

Financial Conflict of Interest Management Plan Guidance

(Adopted by the Investigator Financial Disclosure Committee 14 Feb 2014)

Overview

Texas Tech University (TTU) encourages the recruitment, retention, and recognition of creative individuals who promote interactions with industry, the business community, and other public or private entities, in a manner consistent with their commitment to the university. As outlined in TTU Policy [74.17: Disclosure of Significant Business or Financial Interests that may Represent Conflicts of Interest](#), financial conflict of interest management plans are vehicles for managing, reducing, or eliminating financial conflict of interests. Such management plans 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 sponsored activities are not compromised.

Financial Conflicts of Interest (FCOI) may arise when Investigators have a significant financial and business interest in an Identified Entity, or, engage in significant consulting activities with an Identified Entity, and those interests or activities reasonably appear to be affected by the research or educational activities supported by external funding. FCOI may also arise when business interests or consulting activities reasonably appear to be related to an Investigator's institutional responsibilities.

TTU has a duty to ensure that potential FCOI of its investigators do not negatively impact TTU activities and other TTU employees, students, or research staff, and especially the academic progress of students. This concern extends to the potential FCOI of Investigators' Personnel (students, postdocs, technicians, visiting scientists, other support staff, etc.) who are involved in research that may affect an Identified Entity.

If the Associate Vice President for Research (AVPR) – Integrity determines that a potential FCOI exists, attributed to either significant financial and business interests or significant consulting activities, then the Investigator in concert with the AVPR must develop a plan that manages, reduces, or eliminates the potential FCOI.

The following guidance outlines the processes for developing FCOI Management Plans. All capitalized terms not otherwise defined in this document have their meaning set forth in OP 74.17: Disclosure of Significant Business or Financial Interests that may Represent Conflicts of Interest.

University Oversight Process

The Associate Vice President for Research (AVPR) (Integrity) and the Investigator Financial Disclosure Committee (IFDC) provide oversight of financial interest disclosure policies and management plan procedures. The FCOI general oversight process is as follows.

- The Investigator and the AVPR (Integrity) may meet to review information related to the Investigator's potential FCOI and to develop a FCOI Management Plan. The Investigator's Department Chair, Director, and/or Dean may participate in the meeting.
- If relevant information appears to be missing in prior disclosure documents, the AVPR (Integrity) may request additional information regarding the potential financial conflict of interest.
- The Investigator may request a meeting with the IFDC to review the potential FCOI and/or a proposed management plan.
- Once the Investigator agrees to the FCOI Management Plan, the appropriate signatures will be obtained. A signed copy of the plan and other requested documentation will be submitted to the AVPR (Integrity).
- The AVPR (Integrity) will establish a case file for each FCOI Management Plan and monitor compliance.
- The AVPR (Integrity) may require the Investigator to submit a mid-year report addressing current and new conflict of interest issues.
- The AVPR will review annual disclosures, management plan procedures, and additional information related to the investigator's potential FCOI. Management Plans may be amended as necessary. The Investigator, department chair, and dean / director may participate in an annual review.

Financial Conflict of Interest Management Plan Development

This section provides an outline of safeguards that, although not exhaustive, may be included in the Investigator's management plan. The AVPR (Integrity) or the IFDC may identify additional measures that might be included in a FCOI Management Plan.

Examples of Management Plan Actions

The following are examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate conflicts of interest.

- Public disclosure of significant business or financial interests;
- Disclosure of conflicts of interest in each public presentation of the results of the research;
- Review of research protocol by independent reviewers;
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in the portion of the externally funded research that could affect the significant business or financial interest;
- Divestiture of significant business or financial interests; or
- Severance of relationships that create conflicts.

Notification of Students, Staff, Co-Investigators, and Other Personnel

Key components of FCOI Management Plans are notifications sent to Personnel, Co-Investigators, and external sponsors of research, regarding potential conflicts created by the Investigator's relationship with an Identified Entity. These notifications aim to ensure that potential FCOIs do not negatively impact other TTU employees, students or research staff. **The notification process** may include the following, but is not limited to these procedures.

- Within 30 days of the acceptance of a management plan, the Investigator provides notification letters to all Personnel and copy to the AVPR (Integrity). The **notification letter** (see example in Appendix A) may include the following:
 - The Investigator's relationship with the Identified Entity, the existence of a Management Plan, and the AVPR (Integrity) contact information.

- Whether the Entity issues grants, contracts, gifts, or other funds to TTU to support research in which the Investigator is the principal investigator.
 - Whether the relationship includes a non-disclosure obligation and a description of information that is permitted to be disclosed.
 - The right of students and staff to bring concerns about the effect of the Investigator's relationship with the Identified Entity on their work, studies, or degree progress to their deans, directors, chairs, or the AVPR (Integrity).
 - A description of any restrictions that the Identified Entity wishes to place on the design of research conducted within the University and the scholarship activity of Personnel, including the ability to receive, analyze, or interpret data and to publish reports on TTU research and scholarly activity.
- The Investigator provides a notification letter to any new Personnel within 30 days of their initial project involvement and copy to the AVPR (Integrity).
 - The Investigator provides a notification letter to thesis/dissertation advisors of students who work in or for the Identified Entity. The letter might recommend that advisors should arrange meetings with those students in order to assess their academic progress and discuss any concerns arising from students' relationships to the Identified Entity. The notification letter is copied to the AVPR (Integrity).
 - The Investigator notifies the AVPR (Integrity) of any and all changes in his/her relationship with the Identified Entity (*e.g.*, the name of the Entity changes, the Investigator becomes a Board Member, a student working with the Investigator joins the Entity, etc.).

Regarding Involvement of Personnel in the Identified Entity

- Personnel may not participate in any activity of or receive any compensation from the Identified Entity, including research sponsored by the Entity, without approval from the AVPR (Integrity).

Regarding Protection of Students and Other Personnel

- Students pursuing a thesis or dissertation may not participate in research sponsored by the Identified Entity if the terms and conditions of participation would prevent or inhibit them from meeting applicable TTU degree requirements, such as completion and public defense of their thesis or dissertation. Exceptions to this rule must be approved by the degree program and the AVPR (Integrity).

- The Investigator will not serve as the thesis or dissertation advisor or co-advisor for a graduate student who works (with or without pay) for the Identified Entity (such as through the Entity's grants to TTU). However, the Investigator may serve as a member of the individual's thesis or dissertation committee. Exceptions to this rule must be approved by the AVPR (Integrity).
- The Investigator may supervise technicians, visiting scientists, and postdoctoral associates who also work in or for the Identified Entity. All such individuals must receive notification as described above.

Regarding Publications and Presentations of Research Related to the Identified Entity

- The Investigator's relationship with the Identified Entity may not restrict publication or presentation of TTU research, although publication may be delayed for the purpose of pre-publication review for a period consistent with TTU policies. Potential delays should be documented in FCOI Management Plans.
- Where permitted by the publishing body, articles and presentations should identify funding source(s) of research; i.e., that research was paid for by funds from the Identified Entity to TTU. Disclosure should include a description of the role, if any, of the Identified Entity in study design, data collection, analysis, interpretation of data, writing of the report, and/or the decision to submit the report for publication. Appendix B provides additional guidance about disclosures.
- If a mechanism is in place to do so, the submission transmittal letter to the editor should identify the following:
 - any significant financial and business interests in the Identified Entity, such as stock ownership (see OP 74.17 for examples of other significant financial and business interests).
 - any significant consulting activities, such as paid expert testimony,
 - and, where applicable, include a statement such as, "I had full access to all of the data in this study and I take complete responsibility for the integrity of the data and the accuracy of the data analysis."
- In any presentations, publications, and reports related to the Identified Entity, the Investigator must disclose his/her relationship to Identified Entity.

Regarding Protection of Research Subjects and Regulated Research

- The AVPR (Integrity) may share relevant FCOI Management Plans for Investigators performing regulated research with the appropriate regulatory committee:
 - Human Subjects – Institutional Review Board (IRB)
 - Animals – Institutional Animal Care and Use Committee (IACUC)
 - Biohazards – Institutional Biosafety Committee (IBC)
 - Chemical Hazards – Institutional Laboratory Safety Committee (ILSC)
 - Radiation – Radiation & Laser Safety Committee (RLSC)

Regarding Expenditures

- The Investigator may not be directly involved in making decisions relative to the purchase of items from the Identified Entity using funding under his/her control.
- Any such contractual arrangements must be delegated to an impartial party, who is not under the Investigator's supervision or control, such as the Investigator's department chair or someone designated by the chair.
- If the Investigator is a department chair, then his/her dean should designate someone impartial for making decisions relative to purchase of items from the Identified Entity.
- A review of all supported expenditures will be performed in accordance with University policy.
- Investigators should review TTU Operating Policies and Procedures regarding Purchasing and Contracting (OP 72).

Regarding TTU Resources

- In accordance with OP 74.04, all intellectual property generated using TTU funds, including contracts, grants, and gifts, belong to TTU, except as specified by the funding agreement.
- Activity with the Identified Entity must be conducted under the conditions established by formal TTU agreements.
- Investigators should read and adhere to operating policies and procedures regarding the use of TTU resources, as documented in the TTU Faculty Handbook available at <http://www.depts.ttu.edu/officialpublications>.

Other Documentation That Might Be Included in a FCOI Management Plan (if applicable):

- All intellectual property developed and utilized by the Investigator that may be owned or is owned by the Identified Entity.
- Documentation of any arrangements with the Identified Entity that restrict publication or presentation of research reports and other scholarship.
- Documentation of an impartial third party to develop and execute purchases from the Identified Entity, if the Investigator intends to purchase items from the Identified Entity. The third party should not be under the Investigator's supervision or control.
- Identification of other TTU activities and/or sponsored projects that could reasonably be seen as overlapping with activities or projects for which the Identified Entity receives benefit. If overlap is determined to exist, then the management plan should address how the overlap will be managed, such as the Investigator informing the sponsors of overlapping projects.
- Any formal TTU agreement that is related to the Identified Entity.

I have read, understand, and will abide by the FCOI management plan guidance and procedures mentioned herein.

Investigator's Name (print): _____

Investigator's Signature: _____

Date: _____

Appendix A:

Notification Letter to Personnel and Co-Investigators

One effective way to communicate the details of a potential financial conflict of interest management plan is to hold a meeting to explain the conflict situation, review the provisions of the management plans, and allow participants to ask questions. During this meeting, participants would receive two copies of a written summary signed by the investigator. They would sign and date one copy and return it to the Investigator, who would provide the AVPR (Integrity) scanned copies of signed summaries. Copies of the signed summaries should be updated annually to the AVPR.

Example Notification Letter

The notification letter should be printed on department letterhead and include the following information:

1. Date.
2. Description of the Investigator's involvement with the Identified Entity.
3. Description of the purpose of the Identified Entity.
4. Description of any non-disclosure obligation, along with as much information as the obligation permits.
5. Description of the relationship between the investigator's professional work (research) at the TTU and the Identified Entity.
6. Description of any relationships between TTU and the Identified Entity, such as sponsored research agreements, facilities use agreements, etc.
7. Description of any restrictions placed on the design, conduct, and reporting of TTU research by the Identified Entity.
8. Description of the ownership of any intellectual property resulting from TTU research connected to the Identified Entity.
9. Contact information for impartial representatives, such as the Investigator's dean or director's designee, IVPR (Integrity) and/or the IFDC.
10. Investigator's signature.
11. Statement of acknowledgement to be signed and dated by the recipient.

[Letterhead]

[Date]

To All Personnel in the Laboratory of [PI Name]:

This letter is to inform you that I am [*describe relationship in Identified Entity*] an Entity called [*Name of Entity*], devoted to research in the areas of [*Add text explaining the purpose of the Identified Entity, your involvement with it, and any connections to your research program.*]. My relationship does not carry with it any restrictions on publication of TTU research; any associated intellectual property will be disclosed and processed according to TTU policy.

The purpose of this letter is to inform you of this relationship with [Name of Entity]. If you feel at any time that your academic pursuits and freedoms are compromised by this relationship, you may contact [*Provide contact information for the appropriate dean or director's designee listed above*] or the Associate Vice President for Research (Integrity); ResearchIntegrity@ttu.edu.

Please sign and return one copy of this letter by [*enter date*] and retain the second copy for your records.

Sincerely yours,
[*Your Signature*]

I acknowledge receipt of the above information. I understand that I may address questions about this matter to my dean or director's designee or to the Associate Vice President for Research (Integrity).

Signature and R number: [*of recipient*]

Appendix B:

Disclosing in publications

The following examples are provided as guidance to investigators disclosing in publications and presentations their significant financial interests or significant consulting activities. Investigators may use alternative approaches that meet the requirements laid out in the body of his/her management plan.

- Dr. A has an ownership interest in Entity 1, which has licensed the technology reported in this publication.
- Dr. A performs significant consulting activities with Entity 1, which has licensed the technology reported in this publication.
- The research reported was supported by funding provided by Entity 1, Entity 2, and Entity 3, with which Professor B has significant financial interests or consulting activities.
- Name [*a dependent member Dr. A's household*] owns stock in [has stock options with] Entity 1. (See OP 74.17 for examples of other significant financial and business interests).

Additional information on disclosing potential conflicts of interest in research can be found in:

- Davidoff F, DeAngelis C, Drazen J, et al. Sponsorship, authorship, and accountability. JAMA. 2001; 286:1232-1234. <http://jama.ama-assn.org/content/286/10/1232.full.pdf+html>
- DeAngelis CD, Fontanarosa PB, Flanagin A. Reporting financial conflicts of interest and relationships between investigators and research sponsors. JAMA. 2001; 286:89-91. <http://jama.ama-assn.org/content/286/1/89.full.pdf+html>