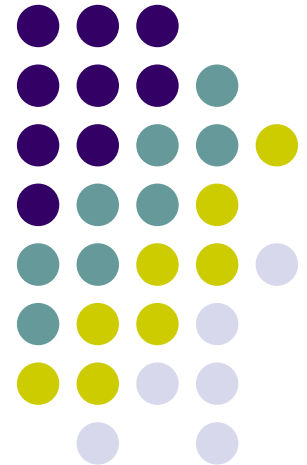


Introduction to UT Southwestern Conflict of Interest Policy

“Conflict of Interest” – any situation in which financial or other personal considerations may unduly influence professional judgment in exercising UT Southwestern responsibilities or in the design, conduct, or reporting of research.

(Policy and Procedures on Conflicts of Interest in Research – Revised December 2007)



Introduction to UT Southwestern Conflict of Interest Policy



The UT Southwestern Conflict of Interest Office assists investigators in identifying, understanding and managing conflicts of interest.

UT Southwestern has established the *Policies and Procedures on Conflicts of Interest in Research* to guide faculty members in properly structuring beneficial, cooperative relationships with outside entities that are consistent with state and federal laws and regulations, while allowing faculty members to enhance their knowledge and creativity through these relationships.

Institutional Responsibilities and Avoiding Conflicts of Interest



A faculty member's primary responsibility is to UT Southwestern.

No faculty member may engage in any outside professional activity if performing that activity presents a conflict of interest, in any way, with the faculty member's ability to discharge his or her teaching, research, clinical, or administrative responsibilities to UT Southwestern.

Research Integrity is Our Responsibility



UT Southwestern and its faculty are responsible for ensuring that there is no expectation that the design, conduct, or reporting of research will be biased by any financial interest of an investigator responsible for the design, conduct, or reporting of that research.



Definitions



Financial Interest - 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, other ownership interests; *not including mutual or pension funds*);
- intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

Definitions (Cont'd)



Significant Financial Interest -

- 1. An equity interest that, when aggregated for the faculty member, their family, or an associated entity, is either equal to or greater than \$10,000 in value, or represents more than a 5% ownership interest in any single business entity; or**
- 2. Salary, royalties, or other payments from a single business entity that, when aggregated over the next 12 months, will be equal to or greater than \$10,000.**



Definitions (Cont'd)

Family – includes a spouse, minor children, or other persons living in the same household, or financially dependent upon, a faculty member.

Associated Entity – includes a trust, organization, or enterprise other than UT Southwestern or its affiliated hospitals, over which the faculty member, alone or together with family, exercises a controlling interest.

Stock Interests



Effective December 2007, stock ownership of any amount connected with any Business Entity with which the Faculty Member, Family, or Associated Entity has a *clinical* research relationship will not be allowed.

Who is Required to Complete a Statement of Financial Interests?



- **All UT Southwestern Faculty**
- **Investigators Involved in Research**
- **Key Personnel listed on Grants**
- **Institutional Review Board (IRB) Members**



A Statement of Financial Interests is Required from



UT Southwestern Faculty

Each faculty member must fully disclose any financial interest, including those of their Family or an Associated Entity, that would:

1. Appear to be directly related to their research interests or institutional responsibilities; or
2. That directly relates to a decision the faculty member may participate in involving funds under UT Southwestern's control.

Failure to submit a Statement of Financial Interests may result in disciplinary action, up to and including non-renewal of a faculty member's appointment.

A Statement of Financial Interests is Required from



Investigators and Key Personnel Involved in Research

Investigators generally include Principal Investigators, co- or sub-investigators, postdoctoral fellows, graduate students, statisticians and others who are responsible for the design, conduct or reporting of research.

Research coordinators, nurses, medical students, and laboratory technicians generally do not need to complete a statement *unless* they are considered key personnel.

A Statement of Financial Interests is Required from



Institutional Review Board (IRB) Members

Both UT Southwestern employees and non-UT Southwestern personnel who serve as IRB members must submit an annual Statement of Financial Interests.

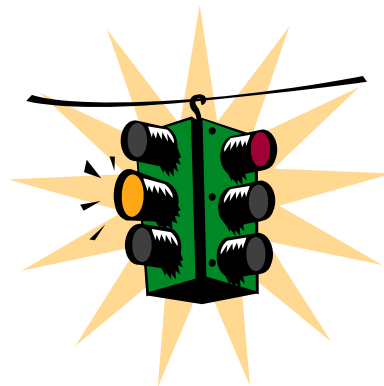
An IRB member must abstain from voting when he or she (1) has equity in, (2) a consulting relationship with, or (3) serves on the advisory board of the sponsor of an IRB-reviewed protocol.



Caution:

The failure to submit a Statement, or the submission of an incomplete or inaccurate Statement, may result in disciplinary action.

Incomplete or inaccurate Statements may also delay or prevent submission of grant proposals and may delay activation of accounts following grant awards.



When Must Statements of Financial Interests Be Submitted



- **Annually, by the deadline announced by the Office of the Associate Dean for Research Administration;**
- **Upon request by the Conflict of Interest Office;**
- **Within thirty (30) days of changes that alter a faculty member's financial interests.**



Outside Employment Policy



Faculty members should not be discouraged from accepting outside employment of a consultative or advisory nature, so long as such employment:

- **Does not impair the faculty member's judgment in performing UT Southwestern duties;**
- **Does not create an actual or potential conflict of interest; or**
- **Might require or induce the faculty member to disclose confidential information.**

Outside Employment Policy



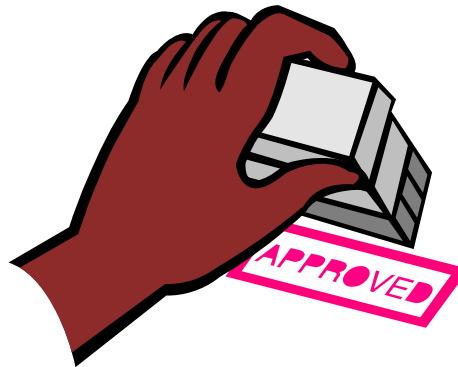
UT Southwestern employees who intend to engage in outside employment (e.g., consulting or advisory services, speaking on multiple occasions, or on behalf of for-profit companies) must:

- **obtain their supervisor's approval;**
- **submit a *Request for Prior Approval of Outside Employment* form to the COI Office;**
- **receive administrative approval prior to performing services.**



Outside Employment Policy

No UT Southwestern employee may accept pay from private sources for tests, assays, chemical analyses, bacteriological examinations, or other such work involving the use of UT Southwestern property, without first obtaining written permission from the President to do so and making provision for the payment of appropriate compensation to UT Southwestern.



Consulting Agreements



Consulting agreements with outside companies are personal contractual arrangements that are signed by the faculty member in his or her individual capacity – not as an employee of UT Southwestern.

UT Southwestern is not bound by the terms of a faculty member's agreement with an outside company.

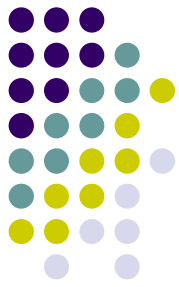
Faculty members have no authority to alter their obligations to UT Southwestern through the terms of a personal consulting agreement.

Consulting Agreements



To ensure an agreement's terms do not conflict with UT Southwestern or UT System policies and guidelines, it is strongly recommended that the language of any consulting agreement include the following paragraph (available online at <W:\PUB\FORMS\COI\Agreement Standard Paragraph.pdf>):

The Company [*insert name of company*] acknowledges that Consultant is a full-time employee of UT Southwestern (and as such, an employee of the State of Texas) and is subject to UT Southwestern's policies, including policies concerning consulting, conflicts of interest, and intellectual property. If there is a conflict between Consultant's obligations under UT Southwestern policies and any of Consultant's obligations to Company under this Agreement, Consultant's obligations under UT Southwestern policies take priority over any obligations the Consultant may have to Company by reason of this Agreement. Company specifically recognizes that, under UT Southwestern's policy on intellectual property (<http://www.utsystem.edu/bor/rules.htm>), Consultant has an obligation to assign to UT Southwestern all intellectual property that is related to Consultant's employment responsibilities to UT Southwestern.



Consulting Agreements (Cont'd)

- A personal consulting agreement should reference the consultant's home address, not UT Southwestern's, and all correspondence should be sent to a home address.
- UT Southwestern does not sign personal consulting agreements. A signature block requesting UT Southwestern's approval should not be included in the agreement.



Exceptions to the Outside Employment Policy



- **Activities considered to be a part of a faculty member's academic duties (e.g., writing a journal article or book chapter; serving as an editor of a journal; serving on NIH or NSF study sections; participating in seminars, lectures, Grand Rounds or similar activities at another university, hospital, or research institute);**
- **Serving on non-profit community boards (e.g., American Cancer Society, American Heart Association);**
- **Providing a service (e.g., giving a talk) on only two (2) days per calendar year for a single (1) entity (exclusive of travel time) which is unrelated to the faculty member's research.**

Vendor Policy



A pharmaceutical company can subsidize an educational event if they provide an unrestricted grant to the university and do not participate in the event.

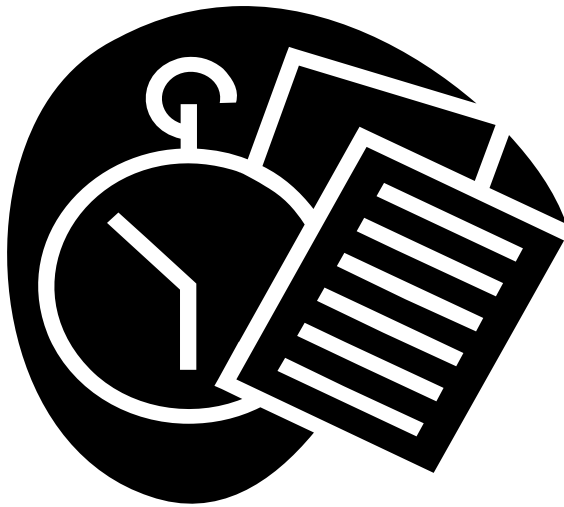
It is permissible to receive an honorarium for a lecture from a pharmaceutical company if it is an approved CME event and the funds were provided to the University, or if it is approved by the University as outside employment.



How Do I Learn More?

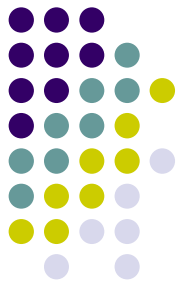
- **Contact the Conflict of Interest Office:**
Conflict of Interest Office
UT Southwestern Medical Center
5323 Harry Hines Blvd.
Dallas, TX 75390-8574
(214) 648-5398 (office)
(214) 645-9847 (fax)
- **Visit the COI web page at:**
<http://www.utsouthwestern.edu/coi>
- **Obtain forms at: W:\PUB\FORMS\COI**

Test Your Knowledge



Several questions follow that test your knowledge of the information presented.

Answer all questions correctly to receive credit for the training. Correct answers must be given before proceeding to the next question.



Question #1

A conflict of interest is any situation in which financial or other personal considerations may unduly influence (choose the best answer):

- a. Professional judgment in exercising UT Southwestern responsibilities**
- b. Conduct of research**
- c. Design of research**
- d. Reporting of research**
- e. All of the above**

Question #2



Who is required to submit a Statement of Financial Interests to the Conflict of Interest Office (choose the best answer)?

- a. All UT Southwestern Faculty**
- b. IRB Members**
- c. Key Personnel Listed on Grants**
- d. a & b only**
- e. All of the above**

Question #3



Which of the following is not considered a Significant Financial Interest?

- a. A spouse's 20% equity interest in a non-publicly traded biotech company**
- b. A faculty member's consulting agreement, wherein the faculty member will receive 4 installments of \$1,500 over the course of 12 months**
- c. A faculty member's stock in Pfizer valued at \$15,000**

Question #4



Updated Statements of Financial Interests are required (choose the best answer):

- a. Annually and upon request by the COI Office**
- b. When a new equity interest is acquired; service on a board or advisory committee begins; paid outside consulting begins; and/or additional sources of income begin**
- c. The last day of the month**
- d. a & b**

Question #5



You should report equity interests held indirectly through mutual or pension funds?

- 1. True**
- 2. False**

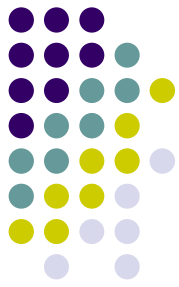
Question #6



You may not own stock of any amount from a business entity in which you or a family member have a clinical research relationship?

1. True
2. False

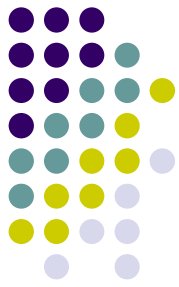
Question #7



Which of the following activities requires submitting a Request for Prior Approval of Outside Employment?

- a. Serving on a NIH study section**
- b. Giving Grand Rounds at another university**
- c. Consulting one day a month with a pharmaceutical company**
- d. Serving on the board of a non-profit organization**

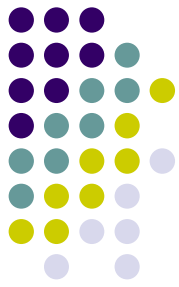
Question #8



Outside employment (consulting) requires prior approval from your departmental chair, the Conflict of Interest Office, and administration prior to the agreement being signed?

- 1. True**
- 2. False**

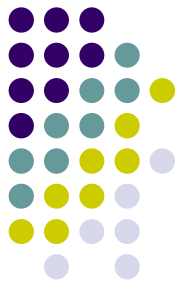
Question #9



A pharmaceutical company can subsidize an educational event if:

- a. They pay enough**
- b. They pay all costs and provide meals**
- c. They provide an unrestricted grant to the university and do not participate**
- d. The event is at a nice resort**

Question #10



It is permissible to receive an honorarium for a lecture from a pharmaceutical company if:

- a. It is an approved CME event and the funds were provided to the University**
- b. It is higher than that provided to a community practitioner**
- c. It is approved by the University as outside employment**
- d. a and c**
- e. None of the above**

Congratulations...



**You have completed your introductory training
on the UT Southwestern Conflict of Interest
Policy.**

