15.01.03 Financial Conflicts of Interest in Sponsored Research

Revised January 13, 2025
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Regulation Summary

The Texas A&M University System (system) recognizes its responsibility to encourage interaction between its employees and the public and private sectors as an important component of its research activities. The system and system members are 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 and influence 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 significant financial interests (SFIs) may reasonably influence or bias the design, conduct or reporting of research, resulting in FCOIs.

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 is maintained. To that end, this regulation adopts standards for the disclosure of financial interests and the management and reporting of FCOIs, beyond those required by federal regulations.

   Members have a responsibility to identify, manage, reduce, or eliminate FCOIs that may arise due to the financial 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 regulation, this regulation applies broadly to all externally sponsored research and 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 is responsible for implementing this regulation. The COI Official must perform the duties assigned by this regulation and any other duties as assigned by the chief executive officer (CEO), as they relate to FCOI determinations and management.

4. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

4.1 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, based on the prior disclosure date(s);

(c) Within 30 days after acquiring a new SFI requiring disclosure or a change in an existing SFI; and

(d) For those investigators participating in externally funded research (e.g. PHS or NSF), not later than the application date for the funded research.

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

(a) Includes all funded 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, from all domestic and international entities, held by the investigator or a covered family member, that is reasonably related to the investigator's institutional responsibilities:

(1) Name, principal address, and other relevant information for the organization with which an SFI exists.

(2) The total amount of salary, compensation, or other payments received in the preceding 12 months, in rounded, whole dollar amounts;

(3) A description and the value of any equity interest (e.g., stock, stock options (vested or unvested), 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 at the time of disclosure;

(4) A description of intellectual property payments or royalty interests received in rounded, whole dollar amounts;

(5) Reimbursed or sponsored travel, including the purpose of the travel, identity(ies) of the sponsors/organizers, and destinations. 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.

4.3 Investigators must submit the required Financial Disclosure Statement(s) online via the designated FCOI management system for that system member.

4.4 An investigator and covered family member(s) must provide any additional documentation related to the SFIs disclosed on a Financial Disclosure Statement upon request by a member's COI Official.

5. REVIEW OF FINANCIAL DISCLOSURE STATEMENTS

5.1 Each member's COI Official, or designee, must review the Financial Disclosure Statement(s) submitted by each investigator and/or covered family member and determine:

(a) Whether an SFI is related to research in which an investigator is participating; and whether an FCOI exists for that SFI.
   a. An FCOI exists when the COI Official reasonably determines that an investigator's SFI is related to a research project (i.e., the SFI could be affected by the research or the SFI is with an entity whose financial interests could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of the research.

6. CERTIFICATION AND REPORTING

6.1 Federal regulations and funding agency guidelines require members to include specific certifications and agreements regarding this regulation and member rules in each application for funding submitted for funding.

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. Other funding agencies may have similar requirements.
   (a) NIH's required FCOI reports must include a description of the management plan, which includes the elements found in section 8.3 of this regulation.

7. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

7.1 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.

If an investigator disagrees with the COI Official's determination that an FCOI exists, the investigator may challenge the COI Official's determination to the member CEO or designee in writing within 10 business days after receiving the COI Official's determination. The challenge must state:

(a) Why the investigator disagrees with the determination;
(b) How the SFI could not reasonably result in the influence or bias of the planning, conduct, or reporting of research, and
(c) Any other additional facts the investigator wishes to have considered.

The CEO or designee must provide the investigator with a written decision on their challenge within 30 business days. The decision of the CEO or designee is final.

7.2 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 in relevant publications, presentations, press releases, informed consent, and other documents;

(b) For research projects involving human subjects, disclosure of the FCOI to the participants during the informed consent process;

(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);

(h) Severance of relationships that create an FCOI.

7.3 A management plan must include a description of the following key elements:

(a) A description of 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 is designed to safeguard objectivity in the research project;

(e) Confirmation of the investigator's agreement to abide by the management plan as evidenced by their acknowledgement of the management plan;

(f) A statement explaining how the management plan I will be monitored to ensure compliance and who is responsible for monitoring compliance with the management plan; and

(g) Any other information as needed.

7.4 The management plan must be signed by the investigator, the investigator's supervisor, approved by the COI Official.

8. NO EXPENDITURE OF RESEARCH FUNDS

There may be no expenditure of sponsored research funds by an investigator or member unless the COI Official has determined that no FCOI exists or, if FCOIs have been identified, that they are manageable under the terms of a management plan that has been implemented.

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. The system will make this regulation available via a publicly accessible website.

9.2 Requests for FCOI Information Related to PHS-Funded Research

9.2.1 Members must make the information available in 9.2.2 available in writing to any requestor within five business days of a written request for SFIs that meet the following three criteria:

(a) The SFI was disclosed and is still held by the senior/key personnel for the PHS-funded research project identified by the member in the grant application, progress report, or any other required report submitted to the PHS;

(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.

9.2.2 The following information that must be provided, at a minimum, includes:

(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.

9.2.3 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 REVIEWS

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

10.1.1 A member is required to complete a retrospective review when:

(a) There is a failure by the investigator to disclose an SFI that is determined by the COI Official to constitute an FCOI;
(b) There is a failure by the member to review or manage an FCOI; or
(c) There is a failure by the investigator to comply with the FCOI management plan.

10.1.2 When a member determines that a retrospective review is required, the FCOI Official, or designee, must within 120 days of the determination of 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.

10.1.3 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, including the nature of the FCOI;
(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).

10.1.4 If bias is found, the member's COI Official must notify the PHS and submit a mitigation report as required by federal regulation. The mitigation report must include, at a minimum:

(a) The key elements documented in the retrospective review;
(b) A description of the impact of the bias on the research; and
(c) The member's plan of action, or actions that have already been taken to eliminate or mitigate the effect of the bias, including the requirement for retraining.

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, or if the investigator did not comply with a management plan, the COI Official must conduct and document a retrospective review as described in Sections 10.1.1 and 10.1.2, but a determination of bias only needs to be conducted if determined to be necessary (for example, a determination of bias may not be necessary if research has not yet been initiated or if the nature of the non-compliance could not have resulted in bias).

11. RESEARCH THROUGH SUB-RECIPIENTS

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, federal regulations, and funding agency requirements, as applicable. The written agreement must incorporate legally enforceable terms that specify whether the FCOI policy of the member or the sub-recipient will apply to the sub-recipient's investigators who participate in the research. The written agreement must also require the sub-recipient to cooperate with the member to provide FCOI reports to a sponsor as required by federal regulation and/or sponsor requirements.

11.2 If the subrecipient's investigators must comply with the subrecipient's FCOI policy, the sub-recipient must certify that its policy complies with applicable federal regulations and sponsor requirements. If the sub-recipient cannot provide this certification, the agreement must state that the sub-recipient's investigators are subject to this regulation's requirements for disclosing SFIs that are related to the work performed by the sub-recipient'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.

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 they are aware of and have 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, unless specific sponsors require more frequent training, 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 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

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.

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. §§75.53(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 – Promoting Objectivity in Research

45 C.F.R. §§ 75.53(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 Proposal & Award Policies & Procedures Guide (PAPPG)

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/or External Professional Employment*

System Regulation *31.05.02, External Employment*

Member Rule Requirements

A rule is required to supplement this regulation.

Contact Office

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