## 15.01.03.C1

# Financial Conflicts of Interest in Sponsored Research



Revised: April 3, 2019

Next Scheduled Review: April 3, 2024

**Revision History** 

## **Rule Summary**

Texas A&M University-Corpus Christi (TAMU-CC) 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 conflict of interest. This rule implements the requirements of system regulation 15.01.03, Financial Conflicts of Interest in Sponsored Research.

## **Definitions**

Definitions of terms used in this rule are found in system regulation 15.01.03, Financial Conflicts of Interest in Sponsored Research.

## Rule

#### 1. APPOINTMENT OF CONFLICT OF INTEREST OFFICIAL

The President/CEO appoints the Vice President for Research and Innovation or their designee as the Conflict of Interest Official (COI Official) for TAMU-CC. The COI Official shall perform the duties established in system regulation 15.01.03, Financial Conflicts of Interest in Sponsored Research relating to the review of financial interest disclosures and the management and reporting of financial conflicts of interest.

## 2. DISCLOSURE AND REVIEW

Each investigator shall submit financial disclosure statements to the TAMU-CC COI Official as required in system regulation 15.01.03, Financial Conflicts of Interest in Sponsored Research.

- 2.1. In accordance with system regulation 15.01.03, Financial Conflicts of Interest in Sponsored Research and federal law, the COI Official will review all financial disclosure statements by investigators and determine whether any disclosed Significant Financial Interest (SFI) is related to the investigator's research and whether a Financial Conflict of Interest (FCOI) exists. If an FCOI exists, the COI Official will develop a management plan specifying the actions that will be taken to manage, reduce, or eliminate the FCOI. All FCOIs identified by the COI Official will 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, Financial Conflicts of Interest in Sponsored Research, the COI Official may appoint a Conflict of Interest Review Committee (CIRC) to assist in the determination of whether an 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 (1) 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 under a management plan shall comply fully and promptly with the plan. The COI Official 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, Financial Conflicts of Interest in Sponsored Research and federal law.

## 4. TRAINING AND CERTIFICATION

Investigators shall complete training as required in system regulation 15.01.03, Financial Conflicts of Interest in Sponsored Research. In addition, each investigator shall annually certify that the investigator is aware of and has read system regulation 15.01.03, Financial Conflicts of Interest in Sponsored Research 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. 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 Director of Communications to make the following information available in writing to any requestor within five (5) 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;
- (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 university shall 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.

#### 5.3. Non-PHS Funded Research

For all public information requests related to non-PHS funded research, the COI Official shall coordinate with the Director of Communications 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, Financial Conflicts of Interest in Sponsored Research and this rule, there may be other ethical considerations that are separate and distinct from conflict of interest questions including but not limited to those relating to external employment and conflict of commitment. The primary responsibility of employees of TAMU-CC 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 related regulations. Additional information regarding external consulting and other outside employment can be found in university rule 31.05.01.C1, Faculty Consulting,

External Professional Employment, and Conflicts of Interest and university procedure 31.05.02.C0.01, External Employment.

## 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

System Policy <u>15.01</u>, <u>Research Agreements</u>

System Regulation <u>15.01.03</u>, Financial Conflicts of Interest in Sponsored Research

System Policy <u>07.01</u>, <u>Ethics</u>

System Policy <u>31.05</u>, External Employment and Expert Witness

System Regulation 31.05.01, Faculty Consulting, External Employment and Conflicts of Interest

System Regulation <u>31.05.02, External Employment</u>

University Rule <u>31.05.01.C1</u>, Faculty Consulting, External Professional Employment, and Conflicts of Interest

University Procedure <u>31.05.02.C0.01</u>, External Employment

## **Appendix**

Financial Conflict of Interest (FCOI) Standard Operating Procedures

## **Contact Office**

Contact for interpretation and clarification: Vice President for Research and Innovation (361) 825-2577