

UNIVERSITY RULE

15.01.03.M1 Financial Conflicts of Interest in Sponsored Research

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Rule Statement

Texas A&M University is committed to conducting Research or Research Activities in a manner consistent with the highest standards of integrity and ethics. This rule is adopted to promote objectivity in Research or Research Activities and to ensure that the Research or Research Activities are conducted in a manner free from bias resulting from Financial Conflict of Interest.

Reason for Rule

This rule implements the requirements of System Regulation *15.01.03, Financial Conflicts of Interest in Sponsored Research*.

Definitions

Definitions of capitalized terms used in this rule are found in System Regulation *15.01.03*.

Procedures and Responsibilities

1. APPOINTMENT OF CONFLICT OF INTEREST OFFICIAL

The President appoints the Vice President for Research or his or her designee(s) as the Conflict of Interest Official (COI Official) for Texas A&M University. The COI Official shall perform the duties established in System Regulation *15.01.03* relating to the review

of Disclosures of Significant Financial Interest and the management and reporting of Financial Conflicts of Interest.

2. DISCLOSURE AND REVIEW

All University employees and students who are Investigators, as defined in System Regulation *15.01.03*, must disclose Significant Financial Interests (SFI) and submit Financial Disclosure Statements to Texas A&M University's COI Official in accordance with this rule and System Regulation *15.01.03*.

2.1 In accordance with System Regulation *15.01.03* and federal law, the COI Official will review all Financial Disclosure Statements by Investigators and determine whether any disclosed SFI is related to the Investigator's Research or Research Activities and whether a Financial Conflict of Interest (FCOI) exists. The COI Official may appoint a Conflict of Interest Review Committee (CIRC) to assist in the determination of whether a FCOI exists. If the COI Official appoints a CIRC, the CIRC must include an Investigator outside the disclosing Investigator's unit and at least one research administrator. The COI Official and/or CIRC may involve the Investigator and unit head(s) to assist in determining whether an SFI is related to the Investigator's Research or Research Activities. If a FCOI exists, the COI Official will develop a management plan, as described in System Regulation *15.01.03*, in consultation with the entities noted above, specifying the actions that must be taken to manage, reduce or eliminate the FCOI. All FCOIs identified by the COI Official must be satisfactorily managed, reduced or eliminated prior to the expenditure of any sponsored research funds.

2.2 The System Ethics and Compliance Officer and/or the Office of General Counsel may be consulted as appropriate.

3. MONITORING

Each Investigator conducting Research or Research Activities under a Management Plan must comply fully and promptly with the Management Plan and each person identified in the Management Plan as having responsibility for monitoring compliance shall carefully and fully monitor that compliance. Additionally, the Office of the Vice President for Research shall be responsible for conducting periodic reviews of Financial Disclosure Statements and Management Plans to determine individual and institutional compliance. The COI Official shall report instances of noncompliance as required in System Regulation *15.01.03* and federal law.

4. TRAINING AND CERTIFICATION

Investigators must complete training as required in System Regulation *15.01.03*. In addition, each Investigator must annually certify that the Investigator is aware of and has read System Regulation *15.01.03* and this rule and is aware of the Investigator's responsibilities regarding disclosure of SFIs and applicable federal regulations.

5. PUBLIC ACCESSIBILITY

5.1 The COI Official must ensure that this rule is available through a publicly accessible website.

5.2 Public Health Service (PHS) funded Research

If the COI Official determines that a FCOI exists that is related to PHS-funded research, the COI Official must coordinate with the public information officer to make the following information available in writing to any requestor within five business days after receipt of a request, so long as the Investigator still holds the SFI:

- (a) The name of the Investigator;
- (b) The title and role of the Investigator in relation to the affected Research or Research Activities;
- (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.

5.3 Non-PHS-funded Research

For all public information request related to non-PHS funded research, the COI Official must coordinate with the public information officer to ensure that responses to requests comply with Texas Government Code, Chapter 552.

6. OTHER CONSIDERATIONS

In addition to the issues addressed in System Regulation *15.01.03* and this rule, there may be other ethical considerations that are separate and distinct from FCOI questions, including but not limited to those relating to external employment and conflict of commitment. The primary responsibility of each employee of Texas A&M University is the accomplishment of the duties and responsibilities assigned to the employee's position of appointment. External consulting or other outside employment should not interfere with those duties and responsibilities as set forth in system policies and regulations.

Related Statutes, Policies, or Requirements

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

45 C.F.R. §§ [75.361](#) and [Part 94](#)

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

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

Supplements:

[System Policy 15.01, Research Agreements](#)

[System Regulation 15.01.03, Financial Conflicts of Interest in Sponsored Research](#)

Cross reference:

[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](#)

[System Regulation 31.05.02, External Employment](#)

Contact Office

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