UNIVERSITY RULE

15.01.03.M1 Financial Conflicts of Interest in Sponsored Research

Approved April 23, 1996
Revised December 13, 1996
Revised August 18, 2011
Revised September 7, 2012
Revised November 1, 2012
Next Scheduled Review: November 1, 2017

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.

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 are 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. If a FCOI exists, the COI Official will develop a Management Plan, as described in System Regulation 15.01.03, 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 In accordance with System Regulation 15.01.03, 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 be composed of Investigators representing a cross-section of disciplines and at least one research administrator. The COI Official and/or CIRC may involve the Investigator to assist in determining whether an SFI is related to the Investigator’s Research or Research Activities. 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 shall 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 shall 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 shall 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. §§ 74.53(b), 92.42(b) and Part 94

21 C.F.R. Parts 54, 312, 314, 320, 601, 807 and 812

Texas Government Code, Ch. 552

National Science Foundation Grant Policy Manual, Chapter V, §510, eff. July 1, 2005

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

Contact Office

Office of the Vice President for Research
(979) 845-8585