for PHS-funded research.

6.2 Each member must comply with the reporting requirements in 42 C.F.R. Part 50, Subpart F, and 45 C.F.R. Part 94, which require members to submit reports to the appropriate federal funding agency within a certain period of time after the member identifies an FCOI related to PHS-funded research.

7. NO EXPENDITURE OF RESEARCH FUNDS

There will be no expenditure of sponsored research funds by an investigator or member unless the COI Official has determined that no FCOI exists or that any identified FCOI is manageable under the terms of a management plan that has been adopted and implemented.

8. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

- 8.1 If a COI Official determines that an FCOI exists, the COI Official or designee must 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.
- 8.2 Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate an investigator's FCOI include, but are not limited to:
 - (a) Public disclosure of the FCOI;
 - (b) For research projects involving human subjects, disclosure of the FCOI to the participants;
 - (c) Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of research against bias resulting from the FCOI;
 - (d) Modification of the research plan or research activities;
 - (e) Requiring a change in personnel and/or responsibilities for all or a portion of the research activities;
 - (f) Disqualification of personnel from participation in that portion of the research activities that would be affected by the FCOI;
 - (g) Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
 - (h) Severance of relationships that create an FCOI.
- 8.3 A management plan must include a description of the following key elements:
 - (a) The research affected by the FCOI, including, if available, the project number;
 - (b) The role and principal duties of the investigator who has the FCOI;
 - (c) The conditions or restrictions to be implemented to manage, reduce or eliminate the FCOI;
 - (d) A statement explaining how the management plan will protect the research from bias resulting from the FCOI;
 - (e) Confirmation of the investigator's agreement to abide by the management plan;
 - (f) 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
 - (g) Any other information as needed.
- 8.4 The management plan must be signed by the investigator and the investigator's supervisor and approved by the COI Official.
- 8.5 For NSF-funded research, if the COI Official determines that imposing conditions or restrictions would be either ineffective or inequitable, and potential negative impacts

arising from the FCOI are outweighed by the interests of scientific progress, technology transfer or the public health and welfare, the COI Official may allow the research to proceed without imposing such conditions or restrictions.

- 8.6 If an investigator disagrees with the COI Official's determination that an FCOI exists, the investigator may appeal the COI Official's determination to the CEO or designee in writing within 10 business days after receiving the COI Official's determination. The decision of the CEO or designee is final.

9. PUBLIC ACCESSIBILITY

- 9.1 Each member must maintain an up-to-date, written, enforced FCOI rule and make that rule and this regulation available via a publicly accessible website.

9.2 PHS-Funded Research

- 9.2.1 If a member's COI Official determines that an FCOI exists that is related to PHS-funded research, the member will make the following information available to the public:

- (a) The name of the investigator;
- (b) The title and role of the investigator in relation to the affected research;
- (c) The name of the entity in which the SFI is held;
- (d) A description of the SFI that was determined to be an FCOI; and
- (e) The approximate dollar value of the SFI. If the dollar value cannot be determined by reference to publicly available prices or another reasonable method, the member must include a statement to that effect. Dollar values may be provided within ranges, e.g., \$0-\$4,999; \$5,000-\$10,000; \$10,000-\$20,000; \$20,000-\$50,000; \$50,000-\$100,000. Amounts over \$100,000 may be stated in increments of \$50,000.

- 9.2.2 Members must make this information available in writing to any requestor within five business days after receipt of a request so long as the following criteria are met:

- (a) The SFI was disclosed and is still held by the investigator;
- (b) The member has determined that the SFI is related to PHS-funded research; and
- (c) The member's COI Official has determined that the SFI is an FCOI.

- 9.2.3 Alternatively, members may make this information available through posting on a publicly accessible website. If a member chooses this option, the member must update the information posted on the website on an annual basis. In addition, for each SFI that is required to be publicly available under this section, the information related to that SFI must be posted on the member's website within 60 days after the FCOI is identified. The website must contain a statement that

the information posted is current and accurate as of the date listed and is subject to updates.

9.2.4 The information required under this section must remain available to any requestor or posted on the internet for three years after the date of the last expenditure on the research project.

9.3 Non-PHS-Funded Research

For each FCOI identified by a member's COI Official that is not related to PHS-funded research, the member's COI Official must retain all information related to the FCOI in a central location and make this information available to the public upon request and as authorized by the Texas Public Information Act, Tex. Gov't Code, Ch. 552.

9.4 Each member's COI Official is responsible for coordinating with the member's public information officer/coordinator to ensure that all responses to public information requests are made in compliance with federal and state law.

10. RETROSPECTIVE REVIEW

10.1 Noncompliance, Retrospective Review and Documentation for PHS-funded Research

10.1.1 If a member 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 member's COI Official or designee must, within 120 days after determining noncompliance:

- (a) Complete a retrospective review of the investigator's research activities and any PHS-funded research project to determine if any PHS-funded research, or portion thereof, conducted during the period of noncompliance, was biased in the design, conduct or reporting of such research; and
- (b) Implement any measures necessary, including but not limited to halting the investigator's participation in any affected research project, to remediate the noncompliance between the date the noncompliance was identified and the date the retrospective review is completed.

10.1.2 The member's COI Official or designee must document each retrospective review including, but not limited to, the following key elements:

- (a) Project number;
- (b) Project title;
- (c) Investigator contact(s);
- (d) Name of the investigator with the FCOI;
- (e) Entity with which the investigator has an FCOI;
- (f) Reason(s) for the retrospective review;

- (g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (h) Findings of the review; and
- (i) Conclusions of the review (i.e., determination, recommended actions and remedial measures implemented).

10.1.3 If bias is found, the member's COI Official must notify the PHS and submit a mitigation report as required by federal law. If necessary, the COI Official must update the FCOI Reports described in Section 9.2 of this regulation.

10.2 Noncompliance, Retrospective Review and Documentation for All Other Research

If a member's COI Official discovers an FCOI related to non-PHS-funded research that was not timely identified or managed, the COI Official must conduct and document a retrospective review as described in Sections 10.1.1 and 10.1.2. If bias is found, the member's COI Official must notify the CEO and, if required by law, the COI Official must also notify the funding agency.

11. RESEARCH THROUGH SUBRECIPIENTS

11.1 If a member conducts research in cooperation with or through a subrecipient (e.g., a subcontractor, contractor or collaborator) who performs part of the statement of work described in the prime contract, the member must enter into a written agreement with the subrecipient to ensure compliance with this regulation and federal law. The written agreement must incorporate legally enforceable terms that specify whether the FCOI policy of the member or the subrecipient will apply to the subrecipient's investigators who will participate in the research. The written agreement must also require the subrecipient to cooperate with the member to provide FCOI reports to a sponsoring agency as required by law.

11.2 If the subrecipient's investigators must comply with the subrecipient's FCOI policy, the subrecipient must certify that its policy complies with applicable federal law. If the subrecipient cannot provide this certification, the agreement must state that the subrecipient's investigators are subject to this regulation's requirements for disclosing SFIs that are related to the work performed by the subrecipient's investigators on behalf of the member.

11.3 If the subrecipient's FCOI policy applies to its investigators, the agreement must specify the time periods for the subrecipient to report all identified FCOIs to the member. These time periods must be sufficient to allow the member to comply with the member's review and management requirements and all federal reporting requirements.

11.4 The requirements of this section apply only to:

- (a) PHS-funded research; and

- (b) Sponsored research in which an investigator subcontracts a portion of the research to a covered family member or an entity in which the investigator or a covered family member holds a financial interest.

12. TRAINING, EDUCATION AND CERTIFICATION

- 12.1 Each member is responsible for complying with the training requirements under federal law, e.g., 42 C.F.R. §50.604(b); 45 C.F.R. §94.4(b).
- 12.2 Each investigator must certify annually that the investigator is aware of and has read this regulation, the applicable member rule and any related procedures, and is aware of the investigator's responsibilities regarding disclosure of SFIs and of applicable federal regulations.
- 12.3 Prior to engaging in research on behalf of a member and at least once every four years thereafter, each investigator must complete training on this policy and other applicable policies, regulations, rules and laws. In addition, investigators must immediately complete training if the system changes this regulation in a manner that affects investigator requirements.
- 12.4 An investigator who is newly employed by a member must complete the requisite training before engaging in any research or research activity on behalf of a member and at least once every four years thereafter.
- 12.5 If a member's COI Official determines that an investigator is not in compliance with this regulation or a management plan agreed upon by the investigator and the member, the investigator must immediately complete training on this regulation and other applicable policies, regulations, rules and laws.
- 12.6 Each member's COI Official or designee must document an investigator's compliance with applicable training requirements. The COI Official or designee must maintain all documentation related to an investigator's compliance with this training requirement in a central location.

13. ENFORCEMENT

- 13.1 Violations of this regulation or applicable member rules must be brought to the attention of the investigator who will be given an opportunity to comply. The investigator must present a proposal for compliance to the member's COI Official for review and action within 10 business days of the notification of noncompliance. Failure to comply will constitute an intentional violation as discussed in the following section.
- 13.2 Repeated or intentional violations of this regulation may be reported to the funding agency and the CEO by the COI Official. Sanctions may be imposed by the CEO or designee and may range from a letter of reprimand to termination.

13.3 Cases involving investigators employed by a member, including appeals of impending sanctions, must be processed in a manner consistent with applicable system policies and regulations, as well as member rules or procedures.

13.4 Cases, including appeals of impending sanctions, involving investigators not employed by or affiliated with a member must be referred to the investigator's home institution or organization for processing. However, a member may remove an investigator not employed by or affiliated with the member from participating in a particular research project or activity until any allegations involving an FCOI are resolved.

14. RECORDKEEPING

The COI Official for each member must maintain all records related to investigators' Financial Disclosure Statements and any FCOI determinations and/or management plans in a central location. These records must be kept for the longer of three years from the date of the last expenditure submitted in the case of sponsored research or as required by applicable federal law, e.g., 45 C.F.R. §§74.53(b), 92.42(b).

15. AUDIT

Each member must provide for regular audits of SFI disclosure statements and related documents and reports to determine individual and institutional compliance with this regulation.

Related Statutes, Policies, or Requirements

[42 C.F.R. Part 50, Subpart F](#)

45 C.F.R. §§ [74.53\(b\)](#), [92.42\(b\)](#) and [Part 94](#)

[21 C.F.R. Parts 54, 312, 314, 320, 601, 807 and 812](#)

[Tex. Gov't Code Ch. 552](#)

[National Science Foundation Grant Policy Manual, Chapter V, §510, eff. July 1, 2005](#)

[System Policy 07.01, Ethics](#)

[System Policy 15.01, Research Agreements](#)

[System Regulation 15.99.03, Ethics in Research, Scholarship and Creative Work](#)

[System Policy 31.05, External Employment and Expert Witness](#)

[System Regulation 31.05.01, Faculty Consulting and External Professional Employment](#)

[System Regulation 31.05.02, External Employment](#)

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Appendices

[Appendix A – Model Rule Template for System Members](#)

[Appendix B – Model Template for Financial Disclosure Statement](#)

(This form describes the information that must be included in the Financial Disclosure Statement; however, this information must be submitted online via Maestro. See Section 4.4.)

Member Rule Requirements

A rule is required to supplement this regulation. See Appendix A for the Model Rule Template.

Contact Office

Research
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