UNIVERSITY RULE
Ver. 5-1-12

15.01.03.M1 Financial Design, Conduct, and Reporting of Sponsored Research: Conflict of Interest in Sponsored Research and Conflict of Commitment
Approved April 23, 1996
Revised December 13, 1996
Revised August 18, 2011
Next Scheduled Review: August 18, 2014

Rule Statement

Texas A&M University is committed to conducting research and educational activities in a manner consistent with the highest standards of integrity and ethics. This rule is adopted to promote objectivity in research and to ensure that the research and educational activities are conducted in a manner free from bias resulting from financial conflicts of interest.

Reason for Rule

This rule addresses the following topics pertaining to conflict of interest in the design, conduct and reporting of sponsored research: 1) guidelines for the disclosure, management and reporting of financial disclosures related to conflicts of interest; and 2) conflicts of interest commitment.

Definitions

Each of the following terms used in this Rule is defined in System Regulation 15.01.03 Financial Conflict of Interest in Sponsored Research

- Financial Conflict of Interest
- Institutional Responsibilities
- Investigator
- Research
- Significant Financial Interest

Official Rule
1. **APPOINTMENT OF DESIGNATED OFFICIAL**

   1.1 The President appoints the Vice President for Research, or his or her designee(s), as the University’s Designated Official(s) to provide oversight of and to perform the duties required by this rule and related system regulation relating to review, management and reporting of conflict of interest disclosures.

2. **APPOINTMENT OF PUBLIC ACCESSIBILITY CONTACT**

   2.1 The President appoints the Vice President for Research, or his or her designee to serve as the University’s Public Accessibility Contact to receive and respond to written requests for information concerning any Significant Financial Interest (SFI) involving U.S. Department of Health and Human Services, Public Health Services (PHS) funded research as set forth in applicable federal regulations. Responses to written requests for information not involving PHS funded sponsored research will be made available to the public in accordance with the Texas Public Information Act and University SAP 61.01.02.M0.01 Public Information.

1.3. **GUIDELINES ON FINANCIAL CONFLICT OF INTEREST IN THE DESIGN, CONDUCT AND REPORTING OF SPONSORED RESEARCH**

   1.3.1 Disclosure of Financial Interests

   The guidelines set forth in System Regulation 15.01.03 *Financial Conflict of Interest in the Design, Conduct and Reporting of Sponsored Research and Educational Activities* apply to all sponsored research administered by or for the University. For each sponsored research proposal, if a potential conflict of interest does exist, Investigators are responsible for disclosing Significant Financial Interests (SFI) in accordance with the required to disclose the required information about any entity that could reasonably be affected by the sponsored research or educational activities being funded. (See System Regulation and federal requirements 15.01.03) All investigators applying for research and/or educational grants or contracts must complete a Significant Financial Interest Certification. If the investigator certifies that he/she may have a SFI significant financial interest, then the investigator must also complete and submit the required Significant Financial Interest Disclosure Form to the Designated Official, with any supporting documentation.

4.23.2 Review and Management of Disclosure

   3.2.1 Investigators must disclose SFIs to the Designated Official(s).

   No later than upon notification of an approved award, the Vice President for Research, or his or her designee, no later than the time a proposal is
submitted for funding; within thirty (30) days of discovering shall forward all pertinent information to the appropriate office designated by the Vice President for Research, or acquiring a SFI; and on an annual basis no later than August 31st of each year during the period ofhis or her designee, to conduct an award.

3.2.2 In accordance with initial review of all financial disclosures according to the College’s standard procedures and System Regulation 15.01.03 and federal requirements, the Designated Official(s) will review all SFI disclosures by Investigators and determine whether any SFI is related to research and a Financial Conflict of Interest (FCOI) exists. If a FCOI exists, the Designated Official(s) will develop a Management Plan specifying the actions that will be taken to manage such conflict. FCOIs identified by the Designated Official(s) will be satisfactorily managed, reduced or eliminated prior to the expenditure of funds under an award.

3.2.3 In accordance with System Regulation 15.01.03, the Designated Official(s) may appoint a Conflict of Interest Review Committee (CIRC) to assist in the determination of whether or not a FCOI exists. The Designated Official(s) and/or CIRC may involve the Investigator to determine whether or not the SFI is related to the research. The System Office of General Counsel may also be consulted as appropriate. The CIRC shall be composed of researchers representing a cross section of disciplines and a research administrator. The Designated Official(s) will appoint the chair of the CIRC.

4. MONITORING

4.1 Each person conducting research under a Management Plan shall comply fully and promptly with the Plan, and each person identified in the Management Plan as having responsibility for monitoring compliance with the Plan shall carefully and fully monitor that compliance. Additionally, the Office of the Vice President for Research shall be responsible for conducting periodic reviews of disclosures and Management Plans to determine individual and institutional compliance.

5. RECORDS

5.1 Records of Investigator SFIs and actions taken to manage FCOI shall be centrally maintained by the Office of the Vice President for Research.

1.2.1 If upon initial review it is determined that there may be a potential conflict of interest, the investigator will be notified by the Vice President for Research, or his or her designee, and the Disclosure packet will be forwarded to the University Conflict of Interest Review Committee and reviewed and administered according to System Regulation 15.01.03.

Conflict of Interest Review Committee members and chair are appointed by the Vice President for Research.
6. TRAINING

6.1 Investigators shall complete a training course relating to this rule prior to engaging in a research project at Texas A&M University and every four years thereafter. Additionally, Investigators must immediately complete training if the University changes this rule in a manner that affects Investigator requirements and whenever an Investigator is found not in compliance with this rule, related system regulation or Management Plan.

7. OTHER CONSIDERATIONS

7.1 In addition to the issues addressed in this rule, there may be other ethical considerations that are separate and distinct from conflict of interest questions including those relating to external employment and conflict of commitment.

CONFLICT OF COMMITMENT. The primary responsibility of employees of Texas A&M University is the accomplishment of the duties and responsibilities assigned to one’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 related regulations referenced below.

Related Statutes, Policies or Requirements

Supplements System Policy 15.01 and System Regulation 15.01.03

42 C.F.R. Part 50, Subpart F; 45 C.F.R. Part 94
21 C.F.R. Parts 54, 312,314, 320,330, 601, 807, 812 and 860
NSF Grant Policy Manual effective July 1, 2005, Chapter V, Section 510

Cross-reference:

System Policy 07.01 Ethics
http://policies.tamus.edu/07-01.pdf

System Policy 31.05 External Employment and Expert Witness
http://policies.tamus.edu/31-05.pdf

System Regulation 31.05.01 Faculty Consulting, External Employment and Conflicts of Interest
http://policies.tamus.edu/31-05-01.pdf

System Regulation 31.05.02 External Employment
http://policies.tamus.edu/31-05-02.pdf

Contact Office

Division of Research