

CONFLICT OF INTEREST IN RESEARCH

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Individual COI in Research

- research conflict of interest = financial conflict of interest in the research
- when an individual researcher's personal financial interest or outside activity directly and significantly affects the design, conduct, or reporting of research



Institutional COI in Research

- when an institutional official's (e.g. President, Executive Vice Presidents, Vice Presidents, Deans, and Department Chairs, etc.) personal financial interest or outside activity could affect or appear to affect the research conducted in his/her department or other area of responsibility (e.g., research oversight, allocation of laboratory space, assignment of personnel or equipment)
- when financial interests of institution pose or may pose risk of undue influence on decisions that affect research

Potential Influence of Outside Interests

Potential influence in **performance of research**

- Bias in the design, conduct, or analysis/interpretation of research
- Bias in the reporting of research- e.g. failure to publish findings in a timely fashion

Potential influence in **protecting human subjects**

- Inappropriate enrollment of study subjects
- Flawed informed consent process
- Inadequate standard of patient care
- Adverse events not appropriately reported/managed

Potential influence in **use of time and resources**

- Use of university-funded time for personal activities or financial interests
- Uncompensated use of university space, equipment, supplies
- Inappropriate use of university personnel (*e.g.*, lab assistants, support staff)



Policies

- **Federal policy** (42 CFR Part 50, Subpart F)- purpose is to “**promote objectivity in research** by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest”
- **UT System policy** (UTS 175)- applies the federal requirements to all research conducted at its component institutions
- **UTHealth Houston policy** (HOOP 94)- addresses requirements for disclosure, identification, review, and management of researchers’ financial interests that may create financial conflicts of interest in research



HOOP 94 Policy



- Applies to all “**covered individuals**” in research
- Covered Individual= an individual who, regardless of title or position, is **responsible for the design, conduct, or reporting of research**
 - principal investigator, co-investigator, project director, senior or key personnel, and any others who direct or can materially influence the research
 - may also include students or collaborators
- The Principal Investigator is responsible for determining who meets this definition in their research projects

HOOP 94 Requirements for Covered Individuals



- **Must** complete the required Research COI Training (online course every two years)
- **Must** submit an Annual COI Disclosure (online form every year)
- **May** have to submit a “Project Certification Form” for every research project regardless of funding source
- **May** have to submit a “Project Disclosure Form” if there is a significant financial interest related to the research



Project Certification Form

Do you or a family member have any **significant financial interest (SFI)** related to this research?



- Compensation for an outside activity from the research sponsor
- Any stock, stock options, business ownership, or rights to such interests in the research sponsor
- Ownership interest or rights to the technology that will be studied in the proposed research
- Financial interest in an entity that owns or licenses the technology that will be studied in the proposed research
- Any other personal relationship or financial interest that could appear to affect, or be affected by the proposed research

Family Member= spouse, dependent child/step-child, any person financially dependent upon the covered individual, and any person with whom the covered individual has joint financial interests where their professional responsibilities could affect or be affected by those interests

SFIs

- **From a publicly traded entity:** Compensation (e.g. fees/honoraria/payments for consulting, lectures, advisory board service, paid authorship, travel reimbursements) in the preceding 12 months and the value of equity interests (e.g. stock, stock options, business ownership) at the time of the disclosure that, when aggregated, exceed \$5,000
- **From a non-publicly traded entity:** Compensation for services (see above) in the preceding 12 months that, when aggregated, exceed \$5,000 or equity interests at the time of disclosure of any value
- **Intellectual property rights** (e.g. patents, patent applications) and agreements to share in the royalties related to those rights. (This does not include intellectual property owned by UT for which the individual has no other related personal financial interests)
- **Officer:** Remuneration or payment for service as Officer, Director, or other fiduciary position for an outside entity in the preceding 12 months
- **Gifts** from outside entity in the preceding 12 months that exceed \$250 value or multiple gifts from single entity that in aggregate exceed \$250 in value

Note: Significant Financial Interest does not automatically result in a determination of a research conflict



Not “SFIs”



- **Salaries** paid to UTHealth Houston employees- salary that is paid as part of a formal contract between UTHealth and an outside entity through a sponsored research agreement
- **Royalties** paid to current UTHealth Houston employees through the UTHealth Office of Technology Management
- **Compensation** for seminars, lectures, teaching engagements, or compensation for service on advisory committees or review panels from federal, state, or local governments, US institutions of higher education, or academic teaching hospitals, medical centers, or research institutes that are affiliated with institutions of higher education
- **Reimbursed or sponsored travel** from federal, state, or local governments, US institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with institutions of higher education, or travel that is part of a formal contract between UTHealth and an outside entity such as a sponsored research agreement
- **Stocks held in mutual funds or retirement accounts**, or income from such investments over which the covered individual has no control over the holdings or investment decisions

Examples

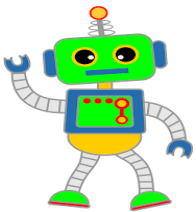
ADVISORY
BOARD



- A clinician received \$6,000 from a pharmaceutical company during the past 12 months for serving on the company's scientific advisory board. She now proposes to be the PI in a study at the University that is sponsored by this company.



- An employee owns stock options in a local biotechnology startup company. The company wants to sponsor research at the University in which the employee will serve as the Co-I.



- An investigator is an inventor of UT-owned intellectual property and conducts research at the University that studies the technology. The Office of Technology Management is now working to license this technology to an outside company that wishes to commercialize it, and the investigator and the University will receive equity in the company.

More Examples

- A newly hired researcher receives royalties from an outside company for licensed intellectual property created during his prior employment. The researcher now proposes to perform research at the University that will validate the technology.



- An investigator participates in a clinical trial at the University sponsored by a medical device company. At the time when the project was approved, the researcher had no personal financial interest with the company. A year into the project, the researcher now wishes to consult for the company and she anticipates that her personal compensation will exceed \$5,000.



COI and Human Subjects Research

The COI review process for human subjects research contains several key factors:
(modified from AAMC guidance)

- Combination of skills, qualifications, expertise of the covered individual
- Specific institutional resources
- Access to certain patient populations (of interest for study)
- Nature of research
- Risk-Benefit Analyses related to the RCOI (to what extent could the conflict increase risk to human subjects that cannot be managed?)
- Degree to which the significant financial interest and the research are linked
- Extent to which the conflicted interest is amenable to effective oversight and management



Note: The Research COI Committee (RCOIC) works with the Committee for the Protection of Human Subjects (CPHS) on these reviews

COI Reviews

CERTIFICATION

Covered Individuals certify if they have any related significant financial interests for a project

DISCLOSURE

RCOIC works with SPA, CPHS, AWC, OTM, Legal Affairs

REVIEW

Review by RCOIC (appointed faculty members, community members, and advisors) with recommendations made to the RCOI Official

DETERMINATION

No conflict

Participation in research approved by RCOI Official without Management Plan

Conflict can be managed

Participation in research approved by RCOI Official with Management Plan

Conflict cannot be managed

Participation in research disapproved by RCOI Official

Management Strategies

- Research project could be performed elsewhere
- Research project could be performed at the University by another non-conflicted researcher who has no financial ties to the company involved or to the technology being used, studied, or validated
- Research project could be conducted at the University by the conflicted researcher with the implementation of an appropriate Management Plan



Management Plan

- Document prepared by the Researcher, COI Office, and RCOIC and signed by the Researcher, Supervisor/Chair, and RCOI Official
- May include the following provisions:
 - Disclosure of financial interests to study participants, sponsors, research collaborators, study personnel, and trainees
 - Disclosure of financial interests in publications and presentations
 - Inclusion of safeguards to promote objectivity in the study plan or research project design
 - Additional oversight or monitoring
 - Monitoring of involvement in trainee education programs
 - Limitation of relationships or payments



Regulations



42 CFR Part 50, Subpart F: Promoting Objectivity in Research- This federal regulation requires that institutions promote objectivity in PHS-funded research by implementing policies for the researcher to disclose and for the institution to review, manage/mitigate, and report financial conflicts of interest in research. Originally implemented in 1995, the regulations were revised in August, 2011.

UT System 175 Policy- Disclosure of Significant Financial Interests and Management of Reporting of Financial Conflicts of Interest in Research- UT System applies the federal requirements to all research conducted at its component institutions.

HOOP 94 Policy- Research Conflicts of Interest- addresses requirements for disclosure, identification, review, and management of researchers' financial interests that may create financial conflicts of interest in research.

HOOP 20 Policy- Conflict of Interest, Conflict of Commitment and Outside Activities- provides guidance regarding outside activities and financial interests in outside entities.

HOOP 221 Policy- Institutional Conflicts of Interest- provides guidance on conflicts of interest involving the university and/or university officials.

Resources

Conflict of Interest Office

research_coi@uth.tmc.edu

Website

<https://www.uth.edu/evpara/rcoi/index.htm>

CITI site with RCOI training for non-UTHealth Houston researchers

<https://www.citiprogram.org/>

HOOP <https://www.uth.edu/hoop/>

Research Conflict of Interest- HOOP 94

Conflict of Interest, Conflict of Commitment and Outside Activities- HOOP 20

Institutional Conflicts of Interest- HOOP 221

