

## Texas A&M Veterinary Medical Diagnostic Laboratory Rules

### 15.01.03.V1 | Financial Conflicts of Interest in Sponsored Research

*Approved: August 1, 2012*

*Reviewed: November 13, 2014*

*Next Scheduled Review: November 13, 2019*



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#### **RULE STATEMENT**

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Texas A&M Veterinary Medical Diagnostic Laboratory (TVMDL) 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.

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#### **REASON FOR RULE**

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

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#### **PROCEDURES AND RESPONSIBILITIES**

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##### 1.0 APPOINTMENT OF CONFLICT OF INTEREST OFFICIAL

The CEO appoints the AgriLife Assistant Director for Risk and Compliance or his or her designee as the Conflict of Interest Official (COI Official) for TVMDL. The COI Official shall perform the duties established in System Regulation 15.01.03 relating to the review of financial interest disclosures and the management and reporting of financial conflicts of interest.

##### 2.0 DISCLOSURE AND REVIEW

Each Investigator shall submit Financial Disclosure Statements to the TVMDL COI Official as required in 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 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, 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 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.

##### 3.0 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 and federal law.

#### 4.0 TRAINING AND CERTIFICATION

Investigators shall complete training as required in System Regulation 15.01.03. In addition, each Investigator shall 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.

#### 5.0 PUBLIC ACCESSIBILITY

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

5.2 If the COI Official determines that a Financial Conflict of Interest exists that is related to PHS-funded research, the COI Official shall coordinate with the Public Information Officer (PIO) 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;
- (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 system member 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 request related to non-PHS funded research, the COI Official shall coordinate with the PIO to ensure that responses to requests comply with Texas Government Code, Chapter 552.

#### 6.0 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 conflict of interest questions, including but not limited to those relating to external employment and conflict of commitment. The primary responsibility of employees of TVMDL 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.

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### **RELATED STATUTES, POLICIES, OR REQUIREMENTS**

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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*

[System Regulation 31.05.01](#), *Faculty Consulting, External Employment, and Conflicts of Interest*

[System Regulation 31.05.02](#), *External Employment*

[TVMDL Procedure 15.01.03.V1.01](#), *Financial Conflict of Interest in Research*

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## **DEFINITIONS**

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

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## **CONTACT OFFICE**

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For additional questions, contact the Texas A&M AgriLife Risk and Compliance Office at 979-845-7879.