Conflicts of Interest and Conflicts of Commitment Compliance Training
Review:
• The federal regulation and UTHHealth’s policy and procedures regarding financial conflicts of interest in research.
• How conflicts are identified, reviewed, and managed.

Objectives

By the end of this lesson, you should be able to:

Recognize:
• The potential for conflicts and how to avoid them in your work.
• Your overall responsibilities regarding potential conflicts.

Recall the requirements for:
• Obtaining approval of outside activities, as they apply to your position at UTHHealth.
• Submitting your financial disclosures, as they apply to your position at UTHHealth.
Mission Statement

UTHealth is committed to ensuring that employees’ personal interests do not interfere with the mission and work of the university.

Your individual responsibility as an employee:
- Accomplish duties that are assigned to your position.
- Do not allow outside activities or financial interests to interfere with the duties assigned to your position.

Federal regulations, The University of Texas System, and UTHealth policies:
- Regulate how you may participate in outside activities and hold financial interests that have the potential to affect UTHealth’s interests.

Managing Potential Conflicts:
- Your involvement in an outside activity or financial interest does not automatically mean that you have a conflict.
- If a potential conflict is identified, UTHealth will work with you to manage, reduce, or eliminate the conflict.
Applicable UTHealth Policies

**HOOP 20**: Conflict of Interest, Conflict of Commitment and Outside Activities

- This Policy applies to all employees of UTHealth and was revised in December, 2013. Requirements for prior approvals of outside activities, and disclosure of outside activities and financial interests, now apply differently to employees depending upon FLSA-exempt status, eligibility for paid benefits, and participation in research.
- Portions of **HOOP 20** also apply to students, interns, residents, clinical fellows, and post-doctoral research fellows.

**HOOP 94**: Research Conflicts of Interest

- This Policy applies to individuals who have been designated as a “covered individual” by a principal investigator of a research project because they are responsible for the design, conduct, or reporting of research.

**Note**: The policies in the Handbook of Operating Procedures (HOOP) that will be reviewed in this training have been developed to protect the credibility and reputation of UTHealth and its employees.
There are two types of conflicts that have the potential to adversely affect, or appear to affect, how you perform your job responsibilities:

Conflicts of interest

AND

Conflicts of commitment
An outside activity or financial interest (or your family member’s activity or interest) that could directly or significantly affect the performance of your UTHealth responsibilities, with the potential to:

1. Influence, or even appear to influence, your conduct or decisions in your job

2. Impair your independence of judgment in your job

3. Induce you to inappropriately disclose confidential or proprietary information that you have obtained in your job

Note: Conflicts of interest are generally issues of financial or personal gain.
Conflict of Interest Examples

Real or Perceived
Conflicts can be real or they can be perceived (only giving the appearance of a conflict). Either may raise concerns by the public, research sponsors, funding agencies, or donors.

- Research Example
- Professional Expertise Example
- Continuing Professional Education Example
- Ownership Interest Example
Conflict of Interest Examples

Research Example
You might have the potential for a conflict of interest if you participate in a research project at UTHealth sponsored by an outside company, and the company has asked if you would like to start doing some consulting work for them.
Conflicts of Interest Examples

Professional Expertise Example
You might have the potential for a conflict of interest if your professional expertise and your work at UTHealth involves web design, and you’ve been asked to provide web design services for a friend’s medical device company. He would give you stock options in the company as payment.
Conflict of Interest Examples

Continuing Professional Education Example

You might have the potential for a conflict of interest if you plan to provide continuing professional education at UTHealth that is sponsored by a non-profit organization, but you become aware that the organization is actually operated by a for-profit company for which you provide consulting services.
Conflict of Interest Examples

Ownership Interest Example

You might have the potential for a conflict of interest if a local company in which you hold an ownership interest wishes to donate funds to UTHealth that would be designated specifically for your research.
Conflict of Commitment

Devoting time or effort to an outside activity that interferes with the fulfillment of your UTHealth job responsibilities.

Using state-owned resources (computers, e-mail, supplies, equipment, personnel, laboratory or administrative space, etc.) without approval in connection with your personal outside employment, board service, or other outside activity.

Note: Conflicts of commitment are generally issues of time and resources.

Conflicts can be real or they can be perceived (only giving the appearance of a conflict). Either may raise concerns by the public, research sponsors, funding agencies, or donors.
You might have the potential for a conflict of commitment if:

- You serve as a consultant and lecturer to several companies, and the time involved in preparing for and performing the outside work has caused you to adjust your UTHealth schedule and even cancel some of your UTHealth job responsibilities (e.g., clinics, teaching responsibilities, etc.).

- You work full-time for UTHealth but have a second job in the evenings. Since you began the second job, you are often late to the office, frequently unproductive, and sometimes leave early to get to your other job. The quality of your work and your ability to fulfill your responsibilities for UTHealth have generally declined.
Unallowable Use of State Resource

Examples

Some inappropriate activities related to personal outside work are easier to identify. All employees should be able to recognize the following as examples of unallowable use of state resources:

- You serve on the board of an outside company and communicate with potential investors using your UTHealth email and telephone.
- You use the department copy machine to make copies of a report you have written for administrative work that you perform for an outside company.
- You consult for an outside company and use your department administrative support staff to schedule travel related to your personal consulting work.
- You use your UTHealth email to let co-workers know about a new personal business you are starting.
- You use your UTHealth phone, email, and office address as your contact information for your personal consulting work with an outside company.
Potential Conflict Examples

Conflicts can be real or they can be perceived (only giving the appearance of a conflict). Either may raise concerns by the public, research sponsors, funding agencies, or donors.

- Family Member Definition
- Family Member Example
- Gift Definition
- Gift Example
- Honorarium Definition
- Honorarium Example
- Procurement and Contracting Activities Definition
- Clinicians and Outside Activities Definition
- Clinician Relationships with Industry
- Relationships with Vendors
- Sponsored Education Activities
Potential Conflict Examples

**Family Member Definition**

An activity or financial interest of a family member also has the potential to create a conflict of interest for you if their activity or interest, or the entity involved, could reasonably appear to be related to or involved with your UTHealth job responsibilities.

“Family member” is defined as:

- Your spouse
- A dependent child or stepchild or other dependent, for purposes of determining federal income tax liability
- A related or non-related, unmarried adult who resides in the same household as you and with whom you are financially interdependent, as evidenced for example by the maintenance of a joint bank account, mortgage, or investments.
Potential Conflict Examples

**Family Member Example**

You might have the potential for a conflict if:

Your spouse holds an executive position with a biotechnology company that proposes to sponsor a research project at UTHealth in which you want to participate.

Your adult son, who lives in your household, owns an interest in a local company that does business with UTHealth. The company now proposes to provide services to a division or unit that you supervise.
Potential Conflict Examples

Gift Definition

In general, Texas law prohibits state employees from accepting any gift that may influence their official job duties.

A “gift” is defined as anything of value, including:
- Food
- Tickets to entertainment or sporting events
- Lodging, transportation, and expenses for a trip
- A cash gift, of any dollar amount
- Gift cards (considered to be the same as cash)

The acceptance of a cash gift, or gift card, of any dollar amount is never allowed.

If your UTHealth job does not involve decisions about university financial transactions, you might be allowed to accept a non-cash gift if it is less than $50 in value. However, there are additional restrictions for some employees and trainees such as clinicians involved in patient care activities.
Potential Conflict Examples

Gift Example

Generally, gifts of minimal value, such as gift baskets or textbooks, are allowed if they are given not to an individual employee but instead to the department or School.

Remember that you may never ask for or accept a gift or favor from an outside source that you know is being offered in exchange for your work-related decision or action.
Potential Conflict Examples

Gift Example

Honorarium Definition

An honorarium is a voluntary payment for professional services for which no fees are normally due.

Employees might be asked to participate in speaking engagements at conferences or meetings because of their professional expertise. Often, they are offered compensation in exchange for their services. You may not accept an honorarium or fee for such an activity if your participation would not have been requested “but for” your official position at UTHealth. This is a “blanket rule” provision of Texas state law that applies to all employees.

You may never accept an honorarium for merely attending a conference.

Honorarium Example

Procurement and Contracting Activities Definition

Clinicians and Outside Activities Definition

Clinic Blues Relationships with Industry

Relationships with Vendors

Sponsored Education Activities
Potential Conflict Examples

Honorarium Example

Another example is a pharmaceutical company that holds meetings to present information on the requirements of a new sponsored clinical trial. The company might offer honoraria as a way to thank those who attended the meeting.

UTHealth employees (investigators, coordinators, etc.) who attend such meetings are doing so as part of their UTHealth job responsibilities (“but for” their work on the clinical trial at UTHealth, they would not otherwise attend the meeting).

So the employees should not personally accept honoraria for attending the meeting.

The company may, if it chooses, forward the honoraria/gift to the department or School as an unrestricted gift.
As a state agency, UTHealth must ensure that no business transactions are perceived as "self-dealing" (conducting public business on behalf of UTHealth with one's own private business).

Employees cannot participate in purchasing or contracting activities between UTHealth and a company in which they have a financial interest (e.g., ownership, stock, serving as a board member or officer).

Only in special circumstances and after considerable review would such interaction be allowed.

To avoid a conflict, the employee with the interest must be completely removed from the review and approval of the actual transaction.
Potential Conflict Examples

**Clinics and Outside Activities Definition**

**HOOP 20** includes specific guidelines for clinicians’ interactions with industry (for-profit entities, and their representatives, that develop, produce, market, sell, or distribute any goods, services, or equipment for use by UTH ealth) that might occur in their work or in the course of training programs.

“Clinicians” are faculty members and trainees at all levels (i.e., students, interns, residents, fellows, post-doctoral trainees) in any patient care discipline, including specialties of medicine, dentistry, nursing, and allied health sciences.

The policy regarding these interactions reflects the ever-increasing complexity of these types of relationships and the heightened national and governmental sensitivity to conflicts of interest in general.

UTH ealth must ensure that the integrity of clinical decision making and the independence and content of its clinical educational programs are not compromised by an employee’s financial or other personal relationship with industry.
Potential Conflict Examples

Clinician Relationships with Industry

Refer to [HOOP 20](#) and its “Decision Matrix for Clinician Relationships with Industry” for guidance. Here are some examples:

- Clinicians **may not** accept any gifts or promotional items from industry, and an employee may not accept them on behalf of the clinician.
- Industry **may not** directly provide meals or food and beverage items for on-campus events that are related to clinical activities or medical education (unrestricted grants may be given to the university).
- Industry **may not** directly provide meals or food and beverage items to clinics, clinician offices, or other areas related to patient care activities.
- Compensation from industry, including sponsored or reimbursed travel, food, and lodging, is **prohibited** if offered for participation in passive activities (merely attending a conference, listening to a sales pitch, etc.).
- Industry **may not** give free drug, device, or product samples to clinicians or any other employees. Drug samples must be appropriately received by UTH ealth using approved university processes, and then may be **given only to patients**.
Potential Conflict Examples

Clinician Relationships with Industry

Relationships with Vendors

Even if you are not a “clinician,” you are encouraged to embrace the spirit and intent of this policy in all your interactions with vendors and other outside companies who propose to do business with UTHealth.

Sponsored Education Activities
Potential Conflict Examples

**Sponsored Education Activities**

- On-campus educational events. Events sponsored by industry on campus must adhere to UTHealth policies. On-campus events involve activities held at any UTHealth building, at UTHealth-owned or leased properties, and at any other location where an event is sponsored by a UTHealth School, department, or other administrative unit. Clinicians should be aware of recognized standards for commercial support established by accrediting organizations such as the Accreditation Council for Continuing Medical Education.

- Speaker bureaus. Industry speaker bureaus comprise a significant portion of a company’s marketing strategy, and participation in them can negatively impact the reputations of both the employee and UTHealth. Involvement in such activities is strongly discouraged.

- Trainees. Industry representatives may not interact directly with trainees solely for the purpose of promoting professional products or for distributing materials.

- Sponsorship of training experiences. Such industry sponsorship is acceptable as long as UTHealth 1) determines that the experience will have educational merit, 2) selects the trainees who will attend, and 3) receives the funds.
Approval of Outside Activities

**In General**
Outside activities (e.g., outside employment, outside board service for which an employee is compensated, and any service to a religious organization) must be performed on the employee’s own time.

**Normal Office Hours**
If the work needs to take place during normal office hours, the employee must use vacation time, compensatory time, or other appropriate leave while providing the service.

**No Cost**
The service should be without cost to the university and, except as noted in HOOP 20, must be approved prior to engaging in the activity and appropriately disclosed in an annual disclosure.

**No Interference**
Remember that employees may not have outside activities or financial interests that interfere with the performance of their UTHealth job responsibilities. This applies to everyone, regardless of job classification, number of hours worked, etc.
Employees obtain approval from their supervisor before beginning an outside activity.

Now applies its prior approval requirement to all employees in positions that are exempt from paid overtime (“FLSA-exempt). Different requirements will apply to the following two employee groups:

- Benefits-eligible: FLSA-exempt employees who are eligible for paid benefits offered by UTHealth; and
- Non-benefits eligible: FLSA-exempt employees who are not eligible for paid benefits.
• If you are unsure of the FLSA-exempt or benefits-eligibility status of your UTHealth position, consider pausing the training program at this point.

• Your individual requirements for prior approval of outside activities, and the disclosure for outside activities and financial interests discussed later in this training, will depend upon knowing this information.
In general, outside activities (e.g., outside employment, outside board service for which an employee is compensated, and any service to a religious organization) must be performed on the employee’s own time.

If the work needs to take place during normal office hours, the employee must use vacation time, compensatory time, or other appropriate leave while providing the service.

The service should be without cost to the university and, except as noted in HOOP 20, must be approved prior to engaging in the activity and appropriately disclosed in an annual disclosure.

Remember that employees may not have outside activities or financial interests that interfere with the performance of their UTHealth job responsibilities. This applies to everyone, regardless of job classification, number of hours worked, etc.
HOOP 20 has always required that employees obtain approval from their supervisor before beginning an outside activity.

In its recent revision (December, 2013), HOOP 20 now applies its prior approval requirement to all employees who are exempt from paid overtime (“FLSA-exempt). Different requirements will apply to the following two employee groups:

- Benefits-eligible: Those employees who are exempt from paid overtime, eligible for benefits offered by UTHealth, and whose job assignment is full-time (defined here as 50% FTE or more); and

- Non-benefits eligible: Those employees who are exempt from paid overtime, not eligible for benefits offered by UTHealth, and whose job assignment is part-time, temporary, or casual (defined here as 49% FTE or less).
If you are unsure of your benefits-eligible status, or the percent time that is assigned to your UTHealth position, consider pausing the training program at this point.

Your individual requirements for prior approval of outside activities, and the disclosure for outside activities and financial interests discussed later in this training, will depend upon knowing this information.
If you are a full-time, benefits-eligible employee (exempt from paid overtime, eligible for benefits offered by UTHealth, and your job assignment is 50% FTE or more):

You must obtain your supervisor’s approval for the following outside activities:

1. All outside employment and all other compensated activities;
2. All board service; and
3. Any other outside activity (regardless of whether you’ll receive compensation) that might reasonably appear to create a conflict with your UTHealth responsibilities.

“Compensation” for outside activities includes not only cash payments but also reimbursements, in-kind (free services, discounts), equity (stock, stock options, ownership), sponsored or reimbursed travel, and non-UTHealth royalties or other fee payments.
The approval requirement applies to outside activities that may differ from the training or expertise that you use in your employment at UTHealth.

For example, the activities below require approval because you plan to receive compensation, or because outside board service is involved:

- You want to work in your spare time providing landscape design services for a friend’s company and you will receive payment for each design.

- You want to work in a clothing department of a local retail store on the weekends or during holidays.

- You want to serve on the board of directors of a small oil company.
If you are a part-time, non-benefits-eligible employee (exempt from paid overtime, not eligible for benefits offered by UTHealth, and your job assignment is 49% FTE or less):

• You are required to obtain your supervisor’s approval only for outside activities that might reasonably appear to create a conflict of interest with your UTHealth job responsibilities (whether or not you plan to receive compensation for the outside activity).

If you have any questions about whether a proposed outside activity might create a potential conflict, discuss with your supervisor or contact the Office of Institutional Compliance.
Approval must be obtained from your supervisor before the outside activity begins.

Such prior approval allows for the opportunity to identify situations that might create a conflict of interest (financial or personal gain) or conflict of commitment (time or resources) with your UTHHealth responsibilities.

In the majority of cases, no conflict will be involved.

But if a potential conflict is identified, UTHHealth is required to review and if needed, develop strategies that will either manage, reduce, or eliminate the conflict through an approved Management Plan.
Outside activities that are primarily personal in nature do not require approval, for example:

- Service to religious organizations
- Political organizations
- Neighborhood associations
- Youth sports or recreation leagues
- Boards of municipalities, school systems
- Affinity groups such as a local gardening society or a collectors club

However, always refer to the HOOP 20 for details, as there are exceptions to some of the requirements. For example:

- You would have to obtain approval if you proposed to serve on the board of a religious organization that provides the same types of services which UTHealth provides (e.g., a religious hospital or academic institution). You would need to show that the board service does not conflict with any of your UTHealth responsibilities, or with UTHealth’s mission.

Some activities that do not require prior approval may still require disclosure.
For faculty members, some specific outside activities do not require prior approval. These include academic activities that are clearly related to the mission of the university and/or a faculty member’s development:

- Serving on a federal, state, or local government agency committee, panel, or commission (e.g., NIH review panels).
- Reviewing journal manuscripts, book manuscripts or grant/contract proposals.
- Developing scholarly communications in the form of books or journal articles, movies, television productions and similar works.
- Acting in an editorial capacity for a professional journal.
- Attending and presenting talks at scholarly colloquia and conferences.
- Serving as a committee member, officer, or board member of a professional or scholarly society.

Cont’d…
If you are a supervisor and review requests from your employees to participate in outside activities, here are some scenarios where a proposed outside activity might conflict with an employee’s UTHealth responsibilities, or give the appearance of a conflict.

The examples represent the potential for a conflict of interest (financial or personal gain), conflict of commitment (use of UTHealth time or state resources), or both:

- The employee participates in research at UTHealth that is sponsored by a pharmaceutical company. She now proposes to enter into a personal consulting agreement with the company.

- The employee helps negotiate contracts at UTHealth (procurement, research, licensing, etc.). He now proposes to provide personal advising services to an outside company. Based on the nature of the company’s work, you know that it is likely this company will do business with UTHealth that will involve the employee’s area of contracting expertise.
• The employee wants to start working for a friend’s local company, and based upon the company’s business, you estimate that it will involve a significant amount of time that will occur during the hours of his normal work schedule. You know that the employee currently has little personal leave time available.

• The employee’s work involves accounting, and he now proposes to start offering his accounting services to the public.

• The employee is responsible for the research that takes place in your department. She has been asked to serve on a foundation board. The foundation grants research funds and the type of funds awarded are in your department’s area of expertise.

• The employee wants to start consulting for an outside company, and when you reminded him that he must not use state resources to perform the work, you learn that he has no personal email account or personal computer to conduct the consulting work.
The Office of Institutional Compliance can provide assistance in reviewing outside activities if the employee or supervisor feels a conflict, or the appearance of a conflict, might be created.

If the supervisor agrees to approve the outside activity that would create a conflict, the employee and supervisor will suggest possible management strategies that would manage, reduce, or eliminate the potential conflict. The OIC will then assist the department or School in the development of an approved Management Plan.

An outside activity involving a financial conflict of interest in research conducted at UTHealth goes through a separate review process and must have a Management Plan approved by the Executive Vice President for Academic and Research Affairs.
A new centralized web-based system for submitting requests for approval of outside activities will be available in the spring of 2014.

The system will provide further guidance about the identification of potential conflicts and possible management strategies.

IMPORTANT: ANNUAL RE-APPROVALS ARE REQUIRED

- Each approved outside activity must be submitted for re-approval on an annual basis if the activity is on-going.
- This applies even in the case of multi-year contracts (e.g., for on-going consulting) that have already received approval. Employees must re-apply for approval each year.
If you have submitted a request for approval of an outside activity and it is denied, or you disagree with the terms and conditions of an approved Management Plan:

• You may request in writing that the decision-making authority reconsider the decision.

• A written summary of the review will be provided to you.

• If you remain unsatisfied with the decision, you may access the applicable university grievance procedures.

Approval for participation in an outside activity may be withdrawn at any time. The appeals process is also available for this circumstance.
Submitting Financial Disclosures

Point 1
Most employees will be required to submit a Financial Disclosure Statement, and they will do so when they are hired and then each year throughout their employment.

Point 2
Requirements for disclosures will vary depending upon certain factors based upon your assigned position and/or job responsibilities at UTHealth.

Point 3
The disclosure process is managed by the Office of Institutional Compliance. The OIC website will have information about the Financial Disclosure Statement so that you may review your disclosure requirements and prepare your information before you enter the on-line form.
Who is Required to Submit Financial Disclosure?

- You are “FLSA-exempt.” This means you are in a position that is not eligible to receive paid overtime. All faculty members are FLSA-exempt. A large portion of other employees are FLSA-exempt. (Your status will appear in the upper right corner of your timesheet.)

- Your job involves the negotiation or execution of contracts on behalf of UTHealth.

- You are a “covered individual” under the Research Conflicts of Interest Policy (HOOP 94). This means you are a principal investigator, co-investigator, research project director, or other faculty member, employee, trainee, or student who participates in a significant way in the design, conduct, or reporting of proposed or existing research.
What is a Financial Disclosure?

A financial disclosure is an after-the-fact description of:

- Compensated outside activities
- Service on outside boards
- Certain financial interests in for-profit business entities
- Other outside activities that might appear to create a conflict
- Activities or interests of family members that might create a conflict
- Gifts received that might appear to create a conflict
- Participation in sponsored research
Why are Financial Disclosures required?

Numerous regulations, laws, and policies provide direction to universities regarding conflicts – evident from the heightened national and governmental sensitivity to these issues.

The University of Texas System collects some of the information for reporting purposes.

Confirms approved participation in outside employment and board service, and informs UTHealth of relevant financial interests, so that potential conflicts may be managed and monitored as appropriate.
How is the Financial Disclosure Submitted?

The Office of Institutional Compliance provides a web-based UTHealth Financial Disclosure Statement.

The regular Financial Disclosure Statement is submitted by:

- Employees who are FLSA-exempt and eligible for paid benefits offered by UTHealth;
- Employees who negotiate or execute contracts on behalf of UTHealth; and
- Employees and trainees who participate in research and are designated as a “covered individual” under the Research Conflicts of Interest Policy (HOOP 94).

A “short form” Financial Disclosure Statement may be submitted by:

- An employee who is FLSA-exempt but is not eligible for paid benefits, does not negotiate or execute contracts, and does not participate in research as a “covered individual.”
When is a Financial Disclosure Submitted?

The initial Financial Disclosure Statement is submitted upon employment.

Annual Financial Disclosure Statements are then submitted each year, usually during January-February-March.

A current annual Financial Disclosure Statement must be on file for any “covered individual” under the *Research Conflicts of Interest Policy* (HOOP 94) at the time of any research grant or contract application, research protocol submission, or application for internal research funds.

Throughout the year, changes to an existing disclosure must be disclosed within 30 days of the change.

If you are required to submit an annual Financial Disclosure Statement but you do not have any outside activities or financial interests to disclose, for yourself or for family members, you must still submit the form each year.
What Should You Disclose?

Introduction

Click each topic to learn what you are required to disclose.

After clicking each topic, wait for the arrow to blink and turn blue before clicking to proceed.

Regular Financial Disclosure Statement

Short Form Financial Disclosure Statement

Unsure?

What happens with my disclosed information?
What Should You Disclose?

Introduction

Regular Financial Disclosure Statement
Those employees required to use the regular Financial Disclosure Statement will disclose the following:

- All outside employment and other compensated work;
- All outside board service (regardless of whether compensation was received);
- Interests in for-profit entities that meet the “substantial interest” definition and that appear to be related to the employee’s professional expertise or UTHealth job responsibilities;
- Any other outside activity, regardless of whether compensation was received, that could appear to be related to the employee’s professional expertise or UTHealth job responsibilities;
- Activities or interests of family members that could appear to be related to the employee’s professional expertise or UTHealth job responsibilities;
- Gifts ≥$250 in value that might appear to create a conflict; and
- Sponsors of research (if applicable) at UTHealth.

Short Form Financial Disclosure Statement

Unsure?

What happens with my disclosed information?
What Should You Disclose?

**Short Form Financial Disclosure Statement**

Employees who are allowed to use the “short form” Financial Disclosure Statement will disclose the following:

- Outside activities and financial interests only if they might reasonably appear to create a conflict of interest with their UTHealth responsibilities. This applies to the following activities and interests:
  - Outside employment and other compensated work;
  - Outside board service;
  - Interests in for-profit entities that meet the “substantial interest” definition; and
  - Any uncompensated outside activity that might reasonably appear to create a conflict.

## Unsure?

## What happens with my disclosed information?
What Should You Disclose?

- Introduction
- Regular Financial Disclosure Statement
- Short Form Financial Disclosure Statement
- Unsure?
  - If you are in doubt about whether an activity or financial interest should be disclosed -- in the interest of transparency, always resolve the doubt in favor of disclosure.
- What happens with my disclosed information?
What Should You Disclose?

Introduction

Regular Financial Disclosure Statement

Short Form Financial Disclosure Statement

Unsure?

What happens with my disclosed information?

- The information you disclose will be reviewed by the Office of Institutional Compliance and may be reviewed by your supervisor and other institutional officials.

- Disclosed information regarding outside employment, board service, and other activities/interests that might reasonably appear to create conflicts will be transmitted to an internal University of Texas System electronic database.

- Employee outside activities and financial interests that UTHealth has determined to represent conflicts and for which Management Plans have been implemented will be posted on a website available to the public.
• A fundamental mission of UTHealth is to promote the advancement of science and improvement of health through research. In conducting research, the institution and investigators are obligated to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias resulting from a financial conflict of interest.

• While personal interests related to research are not inherently wrong, they must be managed to ensure research objectivity, the safety of human subjects, and the reputations of researchers and UTHealth.

• Balancing UTHealth’s mission with the potential for financial conflicts in research requires additional disclosures by investigators and comprehensive reviews by UTHealth.
Purpose of HOOP 94

- Provides direction for the appropriate disclosure and review of financial interests, and for the identification and management of financial conflicts of interest in research.
- Complies with the requirements of federal regulations for Public Health Service (PHS) research. 42 CFR Part 50, Subpart F: *Promoting Objectivity in Research* was originally implemented in 1995 and revised in 2011.

The University of Texas System applies the federal requirements to all research performed at its component institutions.
Here are some key terms:

- **Research**: Any systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge, and includes both basic and applied research and product development.

- **Research Conflict of Interest Official**: The Executive Vice President for Academic and Research Affairs (EVPARA) is UTHealth’s designated Conflict of Interest Official for research.

- **Covered individual**: An individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research. Besides the principal investigator of a research project, it includes co-investigators, project directors, and any other person who directs or can materially influence the research, as designated by the PI. Covered individuals can also include research nurses, research coordinators, data managers, graduate students, and post-doctoral fellows. The definition could also apply to individuals from other institutions or private companies (e.g., through research subcontracts).
**Related research:** This generally means the covered individual’s personal activity or financial interest is with the sponsor of the research, or involves a personal financial interest in the technology being studied.

**Significant financial interest:** Covered individuals on research projects must disclose whether they have any “significant” financial interests related to the specific research being proposed. The disclosure must also include the activities and financial interests of family members. Significant interests are specifically defined by HOOP 94 and include the following:

- From a publicly traded entity - compensation or other payments for services (lectures, advising, paid authorship, honoraria, sponsored or reimbursed travel, etc.) in the past 12 months, and the value of equity (stock, stock options, ownership) at the time of disclosure, that when aggregated are ≥$5,000.

- From a private entity - compensation or other payments for services (lectures, advising, paid authorship, honoraria, sponsored or reimbursed travel, etc.) in the past 12 months that are ≥$5,000.
• From a private entity – equity (stock, stock options, ownership) of any amount at the time of disclosure.

• Income from intellectual property rights (e.g., royalties paid by any non-UTHealth entity).

• Service as an officer, director, or other fiduciary position in any entity for which any kind of compensation was received in the past 12 months.

• Gifts received in the past 12 months valued at ≥$250.

Some exclusions apply to the above categories (i.e., activities and interests that do not require disclosure). Refer to HOOP 94 for additional guidance.

You will also note that some of the definitions and items requiring disclosure by HOOP 94 (research) are different from those in HOOP 20 (outside activities). The disclosure forms in both areas will provide guidance about specific requirements.
Financial conflict of interest in research: A personal outside activity or financial interest held by a covered individual, or his/her family member, that upon review has been determined by UTHealth to be:

- “SIGNIFICANT” (as defined by the HOOP 94);
- “RELATED” to the research; AND
- COULD DIRECTLY AND SIGNIFICANTLY AFFECT THE DESIGN, CONDUCT, OR REPORTING OF THE RESEARCH.
If you have been designated as a “covered individual” on a proposed research project (funded by external sponsors or internally through department funds, gifts, endowments, internal award programs, etc.), you must complete the following requirements:

A. Read and understand the Research Conflicts of Interest Policy (HOOP 94).

   If you participate in federally-funded research, you must also read and understand the applicable federal regulation, 42 CFR Part 50, Subpart F: Promoting Objectivity in Research.

B. Complete required education on research conflicts of interest. Completion of this bi-annual training module satisfies the requirement for UTHHealth employees.
C. Submit a one-page “Research Conflict of Interest Certification Form” at the time of each research application, proposal, or protocol. The form will ask you to disclose any significant financial interests related to the specific research project.

If you do have related significant financial interests that are related to the research, you will then submit a “Research Conflict of Interest Disclosure Form.” The form will ask for more details about the research, your personal financial interests, and how your interests are related to the research.

D. Submit your annual on-line Financial Disclosure Statement to the university (normally submitted only one time per year).
Coordination of Requirements for Covered Individuals

The Office of Institutional Compliance (OIC) maintains the required bi-annual Research COI training, and collects all financial disclosures.

The Office of Sponsored Projects (OSP) collects the one-page “Research COI Certification Form” from all covered individuals on research grant/contract applications. The Committee for the Protection of Human Subjects (CPHS) and the Animal Welfare Committee (AWC) may also collect the form for research protocols submitted to their offices.

Schools, departments, and other units making internal research or award decisions are required to collect the “Research COI Certification Form” for internally funded research projects (e.g., department funds, startup accounts, gifts, endowments, internal award programs). Remember, the requirements apply to all research regardless of the funding source. No further action is needed unless a covered individual discloses a significant financial interest related to the proposed research. The Research COI Office should then be contacted so that a review may be initiated.
Committee Review

If a covered individual has disclosed a “significant” financial interest that may be related to a proposed research project, the Research Conflicts of Interest Committee performs a review.
Committee Review Continued

The Committee:

Is comprised of faculty members and staff advisors who meet on a regular basis to review disclosures of research-related significant financial interests.

Makes a determination whether the significant financial interest is a financial conflict of interest (FCOI) in the research by evaluating if the interest could directly and significantly affect the design, conduct, or reporting of the research.

Submits all recommendations to the Executive Vice President for Academic and Research Affairs

If an FCOI:

If an FCOI in the research is identified, the Committee makes recommendations whether the conflict is manageable.

If an FCOI is manageable, the Committee recommends specific management strategies.
Requirements

1. Comprehensive disclosures by covered individuals, and timely reviews by UTHealth, are required at the time of the research application, proposal, or protocol.

2. Per [HOOP 94](#), no research may be initiated, and no research funds may be expended on any research, unless the EVPARA has determined that no financial conflict of interest exists or that any financial conflict of interest is manageable with the terms of a Research COI Management Plan that has been adopted and implemented.

3. Submit a revised disclosure if any new related “significant” financial interest has been obtained, or if an existing related financial interest has changed, after a research project has begun. Disclosure needs to be made within 30 days of the change. Contact the Research Conflict of Interest Office for assistance.
Scenarios

To complete this section about research and potential conflicts, here are some examples of scenarios that might require a Research COI Management Plan in order for the covered individual to participate in the research (contingent upon approval by the CPHS, AWC, etc. as applicable):

• An employee has received $6,000 in personal consulting compensation in the past 12 months from a publicly-traded pharmaceutical company. She now proposes to be a co-investigator for a new research project to be sponsored by the company.

(If the employee had agreed to personal compensation that would not exceed $5,000 a year, it would not be defined as a “significant” interest and would not require review for a research conflict. The Committee’s review would begin by evaluating her personal relationship with the company and if/how the relationship could affect the employee’s role in the design, conduct, and reporting of the proposed UTHealth research.)
An employee was given a few stock options in a local private biotechnology startup company. The company now wants to sponsor research at UTHealth in which the employee would work on the data analysis portion of the project here.

(A review for a research conflict is required since any amount of stock or stock options in a private company is defined as a “significant” interest. The Committee’s review would begin by evaluating the employee’s close relationship with this biotech company and if/how the personal financial interest could affect the employee’s conduct in the proposed UTHealth research.)
An employee is an inventor on technology that she created at a previous employer. The employer licensed the technology to an outside company and the employee continues to receive a share of royalty payments from the previous employer. She now wants to further study the technology at UTHealth in a proposed National Institutes of Health (NIH) grant.

(A review for a research conflict is required since she receives income from non-UTHealth royalty payments, defined as a “significant” financial interest. The Committee’s review would begin by evaluating if there was a chance that she could personally benefit from the new research, and if/how the employee’s personal financial interest could affect the design, conduct, and reporting of the proposed UTHealth research. In addition, if an NIH grant is awarded and a Research COI Management Plan is implemented, the university is required to report the conflict and its management to NIH and provide annual updates.)
• An employee has been conducting research at UTHealth that is sponsored by a company for a few years. He recently began serving on the scientific advisory board for the company, and his personal compensation has now exceeded $5,000 in the past 12 months.

(Best practice would be for the employee to submit a “Research COI Disclosure Form” as soon as he began the outside activity with the company, if he anticipated that he would receive compensation over $5,000 that would require review for a research conflict in the existing research project. The Committee’s review would begin by evaluating the employee’s personal relationship with the company and if/how the relationship could affect his conduct and reporting of the UTHealth research. The Committee would need to consider not only the research going forward, but also the research that has already been performed and/or presented, and whether either could appear to be affected by the employee’s “significant” financial interest.)
An employee has just been hired and wants to perform research at UTHealth on technology that is licensed to a private biotechnology company in which he holds an ownership interest. His department plans to provide him with internal startup funds to perform research while he applies for external funding.

(The employee’s department must collect a “Research COI Certification Form” from the employee for the proposed research, at which time the employee’s financial interest would be confirmed. A review for a research conflict is required since any amount of ownership interest in a private company is defined as a “significant” interest. The Committee’s review would begin by evaluating whether the employee could personally benefit from research on the technology through his ownership in the company, potential sales of commercialized products, etc. and how the employee’s personal financial interest could affect the design, conduct, and reporting of the UTHealth research.)
When you request approval to participate in outside activities, and when you disclose outside activities and financial interests, the following factors will be considered to screen for potential conflicts:

- The amount of compensation earned or value of financial interest held
- Your UTHealth job responsibilities
- Your ability to clearly separate your UTHealth responsibilities from the work you perform for, or the interest you hold in, the entity
- The type of entity involved
- The nature of your personal relationship with the entity
- The degree to which your outside activity or interest overlaps with your UTHealth job responsibilities
- The potential influence the relationship may have, or appear to have, on your UTHealth job responsibilities
Management of Potential Conflicts

1. If a potential conflict is identified, the next step is to determine if the conflict can be managed.

2. An initial option for you is to eliminate the conflict - by stopping the outside activity or divesting the financial interest.

3. Most conflicts can be managed with an appropriate Management Plan that will outline for you the expected standards of conduct in your UTHealth responsibilities.

4. Management Plans will be monitored on a regular basis.
When you request approval to participate in outside activities, and when you disclose outside activities and financial interests, the following factors will be considered to screen for potential conflicts:

- The type of entity involved.
- The amount of compensation earned or value of financial interest held.
- The nature of your personal relationship with the entity.
- Your UTHealth job responsibilities.
- The degree to which your outside activity or interest overlaps with (is the same nature as) your UTHealth job responsibilities.
- Your ability to clearly separate your UTHealth responsibilities from the work you perform for, or the interest you hold in, the entity.
- The potential influence the relationship may have, or appear to have, on your UTHealth job responsibilities.
If the employee’s outside activity or financial interest has been identified as a potential conflict, and the conflict is determined to be manageable, here are some terms and conditions (management strategies) in a typical Institutional COI Management Plan:

- I will maintain a clear and identifiable separation between my UTHealth responsibilities and the work I will perform for the entity.

- I will not use UTHealth time to perform work for the entity (unless conducted through an approved agreement such as a sponsored research agreement).

- I will not use UTHealth resources (computers, email, equipment, supplies, space, personnel, etc.) to perform work for the entity (unless through an approved agreement).

- I will not transact any business with the entity in my official UTHealth position (e.g., I will not take part in discussions, negotiations, and decision making about or with the entity).
I will continue to meet all my assigned UTHealth administrative, clinical, teaching, research, and service responsibilities.

I will not take part in administrative supervision or mentoring of employees or trainees who have activities or financial interests with the same entity.

I will ensure that my relationship with the entity does not influence my UTHealth responsibilities or the independence of my judgment in the performance of my duties.

If my disclosure situation changes, I will update my disclosure within 30 days of the change.
For financial conflicts of interest in research, UTHealth has the following options to first consider:

- Require the research to be conducted elsewhere.
- Conduct the research at UTHealth but with another investigator who has no related financial interest in the sponsor or in the technology being studied.
- Modify the research plan or design.
- Limit the personal relationship of the conflicted researcher with the entity.
- Require divestiture of the financial interest by the conflicted researcher.
If the employee’s outside activity or financial interest has been identified as a financial conflict of interest in research, and the conflict is determined to be manageable, here are some terms and conditions (management strategies) in a typical Research COI Management Plan:

- Documentation of the scientific methods the researcher will utilize to ensure, to the extent possible, that the design, conduct, and reporting of the research will be free from bias resulting from the financial conflict of interest.
- Disclosure of the financial interest to participants in human subjects research.
- Prohibit or limit participation in the informed consent process.
- Disclosure of the financial interest in all relevant presentations and publications.
- Disclosure of the financial interest to all collaborators and trainees who work on the conflicted research.
- Involve other faculty members in trainee projects or review committees where the conflicted research is involved.
- Ongoing disclosures and updates of relevant activities and financial interests.
Management Plans for research conflicts are recommended by the Research Conflicts of Interest Committee, and approved by the Executive Vice President for Academic and Research Affairs.

Management Plans for all other types of conflicts are developed through the Office of Institutional Compliance, may be recommended or reviewed by the Institutional Conflicts of Interest Committee, and are approved by the Senior Executive Vice President/Chief Operating and Financial Officer.

Management Plans involving an entity in which the employee owns an interest or serves as an employee, officer, or board member, and where the entity proposes to sponsor research or license UT-owned intellectual property, must also be approved by the UT System Executive Vice Chancellor for Health Affairs.
If a potential conflict is identified, the next step is to determine if the conflict can be managed.

An initial option for you is to eliminate the conflict - by stopping the outside activity or divesting the financial interest.

Generally though, most conflicts can be managed with an appropriate Management Plan that will outline for you the expected standards of conduct in your UTHealth responsibilities.

Management Plans will also be monitored on a regular basis.
Overall Responsibilities

To Be Compliant

Failure to comply with applicable federal regulations, state laws, The University of Texas Board of Regents Rules and Regulations, UT System policies, UTHSCSA policies, and/or the terms of an approved Management Plan may result in the total withdrawal of or limitations to the university’s approval of your outside activities. Such failure may result in disciplinary action, up to and including termination of employment. Examples:

- Failure to obtain approval for outside activities, as the requirement applies to your position.
- Failure to disclose outside activities and financial interests, as the requirement applies to your position.
- Failure to disclose in a timely manner.
- Failure to disclose changes to a disclosure situation within 30 days of the change.
- Failure to comply with the terms and conditions of an approved Management Plan if one has been implemented for you.
Overall Responsibilities

To Avoid Conflicts

Here is an overview of your responsibilities to help avoid conflicts of interest, conflicts of commitment, and conflicts in research in your UTH ealth work:

- Read and understand HOOP 20, Conflict of Interest, Conflict of Commitment and Outside Activities.
- If you participate in research, read and understand HOOP 94, Research Conflicts of Interest.
- If you participate in federally-funded research, read and understand 42 CFR Part 50, Subpart F: Promoting Objectivity in Research.
- Understand the ways in which conflicts might typically arise in your job.
- Do not propose an outside activity or financial interest that would contradict the teaching, research, or healthcare missions of UTH ealth.
Overall Responsibilities

To Avoid Conflicts Continued

- Do not propose an outside activity or financial interest that has the potential to adversely affect your UTHealth responsibilities.
- Always consider how your interactions would appear to the public when working with outside vendors and other business entities in your UTHealth responsibilities.
- If you are a clinician, be aware of the additional issues involved regarding potential conflicts in your interactions with representatives of industry, and how clinical decision making and the content of clinical educational programs might appear to be affected.
- Understand the requirements for prior approval of outside activities, and the requirements for disclosure of outside activities and financial interests, that are applicable to your UTHealth position.
- Disclose your outside activities and financial interests as required and in a timely fashion.
Overall Responsibilities

To Avoid Conflicts Continued

- If you are a “covered individual” under the Research Conflicts of Interest Policy (HOOP 94), understand your additional disclosure requirements at the time of each research application, proposal, and protocol.
- Report any changes to your disclosure situation within 30 days of the change (a new activity or interest, a change to an existing activity or interest, or the elimination of an existing activity or interest).
- If an outside activity or financial interest is identified as a potential conflict for you, work with your supervisor to develop appropriate management strategies for your UTH Health responsibilities.
- Comply with all the terms and conditions of an approved Management Plan if one has been implemented for you.
- Provide additional information and updates to institutional officials timely, for monitoring activities or upon request.
Thank You

• Thank you for reading about the applicable policies and the expected standards of conduct regarding the avoidance of conflicts in your UTHealth responsibilities.

• If you have questions about information contained in this module, please contact:

   The UTHealth Office of Institutional Compliance
   (713) 500-3294
   compliance@uth.tmc.edu