



UTIA Procedures for Implementing the UT System Policy for Conflict of Interest

Policies, Responsibilities, and Procedures

Overview

Under federal regulations, the University of Tennessee (UT) System is required to develop management plans for significant financial/program interests that are determined to be a financial or other conflict of interest, including those of sub-recipient investigators. The UT System is also required to monitor compliance with any management plans that are established to monitor financial or other conflicts of interest deemed manageable by the UT Institute of Agriculture (UTIA) UTIA Deans and the Conflict of Interest Committee.

The UTIA Conflict of Interest Committee is responsible for review of outside interests disclosures submitted by the Deans offices of College of Agricultural Sciences and Natural Resources (CASNR), AgResearch, UT Extension and College of Veterinary Medicine (CVM) for covered individuals as defined in UT System Policy FI0125. Refer to the Outside Interests Disclosure Form Routing document found at the end of this document for routing of conflict of interests forms. Upon receipt of a faculty or staff member disclosure form by the UTIA Dean's offices, the Dean's office makes a determination whether the disclosure contains (a) no conflict, (b) potentially a conflict that is manageable or (c) an unmanageable conflict. If the Dean's office determines that a disclosure may represent a potentially manageable conflict, the form is submitted to the UTIA Conflict of Interest Committee. The UTIA Conflict of Interest Committee reviews the disclosure and recommends to the Dean's office whether the disclosure represents no conflict or a manageable conflict which requires a management plan. If the Dean's office does not agree with the Committee recommendation, a discussion and resolution takes place between the Dean's office and the Committee. If the Dean's office agrees with the UTIA Conflict of Interest Committee that the conflict is manageable, the Dean's office notifies the faculty or staff member that a management plan is required for the conflict. The faculty or staff member may work with the UTIA Conflict of Interest Committee during the development of the management plan. The management plan is reviewed by the UTIA Conflict of Interest Committee and then submitted to the Dean. Discussion/revision may take place or the management plan may be approved and submitted by the Dean's office to the appropriate Chief Business Officer for his or her approval. Where disagreements develop between the UTIA Conflict of Interest Committee, faculty/staff member and/or Dean's office, the matter is referred to the UTIA Chancellor for final determination.

General Principles

Covered individuals are expected to take all reasonable precautions to ensure their outside financial interests do not place them in conflict with performing their duties and responsibilities as UTIA employees or as investigators. Generally, a non-manageable conflict of interest exists in the following circumstances:

- A covered individual allows outside financial interests to interfere with or compromise judgment and objectivity with respect to duties and responsibilities to the UTIA or sponsoring organizations.
- A covered individual makes university or university-related decisions or uses university resources in a manner that results in or is expected to result in:
 - ✓ Personal financial gain or financial gain for his or her relatives; or
 - ✓ An unfair advantage to or favored treatment for a third party outside the University.
- A covered individual allows outside financial interests to affect the design, conduct, or reporting of research.

UTIA Conflict of Interest Committee Membership

The UTIA Conflict of Interest Committee consists of ten members:

- UTIA Compliance Officer, Chair
- Representative from the University of Tennessee Research Foundation
- Representative from UT Legal Counsel
- Associate Dean for Research
- Associate Dean for Research, College of Veterinary Medicine
- Associate Dean for Extension
- Associate Dean for Teaching
- Budget Officer from CASNR, or AgResearch, or Extension, or CVM
- Two (2) UTIA faculty members chosen by the Chancellor of UTIA

The UTIA Compliance Officer serves as chair of the UTIA Conflict of Interest Committee and is a non-voting member. The Chair is responsible for organizing and conducting quarterly meetings or other meetings as necessary and communicating committee decisions to the appropriate Dean(s), faculty member, and others on a need to know basis. The UTIA Conflict of Interest Committee makes their recommendations by majority vote of the eligible members.

UTIA Conflict of Interest Committee Responsibilities

The UTIA Conflict of Interest Committee reviews and manages outside activities of covered individuals as defined by UT System Policy FI0125 (*any person, including but not limited to a student, resident, fellow, post-doctoral appointee, and affiliate, volunteer, and adjunct faculty appointee regardless of title or position and regardless of whether compensated or not, who is responsible for the design, conduct, or reporting of research at the University*). Review criteria include: (a) the academic, research, extension outreach and service activities of covered individuals completing an Outside Interests Disclosure Form, (b) whether the activity is

reportable on the Outside Interests Disclosure Form, (c) the value of the financial or other interest associated with an activity, and (d) whether the activity is ongoing or has ended.

At the request of UTIA administration, the UTIA Conflict of Interest Committee may also review the outside activities of any outside individual collaborating in UTIA programs and provide advice on the existence of a financial/program conflict of interest.

No Management Financial/Program Interests

While some outside activities meet the criteria for review, the UTIA Deans and the UTIA Conflict of Interest Committee may determine that these do not require management and assign them to “no management” status. Such activities include:

- Salary, royalties, or other remuneration received from UTIA or affiliated entities;
- Royalties generated by intellectual property rights arising out of university employment that are assigned to organizations created to manage such rights on behalf of UT, for example the UT Research Foundation;
- Income from seminars, lectures, or teaching engagements sponsored by a government agency, a university, an academic teaching hospital, a medical center, or a research institute that is affiliated with a university;
- Income from service on advisory committees or review panels for a government agency, a university, an academic teaching hospital, a medical center, or a research institute that is affiliated with a university;
- Travel related to institutional responsibilities that is reimbursed or sponsored by a U.S. government agency, a U.S. university, academic teaching hospital, or medical center, or a research institute that is affiliated with a U.S. university.
- Interests of any amount in investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not control the investment decisions made in these vehicles.

Where Management of Financial/Program Interests is Needed

An outside activity has a connection or tie with an individual’s UTIA activities if the outside activity arises from or relies upon the academic expertise that qualifies that individual to participate in a teaching, research, extension outreach or service project and the outside activity or interest could directly and significantly affect the individual’s activity. The potential for conflict with an outside activity or financial interest is strengthened by other relationships between the individual or his or her immediate family and the business entity associated with the financial interest or outside activity.

Resolving Disagreements

Where disagreements develop between the UTIA Conflict of Interest Committee, faculty/staff member and/or Dean’s office, the matter is referred to the UTIA Chancellor for final determination.

If the UTIA Deans and the UTIA Conflict of Interest Committee determine that a management plan is required, the following process will be followed.

Guidelines to Follow When Developing a Management Plan

Investigator:

Entity or Entities:

- **Publications and Presentations.** Your relationship with _____ (hereafter “the entity or entities”) may not restrict publication or presentation, although publication may be delayed for the purpose of pre-publication review for a period consistent with UT policies. You, your students, fellows, trainees, and other workers whom you supervise in the course of executing your university program must disclose the relationship with the entity or entities in publications and academic presentations where disclosure is possible and appropriate.
- **Interaction with Students and Staff.** UTIA has a duty to ensure that entrepreneurial activities of its faculty and staff do not have a negative impact on students (especially on the academic progress of students), faculty and staff. To fulfill this obligation, the UTIA Conflict of Interest Committee requires that individuals with potential conflicts of interest inform others who may be impacted by potential conflicts.

You should provide information on potential conflicts of interest to all students, fellows, trainees, and other workers whom you supervise in the course of your UTIA activities (hereafter students and staff). The information should include explanations of (a) your relationship with the entity or entities, and (b) the right of students and staff to bring concerns about the effect of your relationship with the entity or entities on their work, studies, or progress toward degree completion to your dean, director, his or her designee, or the UTIA Conflict of Interest Committee. You must also notify all your co-investigators on federal grants of potential conflicts of interest. The process for providing information should meet the following criteria:

- ✓ Include a written summary of the information for each student or staff member
- ✓ Provide documentation that this process has occurred to the UTIA Conflict of Interest Committee within 60 days of receipt of this management plan
- ✓ Provide any individuals who subsequently join the group comparable information in a timely manner.
- ✓ Update documentation to the UTIA Conflict of Interest Committee at least once a year

Your relationship with the entity or entities may not place restrictions on the ability of your students and staff to receive, analyze, or interpret data. In addition, students may not participate in an activity sponsored by the entity or entities if the terms and conditions of participation would prevent or inhibit them from meeting applicable UT degree requirements, such as completion and public defense of a thesis or dissertation.

Annually, you must notify the UTIA Conflict of Interest Committee of any students and staff involved in the activities of the entity or entities. Such involvement may require modification of this management plan.

The UTIA Conflict of Interest Committee requires that all involvement of students and staff with the entity or entities be conducted under formal university agreements, such as sponsored research agreements or appointments approved by your dean or director's office.

You must direct any of your students and staff with significant interest in the entity or entities to make an annual report of outside activities using the UT Outside Interests Disclosure Form regardless of whether they would normally be required to make such a report. Any of your students and staff who independently have a reportable significant interest in the entity or entities will be reviewed by the UTIA Conflict of Interest Committee and may be issued their own management plans.

- **Human Subjects Research.** Absent written approval from the UTIA Conflict of Interest Committee, you cannot serve as principal investigator (PI), co-investigator (co-PI), or key personnel for a human subjects protocol reviewed by the UT Institutional Review Board (IRB) if the entity or entities (a) sponsors the study, or (b) owns or licenses a technology tested in the study. Likewise, you cannot recruit potential subjects for a human subjects protocol if the entity or entities (a) sponsors the study, or (b) owns or licenses a technology tested in the study. You may refer potential subjects to an independent third party for study information and possible enrollment in human subjects protocols.

The UTIA Conflict of Interest Committee may grant you an exception to restrictions on participation in human subjects research. The UTIA Conflict of Interest Committee only grants exceptions for specific protocols. The exception process depends on the risk level of the proposed research. If the UT IRB determines that a study poses no greater than minimal risks to subjects, investigators will normally be granted an exception to this prohibition upon UTIA Conflict of Interest Committee review. For all other protocols, individuals must apply to the UTIA Conflict of Interest Committee for exceptions in writing. The UTIA Conflict of Interest Committee only grants exceptions for protocols that pose greater than minimal risks to subjects in very rare circumstances. For example, the UTIA Conflict of Interest Committee might grant an exception if an individual is uniquely qualified by virtue of expertise or experience to participate in the research and the research could not be conducted as safely or effectively without the individual. If the UTIA Conflict of Interest Committee approves an exception, it may require modifications to the human subjects protocol or this management plan. Required modifications could include disclosure of financial and/or other interests to participants, disclosure of financial and/or other interests to research collaborators, additional protocol monitoring, restriction of your roles in the study, or other management, as determined by the committee.

You may not receive payments from University accounts or directly or indirectly from the entity or entities for particular results or outcomes related to human subject protocols conducted at or through UT. Further, you, or your immediate family, may not receive any personal incentives from University accounts or directly or indirectly from business entities, such as recruitment incentives, performance incentives, fellowships, or other research support, except through an agreement entered into by the University for a sponsored human subjects study. The UT only permits payments for subject enrollment, or for the referral of potential subjects to human subjects studies, when all of the following are present:

- ✓ The payment reasonably relates to costs incurred, as specified in agreements between the sponsor and the UT.
 - ✓ The payment reflects the fair market value of services performed.
 - ✓ The payment is commensurate with the efforts of the investigator(s) performing the research or other activity.
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- **Support from the Entity or Entities.** Before accepting any support (e.g. grants, contracts, unrestricted gifts, or material(s) from the entity or entities, you must specifically disclose details of the award, including the scope of the work and any award conditions, to your Dean's office for approval. The Dean's office will transmit a copy of the materials to the UTIA Conflict of Interest Committee so that it may be noted in the committee's records.

 - **Reporting of Outside Activities.** As a reminder, you are required to submit an annual report of outside activities each year. In addition, if you have major changes in your outside activities between annual reports, you must update your report.

 - **Outside Activities Agreement.** A departmental agreement on the appropriate level of outside activities in light of your faculty appointment needs to be established.

 - **Use of University Facilities and Services.** Any activity involving the use of University facilities or services for the benefit of the entity or entities must be conducted in accordance with all relevant University policies pertaining to the use of University facilities. If you wish to use University facilities for the benefit of the entity or entities, you must make arrangements through your Department Head and Dean. An approved Facilities Use Agreement must be in place before the activity begins.

 - **Purchases.** You may not be directly involved in making decisions involving the purchase of items from the entity or entities using funding under your control. Any such contractual arrangements are to be delegated to an impartial party, who is not under your supervision or control, such as your Department Head or someone designated by your Head. If you are a Department Head, your Dean should be asked to designate someone on your behalf.

- Annual Review. You must meet annually with your Department Head, or, if you are the Department Head, with your Dean or his/her designee, to review information related to your relationship with the entity or entities, its influence on your University activities, and compliance with the terms of this management plan. The assessment will then be forwarded to the UTIA Conflict of Interest Committee and utilized in its annual review of the relationship between your University appointment and the entity or entities.

Appendix A: Disclosing in Publications

The UTIA Conflict of Interest Committee provides the following examples to guide investigators disclosing their significant financial and/or other interests in publications and presentations. Investigators may use alternative approaches that meet the requirements laid out in the body of this management plan.

- Dr. A has an ownership interest in Company 1, which has licensed the technology reported in this publication.
- The research reported was supported by funding provided by Company 1, Company 2, and Company 3, with which Professor B has significant financial and/or other interests.
- Name [A member of Name's family] owns stock in [has stock options with] Company 1.

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

- Davidoff F, DeAngelis C, Drazen J, et al. Sponsorship, authorship, and accountability. *JAMA*. 2001;286:1232-1234.
- DeAngelis CD, Fontanarosa PB, Flanagin A. Reporting financial conflicts of interest and relationships between investigators and research sponsors. *JAMA*. 2001;286:89-91.

Appendix B: Informing Students and Staff of Potential Conflicts of Interest

The UTIA Conflict of Interest Committee provides the following guidance to help investigators communicate the details of conflict of interest management plans. Investigators may use alternative approaches, if they meet the requirements laid out in the body of this management plan.

One effective way to communicate the details of conflict of interest management plans 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. The investigator would provide the UTIA Conflict of Interest Committee a single copy of the written summary and a list of all individuals who received and signed the summary. After an initial meeting, the investigator would speak individually with anyone new who should receive information. The list of individuals who have received information must be updated annually for the UTIA Conflict of Interest Committee.

The written summary would be printed on department letterhead and include the following (See example letter below.):

- Date
- Description of the investigator's involvement with the company
- Description of the purpose of the company
- Description of the relationship between the investigator's professional work at UT and the company
- Description of any relationships between UT and the company, such as sponsored agreements, facilities use agreements, etc.
- Description of any restrictions placed on the design, conduct, and reporting of activity by the company
- Description of the ownership of any intellectual property resulting from activity connected to the company
- Impartial contacts for students and staff (the investigator's dean or director's designee) AND a representative of the UTIA Conflict of Interest Committee
- Investigator's signature
- Statement of acknowledgment to be signed and dated by the recipient

Example Letter

[Letterhead]

[Date]

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

This letter is to inform you that I am [List position in company] of a company called [Name of Company], devoted to research and/or other activity in the areas of [Add text explaining the purpose of the company, your involvement with it, and any connections to the lab.]. My relationship does not carry with it any restrictions on publication, and any associated intellectual property will be disclosed and processed according to UT policy.

The purpose of this letter is to inform you of this potential conflict of interest, and, if you feel that at any time your academic pursuits and freedoms are compromised by this relationship, that you may contact [Provide contact information for the appropriate Dean and Chair of the UTIA Conflict of Interest Committee).

Sincerely yours,

[Signature]

I acknowledge receipt of the above information on a potential conflict of interest. I understand that I may address questions about this matter to my Dean or to the UTIA Conflict of Interest Committee.

Name: [of recipient]

Date:

Terminating a Management Plan

When an investigator ends his or her relationship with an outside entity for which a management plan was issued, he or she must update his/her Outside Activities Report to reflect the change in their relationship. The termination process is as follows:

- An investigator files an updated Outside Activities Report indicating that the relationship has ended.
- The UTIA Conflict of Interest Committee reviews the information provided in the request for termination of a management plan.
- If the UTIA Conflict of Interest Committee determines the plan is no longer necessary, the committee will vote to terminate the management plan.
- The Chair of the UTIA Conflict of Interest Committee informs the investigator in a letter that a management plan has been terminated. If the individual's original management plan covered more than one entity, the staff will update the individual's management plan to reflect any new committee determinations and the management plan cover letter will note which entities are no longer covered by the plan.

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Outside Interests (Conflict of Interest) Disclosure Form Routing

