



TEXAS TECH UNIVERSITY™

Operating Policy and Procedure

OP 70.37: Disclosure of Significant Business or Financial Interests that may Represent Conflicts of Interest

DATE: August 23, 2012

PURPOSE: The purpose of this Operating Policy/Procedure (OP) is to ensure that faculty and staff ~~are aware of and~~ remain free from conflicts of interest as a result of interaction with the public and private sectors.

REVIEW: This OP will be reviewed in August of even-numbered years by the associate vice president for research, ~~(integrity)~~ (AVPR) with substantive revisions presented to the ~~vice president for research.~~

POLICY/PROCEDURE

1. Introduction

Texas Tech University (TTU) recognizes its responsibilities as a public institution to encourage interaction between its employees and the public and private sectors as an important component of its research, instructional, and service activities. The university encourages the recruitment, retention, and recognition of creative individuals who promote interactions with industry, the business community, and other public or private entities consistent with their primary commitment to the university. The university and its employees also are committed to conducting themselves and their activities in a manner consistent with the highest standards of integrity and ethics.

Federal regulations require that institutions have policies and procedures in place to ensure that employees disclose any significant financial interests that may represent an actual or potential conflict of interest in relationship to externally sponsored projects. Therefore, this document articulates the general university regulations and procedures regarding conflicts of interest, which serve to protect the credibility and the integrity of the university's faculty and staff, as well as the institution, so that public trust and confidence in its sponsored activities are not compromised in any way. Furthermore, the National Institutes of Health (NIH) requires that institutions promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest. Therefore, this document provides specific reference to unique requirements for employees who are planning to participate in, or are participating in, PHS research funding received as a grant or cooperative agreement.

The potential for conflict arises because of the nature and scope of activities engaged in by the university and its employees. The university assumes that potential for conflicts will occur regularly in the normal conduct of activities. However, it is essential that any significant potential for conflicts be disclosed and reviewed by the university. After disclosure, the university can then

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make an informed judgment about a particular case and require appropriate oversight, limitations, or prohibitions on the activity. Employees may not engage in activities in which an actual unmanageable conflict of interest occurs.

In addition to issues addressed in these regulations, there may be ethical considerations that are distinct and separate from conflict of interest questions.

2. Applicability

This policy applies to all employees of TTU. Section 3 applies to all employees of TTU, and to persons who are subgrantees, contractors, consortium participants, collaborators, or consultants, who are not covered by section 4. Section 4 applies to all employees of TTU and to persons who are subgrantees, contractors, consortium participants, collaborators, or consultants, who are planning to participate in, or are participating in, PHS research funding received as a grant or cooperative agreement.

3. For All TTU Employees and Other Individuals, Who are Not Covered by Section 4

a. Definitions

- (1) "Investigator" means the principal investigator, co-principal investigators, project director, and any other person at TTU or its subgrantees, contractors, or collaborators who is responsible for the design, conduct, or reporting of research or educational activities that are funded or proposed for funding by any external entity. Usually, these will be the individuals whose names appear on the *Internal Routing Sheet for Sponsored Projects*. The definition of investigator includes the investigator's family members, defined as a spouse and dependent relatives or household members. These definitions align with those in Chapter 03, *Regents' Rules*, regarding conflicts of interest.

- (2) "Significant business or financial interest" means anything of monetary value including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). Examples of Significant Business or Financial Interests are:

(1) An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent relatives or household members, (1) exceeds \$5,000 in value, as determined through reference to public prices or other reasonable measures of fair market value; or (2) represents more than a 5 percent ownership interest in any single entity; or

(2) Salary, royalties, gifts such as paid travel, or other payments that, when aggregated for the investigator and the investigator's spouse and dependent relatives or household members, are expected to exceed \$5,000 from any single entity during the next 12-month period.

Significant Business or Financial Interest does not include:

- (a) Salary, royalties, or other remuneration from TTU;

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Viator, Ralph 10/25/13 4:05 PM

Comment [1]: Proposed wording change by Ralph Viator. The statement that the following "must be disclosed" is incorrect.

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Comment [2]: Delete wording. Ralph Viator

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Comment [3]: Changed from \$10,000 to \$5000.

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Comment [4]: Amy, we need to change the wording from "and" to "or". Ralph Viator

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Comment [5]: Changed from \$10,000 to \$5000.

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- (b) Royalties and honoraria for published scholarly or creative works;
- (c) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (d) Income from service on advisory committees or review panels for public or nonprofit entities;

(e) Mutual funds and other managed accounts, such as retirement accounts; however, investments in retirement accounts in which the investigator has control over which specific stocks or other equity interests are purchased, might trigger a need for disclosure if a particular holding directed by the investigator would reasonably appear to be affected by the specific research project.

- (3) "Unit head" means department chair, area coordinator, director, or, in the case of colleges that do not have areas or departments, the dean.
- (4) "Designated official" means dean of a college, director of a center or institute, or a vice president in charge of a non-academic unit. In some cases, the unit head and the designated official will be the same person.
- (5) "Entity" means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent relatives or household members) receives remuneration or in which any person has an ownership or equity interest.

b. Procedure

(1) Annual Disclosure

All employees and other individuals planning to act as investigators shall disclose to the AVPR by October 1 of each year, the following significant business or financial interests, including interests of their spouse and dependent relatives or household members:

- (a) Any significant business or financial interest that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
- (b) Any significant business or financial interest in an entity whose business or financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

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Comment [6]: These two paragraphs were removed from "does not include" and moved above to affirmatively define what shall be disclosed as a significant business and financial interest. (e and f are now 3. a. (2) (1) and (2) above.

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Comment [7]: Clarification proposed by the Faculty Senate Committee (Faculty Status and Welfare Committee).

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Comment [8]: To ensure compliance, the primary person to report to (to disclose to) is the AVPR. Disclosure procedure is below.

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Employees planning to act as investigators who have no significant business or financial interests as described above shall submit a certification to that effect.

The general declaration form, *Confidential General Disclosure of Either Significant or No Significant Business or Financial Interests in any External Entity* (Attachment B), and the detailed disclosure form, *Confidential Supplemental Detailed Disclosure of Significant Business or Financial Interest* (Attachment C), shall be used for general declarations and detailed disclosures. Employees with no significant business or financial interests should complete and sign only Attachment B. Employees with significant interests should complete and sign both Attachment B and Attachment C for each entity in which they have a significant business or financial interest.

All forms (those reporting no significant business or financial interests and those reporting significant business or financial interests) must be forwarded to the unit head, then from the unit head to the designated official, and finally from the designated official to the AVPR. The forms should be completed and submitted via the secure, online interactive questionnaire available via an eRaider-authenticated link or in hard copy if the online system is not available.

Further, the outside employment or consulting approval form, *Other Employment, Faculty Consulting, and Public Offices Form* (Attachment A), can be used to request approval of outside employment, as required by OP 32.07. This approval process is managed by the Office of the Provost and Senior Vice President, and the form can be submitted using the instructions on the form.

If there is a change in the reported information during the year, the employee shall submit an updated form to the AVPR (See section 3, a, (2)).

Regardless of the minimum requirements above, an employee may choose to disclose any other business, financial, or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Such reporting shall not predate any required submissions to the Securities and Exchange Commission (SEC), nor shall such reports contain information that would be restricted under insider information regulations of the SEC.

If a conflict of interest has been declared, the AVPR shall take actions necessary to ensure that such conflicting interests will be managed, reduced to an acceptable level, or eliminated. In making this determination, the AVPR may choose to seek the advice of individuals, chairpersons, deans, a committee appointed by the AVPR, the Office of the General Counsel, the TTUS Office of Technology Commercialization, the TTUS Office of Audit Services, or other university administrators. The AVPR, in concert with the investigator, will prepare a management plan for managing, reducing, or eliminating the conflict; this document will be signed by the investigator, unit head, designated official, and AVPR. A signed management plan must be in place prior to expenditure of funds under the award.

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If the AVPR and the investigator have not agreed upon a management plan 30 days following a determination that a conflict exists, the investigator may seek the intervention of the vice president for research (VPR).

The AVPR shall maintain records of all business or financial disclosures and all actions taken with respect to each conflicting interest for three years beyond the termination or completion of the award to which they relate, or until the resolution of any government action involving those records, whichever is longer.

The AVPR shall maintain the confidentiality of disclosures and management plans, insofar as possible. Disclosures should be forwarded as per instructions in the disclosure forms.

(2) Certification at the Time of Proposal Submission

Prior to submitting a proposal for funding to any external agency, each investigator shall certify that he/she has disclosed any significant business or financial interests (including those of a spouse and dependent relatives or household members) that would reasonably appear to be affected by the project for which funding is sought, and the unit head shall certify that, based on the investigator's disclosure, either: (1) no conflicts of interest exist; or (2) existing conflicts will be managed, reduced to an acceptable level, or eliminated prior to expenditure of funds under the award. These certifications shall be made by signing the *Internal Routing Sheet for Sponsored Projects*.

(3) Review of Disclosures

The process outlined in section b. (1) above is applicable.

The AVPR shall review the disclosure. If the AVPR determines that no conflict of interest exists, the AVPR or designee shall make the appropriate notation on the form and the form will be stored in a manner to protect confidentiality. The AVPR or designee shall make his/her determination within 30 days of receipt of the disclosure.

If the AVPR determines that a conflict of interest exists, the AVPR shall take actions necessary to ensure that such conflicting interests will be managed, reduced to an acceptable level, or eliminated. In making this determination, the AVPR may choose to seek the advice of individuals, chairpersons, deans, a committee appointed by the AVPR, the Office of the General Counsel, the TTUS Office of Technology Commercialization, the TTUS Office of Audit Services, or other university administrators. The AVPR, in concert with the investigator, will prepare a management plan for managing, reducing, or eliminating the conflict; this document will be signed by the investigator, unit head, designated official, and AVPR. A signed management plan must be in place prior to expenditure of funds under the award.

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If the AVPR and the investigator have not agreed upon a management plan 30 days following a determination that a conflict exists, the investigator may seek the intervention of the SVPR.

The AVPR shall maintain records of all business or financial disclosures and all actions taken with respect to each conflicting interest for three years beyond the termination or completion of the award to which they relate, or until the resolution of any government action involving those records, whichever is longer.

The AVPR shall maintain, insofar as possible, the confidentiality of disclosures and management plans. Disclosures should be forwarded as per instructions in the disclosure forms.

c. External Reporting

The AVPR shall be responsible for all reporting requirements to external agencies. These include the following:

- (1) The AVPR will sign institutional certifications required in proposals.
- (2) The AVPR will report the existence of a conflict and its management plan to the SVPR.

- (4) The AVPR will notify the sponsoring agency in the event an employee has failed to comply with the university's policy.
- (5) The AVPR will notify the sponsoring agency in the event that TTU is unable to manage a conflict of interest satisfactorily.
- (6) In the event a conflict of interest is identified after the expenditure of funds under an award, the AVPR will, within 60 days of identifying the conflict (less time if required by the sponsoring agency), notify the agency of the existence of the conflict and assure that the conflict has been managed, reduced to an acceptable level, or eliminated.
- (7) Upon request from any sponsoring agency or other authorized government entity, the AVPR will provide information regarding all conflicting interests identified by TTU and describe how those interests have been managed, reduced to an acceptable level, or eliminated.
- (8) In the event that an investigator fails to comply with the university's conflict of interest policy and has biased the design, conduct, or reporting of an externally funded project, the AVPR will notify the agency of corrective action taken.

d. Guidelines

A conflict of interest exists when the designated official reasonably determines that a significant business or financial interest could directly and significantly affect the design, conduct, or reporting of externally funded research, service, or educational activities.

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Comment [9]: No longer applicable in this section.

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Significant financial interests in companies submitting proposals to Small Business Innovation Research Programs and Small Business Technology Transfer Programs are specifically excluded from the federal definition of conflict of interest.

- (1) Examples of manageable conflicts of interest include, but are not limited to, the following:
 - (a) Situations in which the outside activity will conflict with previously established responsibilities to the university;
 - (b) Situations that might allow a university employee to influence the university's dealings with an outside organization, such that personal gain for the employee or improper advantage for anyone is the result; and
 - (c) Supervision of student research activities when research in that area might lead to financial or personal gain for the faculty member
- (2) Examples of unacceptable conflicts of interest include, but are not limited to, the following:
 - (a) Use for personal profit of unpublished information originating from university research or other confidential university sources;
 - (b) Consulting under arrangements that impose obligations that conflict with the university's intellectual property policy or with the university's obligations to research sponsors or that inhibit the publication of research results obtained within the university; and
 - (c) Circumstances in which a substantial body of research that could, and ordinarily would, be carried on within the university is conducted elsewhere to the disadvantage of the university and its legitimate interests
- (3) Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate conflicts of interest include, but are not limited to:
 - (a) Public disclosure of significant business or financial interests;
 - (b) Disclosure of conflicts of interest in each public presentation of the results of the research;
 - (c) Review of research protocol by independent reviewers;
 - (d) Monitoring of research by independent reviewers;
 - (e) Modification of the research plan;
 - (f) Disqualification from participation in the portion of the externally funded research that would be affected by the significant business or financial interests;
 - (g) Divestiture of significant business or financial interests; or

(h) Severance of relationships that create conflicts

e. Compliance

No proposals will be submitted without the required certifications. If a conflict is identified, the proposal may be submitted before the management plan is implemented if the designated official determines that the conflict can be managed or eliminated prior to the award of funds. No awarded funds will be spent until the conflict is resolved.

If breaches of the policy occur, sanctions will be imposed. Breaches include, but are not limited to: failure to file; intentionally filing an incomplete, erroneous, or misleading disclosure form; failing to provide additional information as required by the unit head or designated official; or violation of terms outlined in the management plan. If sanctions are necessary, they will be imposed in accordance with the university's OPs (e.g., OP 74.08, Allegations of Misconduct in Research or Scholarly Activity). The potential sanctions may include, but are not limited to, the following:

- Letter of admonition
- Suspension of award funds
- Ineligibility of the employee for grant applications or supervision of graduate students
- Suspension, including withholding of salary
- Non-renewal of appointment
- Dismissal

Impending actions may be appealed by the employee to the university in accordance with procedures outlined in OP 32.05, Faculty Grievance Procedures, or OP 70.10, Non-faculty Employee Complaint Procedures.

For additional information on conflicts of interest, see Chapter 03, *Regents' Rules*, OPs 10.11, 32.07, 70.31, 74.04, and 74.08, and Government Code, § 572.051, Standards of Conduct; State Agency Ethics Policy.

4. For All TTU Employees and Other Individuals Participating in, or Planning to Participate in, PHS Research Funding Received as a Grant or Cooperative Agreement

a. Definitions

- (1) "Investigator" means the principal investigator, project director, and any other person at TTU, or its subgrantees, contractors, or collaborators, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the Public Health Service (PHS), or proposed for such funding. The definition of investigator includes the investigator's family members, defined as a spouse and dependent relatives or household members. These definitions align with those in Chapter 03, *Regents' Rules*, regarding conflicts of interest.

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- (2) Key personnel includes the PD/PI and any other personnel considered to be essential to work performance, in accordance with HHSAR subpart 352.242–70 (see http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf) and identified as key personnel in the contract proposal and contract.
- (3) "Significant business or financial interest" means:
- (a) A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and dependent relatives or household members) that reasonably appears to be related to the investigator's institutional responsibilities:
- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests

(b) Investigators who are planning to participate in PHS-funded research must disclose their reimbursed or sponsored travel related to their institutional responsibilities for which the aggregate amount exceeds \$5000 in value from a single entity over the previous twelve-month period. Reimbursed or sponsored travel includes that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The AVPR will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest (FCOI) with the PHS-funded research. Once Investigators have made their initial disclosure, they are required to update their disclosures within 30 days of acquiring reimbursed or sponsored travel that exceeds \$5000 in value from a single entity over the previous twelve-month period. These reimbursements apply to the Investigator and his/her spouse and/or dependent children.

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Comment [10]: The threshold to disclose travel is increased from any amount to an aggregate amount of \$5000 from a single entity in the 12 months prior to disclosure/application to PHS.

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- (c) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by TTU to the investigator if the investigator is currently employed or otherwise appointed by TTU, including intellectual property rights assigned to TTU and agreements to share in royalties related to such rights; any ownership interest in TTU held by the investigator; income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- (4) "Unit head" means department chair, area coordinator, director, or, in the case of colleges that do not have areas or departments, the dean.
- (5) "Designated official" means dean of a college, director of a center or institute, or a vice president in charge of a non-academic unit. In some cases, the unit head and the designated official will be the same person.
- (6) "Entity" means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent relatives or household members) receives remuneration or in which any person has an ownership or equity interest.

b. Procedure

(1) Training

All employees and other individuals planning to act as investigators must complete training regarding financial conflict of interest prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

- (a) TTU revises its financial conflict of interest policies or procedures in any manner that affects the requirements of investigators;
- (b) An investigator is new to TTU; or
- (c) TTU finds that an investigator is not in compliance with TTU's financial conflict of interest policy or management plan.

Appropriate training is provided by NIH and Collaborative Institutional Training Initiative (CITI) <https://www.citiprogram.org/Default.asp>. To identify appropriate

training and submit training records, an investigator should contact ResearchIntegrity@TTU.edu.

(2) Annual Disclosure

All employees **and other individuals** planning to act as investigators shall disclose, no later than the time of application for PHS-funded research and annually thereafter, by October 1 of each year, to the unit head the following significant business or financial interests, including interests of their spouse and dependent relatives or household members:

- (a) Any significant business or financial interest that would reasonably appear to be **related to the Investigator's institutional responsibilities; or**
- (b) Any significant business or financial interest in an entity whose business or financial interest would reasonably appear to be **related to the Investigator's institutional responsibilities.**

The annual disclosures shall include any information that was not disclosed initially to TTU or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

Each investigator who is participating in the PHS-funded research shall submit an updated disclosure of significant financial interests within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Employees planning to act as investigators who have no significant business or financial interests as described above shall submit a certification to that effect.

The general declaration form, *PHS-Specific Confidential General Disclosure of Either Significant or No Significant Business or Financial Interests in any External Entity* (Attachment D), and the detailed disclosure form, *PHS-Specific Confidential Supplemental Detailed Disclosure of Significant Business or Financial Interest* (Attachment E), shall be used for general declarations and detailed disclosures. Employees with no significant business or financial interests should complete and sign only Attachment D. Employees with significant interests should complete and sign both Attachment D and Attachment E for each entity in which they have a significant business or financial interest.

All forms (those reporting no significant business or financial interests and those reporting significant business or financial interests) must be forwarded to the unit head, then from the unit head to the designated official, and finally from the designated official to the AVPR. The forms should be completed and submitted via the secure, online interactive questionnaire available via an eRaider-authenticated link or in hard copy if the online system is not available. Further, the outside employment or consulting approval form, Other Employment, Faculty Consulting, and Public Offices Form (Attachment A), can be used to request approval of outside employment, as

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required by OP 32.07. This approval process is managed by the Office of the Provost and Senior Vice President, and the form can be submitted using the instructions on the form.

If there is a change in the reported information during the year, the investigator shall submit updated forms to the AVPR.

Regardless of the above minimum requirements, an investigator may choose to disclose any other business, financial, or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Such reporting shall not predate any required submissions to the Securities and Exchange Commission (SEC), nor shall such reports contain information that would be restricted under insider information regulations of the SEC.

If a conflict of interest has been declared, the AVPR shall take actions necessary to ensure that such conflicting interests will be managed, reduced to an acceptable level, or eliminated. In making this determination, the AVPR may choose to seek the advice of individuals, chairpersons, deans, a committee appointed by the AVPR, the Office of the General Counsel, the TTUS Office of Technology Commercialization, the TTUS Office of Audit Services, or of other university administrators. The AVPR, in concert with the investigator, will prepare a [management plan](#) for managing, reducing, or eliminating the conflict; this document will be signed by the investigator, unit head, designated official, and AVPR.

If the AVPR and the investigator have not agreed upon a [management plan](#) 30 days following the determination that a conflict exists, the investigator may seek the intervention of the [vice president for research \(VPR\)](#).

The AVPR shall maintain records of all business or financial disclosures and all actions taken with respect to each conflicting interest for three years beyond the termination or completion of the award to which they relate, or until the resolution of any government action involving those records, whichever is longer.

The AVPR shall maintain the confidentiality of disclosures and [management plans](#), insofar as possible. Disclosures should be forwarded as per instructions in the disclosure forms.

(3) Certification at the Time of Proposal Submission

Prior to submitting a proposal for funding to the Public Health Service (PHS), each investigator shall certify that he/she has disclosed any significant business or financial interests (including those of a spouse and dependent relatives or household members) that would reasonably appear to be [related to the Investigator's institutional responsibilities](#), and the unit head shall certify that, based on the investigator's disclosure, either: (1) no conflicts of interest exist; or (2) existing conflicts will be managed, reduced to an acceptable level, or eliminated prior to expenditure of funds under the award. These certifications shall be made by signing the *Internal Routing Sheet for Sponsored Projects*.

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Comment [11]: PHS regulation requires Investigators to disclose interests that are related to the Investigator's institutional responsibilities.

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(4) Review of Disclosures

The process outlined in section b.(2) above is applicable.

The AVPR shall review the disclosure. If the AVPR determines that no conflict of interest exists, the AVPR or designee shall make the appropriate notation on the form and the form will be stored in a manner to protect confidentiality. The AVPR or designee shall make his/her determination within 30 days of receipt of the disclosure.

If the AVPR determines that a conflict of interest exists, the AVPR shall take actions necessary to ensure that such conflicting interests will be managed, reduced to an acceptable level, or eliminated. In making this determination, the AVPR may choose to seek the advice of individuals, chairpersons, deans, a committee appointed by the AVPR, the Office of the General Counsel, the TTUS Office of Technology Commercialization, the TTUS Office of Audit Services, or other university administrators. The AVPR, in concert with the investigator, shall prepare a management plan for managing, reducing, or eliminating the conflict; this document will be signed by the investigator, unit head, designated official, and AVPR.

If the AVPR and the investigator have not agreed upon a management plan 30 days following a determination that a conflict exists, the investigator may seek the intervention of the SVPR.

The AVPR shall maintain records of all business or financial disclosures and all actions taken with respect to each conflicting interest for three years beyond the termination or completion of the award to which they relate, or until the resolution of any government action involving those records, whichever is longer.

The AVPR shall maintain, insofar as possible, the confidentiality of disclosures and management plans. Disclosures should be forwarded as per instructions in the disclosure forms.

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c. External Reporting

The AVPR shall be responsible for all reporting requirements to external agencies. These include the following:

- (1) The AVPR will sign institutional certifications required in proposals.
- (2) The AVPR will report the existence of a conflict and its management plan to the SVPR.
- (3) For proposals to the PHS, the AVPR will report to PHS the existence of a conflict, but not the details of the conflict, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI. Furthermore, whenever TTU implements a management plan in accordance with PHS policy, the AVPR shall monitor investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

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Prior to expenditure of any funds under a PHS-funded research project, TTU shall provide to the PHS awarding component an FCOI report regarding any investigator's significant

financial interest found by AVPR to be conflicting and ensure that TTU has implemented a management plan in accordance with this section. In cases in which the AVPR identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, TTU shall not submit an FCOI report to the PHS awarding component.

For any significant financial interest that the AVPR identifies as conflicting subsequent to TTU's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an investigator who is new to the research project), TTU shall provide to the PHS awarding component, within 60 days, an FCOI report regarding the financial conflict of interest and ensure that TTU has implemented a management plan in accordance with this section. Pursuant to subsection (7) below, where such FCOI report involves a significant financial interest that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed or managed by the institution (e.g., it was not reviewed in a timely manner or reported by a subrecipient), TTU also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, TTU is required to notify the PHS awarding component promptly and submit a mitigation report to the PHS awarding component.

- (4) Any required FCOI report shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the financial conflict, and to assess the appropriateness of TTU's management plan. Elements of the FCOI report shall include, but are not necessarily limited to, the following:
 - (a) Project number;
 - (b) PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - (c) Name of the investigator with the financial conflict of interest;
 - (d) Name of the entity with which the investigator has a financial conflict of interest;
 - (e) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - (f) Value of the financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
 - (g) A description of how the financial interest relates to the PHS-funded research and the basis for TTU's determination that the financial interest conflicts with such research; and
 - (h) A description of the key elements of TTU's management plan including:
 - Role and principal duties of the conflicted investigator in the research project;
 - Conditions of the management plan;

- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the investigator's agreement to the management plan;
- How the management plan will be monitored to ensure investigator compliance; and
- Other information as needed

For any financial conflict of interest previously reported by TTU with regard to an ongoing PHS-funded research project, TTU shall provide to the PHS awarding component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. TTU shall provide annual FCOI reports to the PHS awarding component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS awarding component.

- (5) Whenever, in the course of an ongoing PHS-funded research project, an investigator who is new to participating in the research project discloses a significant financial interest or an existing investigator discloses a new significant financial interest to TTU, the AVPR shall, within 60 days: (1) review the disclosure of the significant financial interest; (2) determine whether it is related to PHS-funded research; (3) determine whether a financial conflict of interest exists; and, if so, (4) implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, TTU may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS-funded research project between the date of disclosure and the completion of TTU's review.
- (6) The AVPR will notify the sponsoring agency in the event an employee has failed to comply with the university's policy.
- (7) Whenever TTU identifies a significant financial interest that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed by TTU during an ongoing PHS-funded research project (e.g., was not reviewed in a timely manner or reported by a subrecipient), the AVPR shall, within 60 days: (1) review the significant financial interest; (2) determine whether it is related to PHS-funded research; (3) determine whether a financial conflict of interest exists; and, if so:
 - (a) Implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage such financial conflict of interest going forward.
 - (b) In addition, whenever (1) a financial conflict of interest is not identified or managed in a timely manner, including failure by the investigator to disclose a significant financial interest that is determined by TTU to constitute a financial conflict of interest; (2) failure by TTU to review or manage such a financial conflict of interest; or (3) failure by the investigator to comply with a financial

conflict of interest management plan, TTU shall, within 120 days of TTU's determination of noncompliance, complete a retrospective review of the investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

By PHS policy, TTU is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- Project number;
 - Project title;
 - PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - Name of the investigator with the FCOI;
 - Name of the entity with which the investigator has a financial conflict of interest;
 - Reason(s) for the retrospective review;
 - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - Findings of the review; and
 - Conclusions of the review
- (c) Based on the results of the retrospective review, if appropriate, TTU shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, TTU is required to notify the PHS awarding component promptly and submit a mitigation report to the PHS awarding component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of the bias on the research project, and TTU's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, TTU will submit FCOI reports annually, as specified above. Depending on the nature of the financial conflict of interest, TTU may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the investigator's noncompliance is determined and the completion of TTU's retrospective review.
- (8) The AVPR will notify the sponsoring agency in the event that TTU is unable to manage a conflict of interest satisfactorily.
- (9) In the event a conflict of interest is identified after the expenditure of funds under an award, the AVPR will, within 60 days of identifying the conflict (or in less time if required by the sponsoring agency), notify the agency of the existence of the conflict and assure that the conflict has been managed, reduced to an acceptable level, or eliminated.

- (10) Upon request from any sponsoring agency or other authorized government entity, the AVPR will provide information regarding all conflicting interests identified by TTU and describe how those interests have been managed, reduced to an acceptable level, or eliminated.
- (11) In the event that an investigator fails to comply with the university's conflict of interest policy and has biased the design, conduct, or reporting of PHS-funded research, the AVPR shall promptly notify the PHS awarding component of the corrective action taken or to be taken.
- (12) Prior to TTU's expenditure of any funds under a PHS-funded research project, TTU shall ensure public accessibility, via written response from the AVPR to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to TTU that meets the following three criteria:
 - (a) The significant financial interest was disclosed and is still held by the senior/key personnel as defined in section 4.a.(3) above;
 - (b) TTU determines that the significant financial interest is related to the PHS-funded research; and
 - (c) TTU determines that the significant financial interest is a financial conflict of interest.

The information that TTU makes available via written response to any requestor within five business days of a request shall include, at a minimum, the following: the investigator's name; the investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Information concerning the significant financial interests of an individual subject to this section shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

d. Guidelines

A conflict of interest exists when the designated official reasonably determines that a significant business or financial interest could directly and significantly affect the design, conduct, or reporting of externally funded research, service, or educational activities.

Significant financial interests in companies submitting proposals to Small Business Innovation Research Programs and Small Business Technology Transfer Programs are specifically excluded from the federal definition of conflict of interest.

- (1) Examples of manageable conflicts of interest include, but are not limited to, the following:

- (a) Situations in which the outside activity will conflict with previously established responsibilities to the university;
 - (b) Situations that might allow a university employee to influence the university's dealings with an outside organization such that personal gain for the employee or improper advantage for anyone is the result; and
 - (c) Supervision of student research activities when research in that area might lead to financial or personal gain for the faculty member
- (2) Examples of unacceptable conflicts of interest include, but are not limited to, the following:
- (a) Use for personal profit of unpublished information originating from university research or other confidential university sources;
 - (b) Consulting under arrangements that impose obligations that conflict with the university's intellectual property policy or with the university's obligations to research sponsors or that inhibit the publication of research results obtained within the university; and
 - (c) Circumstances in which a substantial body of research that could and ordinarily would be carried on within the university is conducted elsewhere to the disadvantage of the university and its legitimate interests
- (3) Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate conflicts of interest include, but are not limited to:
- (a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
 - (b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - (c) Review of research protocol by independent reviewers;
 - (d) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
 - (e) Modification of the research plan;
 - (f) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - (g) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - (h) Severance of relationships that create conflicts

- (4) In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator with an FCOI that was not managed or reported by the institution as required by the regulation, the institution shall require the investigator involved to:

- (a) Disclose the FCOI in each publication of the results of the research; and
- (b) Request an addendum to previously published presentations.

e. Compliance

No proposals will be submitted without the required certifications. If a conflict is identified, the proposal may be submitted before the [management plan](#) is implemented if the designated official determines that the conflict can be managed or eliminated prior to the award of funds. No awarded funds will be spent until the conflict is resolved.

If breaches of the policy occur, sanctions will be imposed. Breaches include, but are not limited to: failure to file; intentionally filing an incomplete, erroneous, or misleading disclosure form; failing to provide additional information as required by the unit head or designated official; or violation of terms outlined in the resolution plan. If sanctions are necessary, they will be imposed in accordance with the university's operating policies and procedures (e.g., OP 74.08, Allegations of Misconduct in Research or Scholarly Activity). The potential sanctions may include, but are not limited to, the following:

- Letter of admonition
- [Suspension of award funds](#)
- Ineligibility of the investigator for grant applications or supervision of graduate students
- Suspension, [including withholding of salary](#)
- Non-renewal of appointment
- Dismissal

Impending actions may be appealed by the investigator to the university in accordance with procedures outlined in OP 32.05, Faculty Grievance Procedures, or OP 70.10, Non-faculty Employee Complaint Procedures.

For additional information on conflicts of interest, see Chapter 03, *Regents' Rules*, OPs 10.11, 32.07, 70.31, 74.04, and 74.08, and Government Code, § 572.051, Standards of Conduct; State Agency Ethics Policy.

Attachment A: Other Employment, Faculty Consulting, and Public Offices Form

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Attachment B: Confidential General Disclosure of Either Significant or No Significant Business or Financial Interests in Any External Entity

Attachment C: Confidential Supplemental Detailed Disclosure of Significant Business or Financial Interest

Attachment D: PHS-Specific Confidential General Disclosure of Either Significant or No Significant Business or Financial Interests in any External Entity

Attachment E: PHS-Specific Confidential Supplemental Detailed Disclosure of Significant Business or Financial Interest

Link to secure, online disclosure site: <https://webapps.itsd.ttu.edu/shim/qualtrics/ovpr2.php>