

Approved: February 2, 2012

Revised: August 1, 2012

Reviewed: November 13, 2014

Next Scheduled Review: November 13, 2019



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## PROCEDURE STATEMENT

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Texas A&M Veterinary Medical Diagnostic Laboratory (TVMDL) is committed to conducting research and related activities in a manner consistent with the highest standards of integrity and ethics. As provided in System Regulation 15.01.03, *Financial Conflict of Interest in Sponsored Research*, TVMDL requires disclosure of individual financial conflict of interests during all phases of sponsored research and related activities. Protection of both the integrity and credibility of TVMDL staff and researchers is crucial in maintaining public trust and confidence in the agency's sponsored research and related activities.

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## REASON FOR PROCEDURE

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This procedure supplements System regulation 15.01.03, *Financial Conflict of Interest in Sponsored Research*, and TVMDL Rule 15.01.03.V1, *Financial Conflict of Interest in Sponsored Research*.

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## PROCEDURES AND RESPONSIBILITIES

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### 1.0 GENERAL

System Regulation 15.01.03, *Financial Conflict of Interest in Sponsored Research*, provides the standards for system member procedures in disclosure, review, appeal, recordkeeping, enforcement, training, research through sub-recipients and public accessibility relating to financial conflicts of interest in sponsored research, and applies to all sponsored research conducted by or for TVMDL. Other ethical considerations that are distinct and separate from conflict of interest questions may arise in addition to those addressed in System Regulation 15.01.03.

Since TVMDL is committed to the management, reduction, and/or elimination of any conflict of interest that may arise due to either financial or other personal interest of an "Investigator" (as defined in System Regulation 15.01.03), disclosure of any significant financial interest (SFI) related to an Investigator's institutional responsibility is required.

As provided in in System Regulation 15.01.03, corresponding policies, regulations, rules, and procedures apply broadly to all research activities regardless of funding source, as well as to research activities that do not have external funding, except as otherwise provided by federal law.

### 2.0 CONFLICT OF INTEREST OFFICIAL (COI)

The Assistant Director for Risk and Compliance or designee has been designated as the COI for TVMDL, as provided in TVMDL Rule 15.01.03.V1.

### 3.0 DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

3.1 Every Investigator and key personnel, as defined in System Regulation 15.01.03 (Section 4.1) will submit or update AG-116, *Financial Disclosure Statement*, to the COI Official identifying the requirements provided in Section 4.1 of System Regulation 15.01.03. AG-116 must be submitted annually no later than

August 31, and when any other conditions outlined in System Regulation 15.01.03 (Section 4.2) materialize.

- 3.2 Investigators must also submit or update a separate AG-116, *Financial Disclosure Statement*, for each Covered Family Member within the time periods specified in System Regulation 15.01.03 (Section 4.2), and will provide any additional documentation in relation to the disclosed SFI upon the request of the COI Official.

#### 4.0 REVIEW OF FINANCIAL INTEREST DISCLOSURE STATEMENTS AND EXPENDITURE OF FUNDS

- 4.1 The TVMDL COI Official will review form AG-116 submitted by Investigators, in accordance with System Regulation 15.01.03 (Section 5). Financial Conflict of Interest (FCOI) exist when the COI Official reasonably determines that an SFI held by either the Investigator or Covered Family Member could directly and significantly affect the design, conduct, or reporting of an Investigator's research.
- 4.2 There will be no expenditure of research funds by an Investigator or member in cases involving sponsored research unless the COI Official has determined that no FCOI exists or that any identified FCOI is managed under the terms of the Management Plan that has been both adopted and implemented, in accordance with System Regulation 15.01.03.
- 4.3 For unfunded research, research will not begin unless the COI Official has determined that no FCOI exists, or that any identified FCOI is managed under the terms of a Management Plan that has been both adopted and implemented.

#### 5.0 MANAGEMENT & APPEALS OF FINANCIAL CONFLICTS OF INTEREST

- 5.1 In accordance with System Regulation 15.01.03 (Section 8), in cases where the COI Official determines that a FCOI does exist, the COI Official will notify the Investigator, in writing, and work with the Investigator to develop a Management Plan that specifies the steps to be taken to manage, reduce, or eliminate the FCOI. The Management Plan must be signed by the Investigator, the Investigator's supervisor, and the COI Official.
- 5.2 Examples of conditions or restrictions that could be imposed to manage, reduce, or eliminate a FCOI are provided in System Regulation 15.01.03 (Section 8.2).
- 5.3 The Management Plan will include descriptions of the key elements as outlined in System Regulation 15.01.03 (Section 8.3).
- 5.4 In the case of NSF-funded research, the COI Official may allow the research to proceed without imposing conditions or restrictions in accordance with System Regulation 15.01.03 (Section 8.5).
- 5.5 If an investigator disagrees with the determination by the COI Official of the existence of a FCOI, the Investigator can appeal the decision to the CEO or TVMDL Compliance Committee in writing within 10 business days after receiving the COI Official's determination. Decisions by the CEO or TVMDL Compliance Committee are final.

#### 6.0 PUBLIC ACCESSIBILITY

The Public Information Officer (PIO) will make information for both PHS-funded and non PHS-funded research available to the public in accordance with procedures outlined in System Regulation 15.01.03 (Section 9), and Section 5.2 of TVMDL rule 15.01.03.V1.

#### 7.0 RETROSPECTIVE REVIEW

Retrospective reviews and noncompliance for all research will be conducted in accordance with System Regulation 15.01.03 (Section 10).

#### 8.0 RESEARCH THROUGH CONTRACTORS OR SUBRECIPIENTS

In accordance with System Regulation 15.01.03 (Section 11), when the agency conducts research in cooperation with or through a subrecipient, TVMDL will enter into a written agreement with the subrecipient in efforts to ensure compliance with all applicable laws, policies, regulations, rules, and procedures. In regards to FCOI disclosures, all research conducted in cooperation or through subrecipients will be in accordance with procedures provided in System Regulation 15.01.03 (Section 11).

## 9.0 TRAINING, EDUCATION, & CERTIFICATION

As provided in System Regulation 15.01.03, all Investigators and key personnel are required to comply with training requirements under federal law. Investigators will complete TrainTraQ Course number 2111453, *Conflict of Interest Training – Research Compliance*, according to the frequency of training outlined in System Regulation 15.01.03 (Section 12).

Annual certification that the Investigator is aware of and has read System Regulation 15.03.01 and related TVMDL Rules and Procedures as required by System Regulation 15.01.03 (Section 12) will be accomplished in conjunction with the annual disclosure of SFIs using form AG-116.

## 10.0 ENFORCEMENT

Oversights, violations, and compliance of this procedure and applicable System policies and regulations will be managed in accordance to System Regulation 15.01.03.

## 11.0 RECORDKEEPING

All FCOI disclosures and related documentation will be kept in Laserfiche in accordance with the records retention schedule defined in System Regulation 15.01.03 (Section 14).

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

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[System Policy 15.01](#), *Research Agreements*

[System Regulation 15.01.03](#), *Financial Conflict of Interest in Research*

Texas Veterinary Medical Diagnostic Laboratory Rule 15.01.03.V1, *Financial Conflict of Interest in Research*

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## **DEFINITIONS**

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Definitions of terms used in this procedure 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.