

15.01.03.E1.01 Documentation Requirements and Review Procedures for Individual Financial Conflict of Interest in the Sponsored Research and Other Sponsored Activities

Approved February 27, 2002
Revised October 21, 2008
Revised June 3, 2009
Revised July 14, 2011
Next Scheduled Review: July 14, 2014

Supplements System Policy 15.01, System Regulation 15.01.03, TEES Rule 15.01.03.E1

Standard Administrative Procedure Statement

The Texas Engineering Experiment Station (TEES) requires that individual financial conflict of interest be properly documented and reviewed as provided in System Regulation 15.01.03, TEES Rule 15.01.03.E1, and by this Standard Administrative Procedure (SAP).

Reason for Standard Administrative Procedure

This SAP is provided as a guide to implement TEES Rule 15.01.03.E1.

Procedures and Responsibilities

1. GENERAL

Investigators (as defined by System Regulation 15.01.03, Section 2.2) have a responsibility to disclose significant financial interests that might reasonably appear to be directly and significantly affected by the research or educational activities funded under a contract or grant.

2. DOCUMENTATION REQUIREMENTS

- 2.1 No later than the proposal submission, investigators are required to complete and submit form 3.1.01a, attaching all required supporting documentation (Disclosure Packet). The Disclosure Packet must contain the information required by System Regulation 15.01.03, Section 3.1. The completed Disclosure Packet shall be submitted to the Deputy Director through the investigator's division head and shall include a proposed resolution plan as required by System Regulation 15.01.03, Section 3.2.4. Each investigator shall submit separate forms for him/herself, his/her spouse and his/her dependent children.

Form 3.1.01a and the Disclosure Packet are available at the end of this SAP.

- 2.2 Supplemental disclosures are required to be filed by all investigators annually by August 31 of each year on form 3.1.01a through the investigator's division head to the Deputy Director.
- 2.3 Funds may not be expended until a formal decision has been received by Research Services indicating that the conflict of interest has been managed, reduced or eliminated. If a conflict of interest has been identified and a management plan approved, if required, it shall be reported to the funding agency, and if requested, the plans to manage, reduce or eliminate the conflict of interest may also be provided to the funding agency.
- 2.4 Prior to proposal submission, Research Services will obtain appropriate certification from subawardees, contractors or collaborators as required by System Regulation 15.01.03, Section 3.1.5.

3. DISCLOSURE REVIEW PROCESS

- 3.1 Completed Disclosure Packets shall be provided to the Deputy Director, who will conduct an initial review to determine if an existing or potential conflict of interest exists.
- 3.2 If, upon review, it is determined that a potential conflict of interest may exist, the handling, review, management, record keeping and enforcement actions used by TEES will be guided by System Regulation 15.01.03 and are the responsibility of the Deputy Director.
- 3.3 The Deputy Director will appoint a TEES Conflict of Interest Review Committee (CIRC), properly composed, to review submitted disclosures and proposed management plans.
 - 3.3.1 The CIRC shall rule on the request by either approving the resolution plan, amending the plan, or creating additional conditions to manage, reduce or eliminate any actual or potential conflict of interest. The CIRC shall rule on the request within 30 business days of receipt of the complete Disclosure Packet. An extension of time for this ruling must be approved by the Deputy Director.
 - 3.3.2 Within 10 business days of the date of the CIRC's decision the chair of the CIRC is responsible for incorporating the approved resolution plan into a Memorandum of Understanding to be signed by the investigator, the division head and chair of the CIRC.

3.3.3 Appeals of decisions by the CIRC must be made within 10 business days of the date of the decision. Appeals will be made directly to the Agency Director, whose decisions on appeals are final.

4. COMPLIANCE COMMITTEES

If the research or other sponsored activity involves human or animal subjects, the CIRC report shall be made available to the appropriate Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) upon request of that committee.

Related Statutes, Policies, or Requirements

[Policy 15.01, Research Agreements](#)

[Regulation 15.01.03, Conflict of Interest In the Design, Conduct and Reporting of Sponsored Research and Educational Activities](#)

[TEES Rule 15.01.03.E1, Individual Financial Conflict of Interest in the Design, Conduct and Reporting of Sponsored Research and Other Sponsored Activities](#)

[U.S. Department of Health & Human Services, 42 CFR Part 50 Subpart F](#)

Contact Office

Deputy Director
(979) 845-6946

Form 3.1.01a
Texas Engineering Experiment Station
Significant Financial Interest Disclosure Form
(Applicable to all TEES sponsored project proposals.)

Investigator/Staff Name _____
Division _____
Proposal Submitted To _____

I am disclosing the following Significant Financial Interests (check one) and attaching supporting documentation (Conflict of Interest Disclosure Packet) in an envelope marked "CONFIDENTIAL" that identifies the business enterprise(s) or entity(ies) involved and the nature* and amount of the interest:

("Significant Financial Interests" are defined when either of the following two conditions are met: 1) an equity interest that when aggregated for the investigator and the investigator's spouse and dependent children exceeds \$10,000 in value as determined through reference to public access or other reasonable measures of fair market value and represents more than a 5% ownership interest in any single entity or 2) salary, royalties or other payments that when aggregated for the investigator and investigator's spouse and dependent children over the next 12 months, are expected to exceed \$10,000. (See System Regulation 15.01.03, Section 2.3)

- Salary or other payment for services (e.g., consulting fees or honoraria).
- Equity interests (e.g., stocks, stock options, or other ownership interests).
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights).
- Other Significant Financial Interest of the investigator that possibly could affect or be perceived to affect the results of the research or educational activities funded or proposed for funding.

*Does the nature of the research proposed have a potential to affect the activities of the business enterprise or entity(ies) involved? Activities include research, marketing, and sales activity of a product or service.

I agree Further:

- To update this disclosure during the period of the award, on an annual basis and as new significant financial interests are obtained;
- To cooperate in the development of a Memorandum of Understanding (MOU) that constitutes a conflict of interest "resolution plan;" and
- To comply with any conditions or restrictions imposed by the University/TEES to manage, reduce, or eliminate actual or potential conflicts of interest or forfeit the award.

Signed: _____ Date: _____
(Original signature ONLY- a "per" signature will not be accepted.)

Endorsements:

I have reviewed the Significant Financial Interest disclosure and believe that it will be possible to develop and execute, prior to the expenditure of any fund under the award, an MOU to manage, reduce, or eliminate any actual or potential conflict of interest; and, therefore, I recommend that the proposal be submitted to the agency at this time.

Division Head: _____ Date: _____
Signed
Associate Director: _____ Date: _____
Signed

Accepted- No actual conflict. Referred to Committee

Committee Action:

SUGGESTED OUTLINE
CONFLICT OF INTEREST DISCLOSURE PACKET
(Version July 2011)

Name:

Date:

Title:

Division:

1. Name of Company with which there is a proposed/existing relationship:
2. Describe the nature of the relationship.
3. Describe your role in the proposed activity/relationship.
4. Who else will be involved in the activity (i.e. students, other faculty, etc.) and how?
5. Describe how the proposed relationship might affect your TEES research including the research projects of your students and postdocs.
6. How will the research and scholarship of students and others be protected from any consequences of your relationship with outside entities?
7. Describe how you intend to separate any potential conflicts between your TEES responsibilities and your proposed activities with the business entity.
8. Do you or a member of your immediate family hold a substantial interest in, or participate in the management or conduct the affairs the business entity (see, TAMUS Regulation 31.05.01)?
Yes _____ If so, identify.
No _____
9. Do you or a member of your immediate family or any combination thereof have a controlling interest in the business entity?
Yes _____ If so, identify.
No _____
10. Do you or a member of your immediate family have ownership in excess of ten percent of the voting interest in the business entity?
Yes _____ If so, identify.
No _____
11. Do you or a member of your immediate family have ownership in excess of \$25,000 of the fair market value of the business entity?
Yes _____ If so, identify.
No _____
12. Do you or a member of your immediate family have any participating interest, either direct or indirect, by shares, stock, or otherwise, whether or not voting rights are included, in the profits, proceeds or capital gains of the business entity in excess of 10 percent?
Yes _____ If so, identify.
No _____

CONFLICT OF INTEREST DISCLOSURE PACKET - continued

13. Do you or a member of your immediate family serve as an officer, board member and/or employee of the business entity?
Yes _____ If so, identify.
No _____
14. What is the amount of compensation received from the activities listed in item 13, including any benefits, direct or indirect (reported by range amounts)?
[See TAMUS Regulation 15.01.03, Section 3.1(4)]
15. Are you the creator/developer of technology which is the subject matter of the proposed relationship?
Yes _____ If so, describe.
No _____
16. Does the business entity have an agreement with TAMUS relating to the research, development, licensing or exploitation of intellectual property in which TAMUS has an ownership interest?
17. What is the amount of benefits you have received from the intellectual property rights for technology you developed that have been licensed to the business entities identified in item 16?
18. When aggregated, do you and any members of your immediate family hold an equity interest in the business entity that both exceeds \$10,000 in value and represents more than a 5% ownership interest in the business entity?
[See, TAMUS Regulation 15.01.03, Section 2.3.1(1)]
19. When aggregated, do you and any members of your immediate family expect to receive more than \$10,000 in salary, royalties or other payments from the business entity in the next twelve months?
[See, TAMUS Regulation 15.01.03, Section 2.3.1(2)]

The foregoing suggested outline is intended to provide a brief overview of that which must be disclosed pursuant to TAMUS Policies and Regulations. It is not intended to address all conflicts which may arise. For specific details, consult TAMUS Policies 07.01, 17.01, Section 6, and 31.05; TAMUS Regulations 15.01.03 and 31.05.01.

SUGGESTED OUTLINE
CONFLICT OF INTEREST MANAGEMENT PLAN
(Verizon July 2011)

Name: _____ Date: _____
Title: _____
Division: _____

A. Identification of actual or apparent conflict of interest relating to position at TEES.

B. Recommended Management Plan

[Steps that will be taken to manage, reduce or eliminate any actual or potential conflict of interest presented by the Significant Financial Interest including as appropriate:

- (1) public disclosure of Significant Financial Interests;
- (2) review of research protocol by independent reviewers;
- (3) monitoring of research by independent reviewers;
- (4) modifying the research plan;
- (5) disqualification from participating in all or a portion of the research funded;
- (6) divestiture of significant financial interests; and
- (7) severance of relationships that create actual or potential conflicts of interest.]

INVESTIGATOR SIGNATURE

DIVISION HEAD SIGNATURE