



Policy on Conflict of Interest for Academic Staff

Presented by:

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Office of Research Policies, Compliance
and Committees

Purpose of Division of Research FCOI Policy

- An *investigator* may have an outside financial interest that could conflict or be perceived to conflict with his or her University of Houston research or other institutional responsibilities.
- To address these situations and to comply with federal regulations and sponsor requirements, the University has updated its financial conflict of interest policy in 2012 to comply with the latest federal regulations.

IMPORTANT: Please note that these requirements are specific to the DOR Conflict of Interest Policy for investigators and do not replace the disclosures required under SAM 02.A.08 Consulting and Paid Professional Services and the UH System Conflict of Interest Policy (SAM 02.A.09).

Division of Research FCOI Policy (continued)

- The cornerstone of this policy:
 - Annual conflict of interest certification and disclosure of financial outside interests when they reach regulatory thresholds
 - The appropriate updating of these certifications
 - Managing these conflicts in a way that ensures that the integrity of the research remains intact.
- What are the thresholds (generally)?
 - \$10,000 for non-PHS funded investigators
 - \$5,000 for PHS funded investigators
- Some have no thresholds, such as:
 - Equity in a non-publicly traded entity
 - Intellectual property rights income received from any source other than the Investigator's current Institution

What is PHS funded?



- PHS = Public Health Service, a U.S. government agency made up of 10 other agencies/operating divisions. Most common PHS funding at UH is from National Institutes of Health (NIH).

Public Health Service/DHHS Agencies

1. Administration for Children and Families (ACF)
2. Administration for Community Living/Administration on Aging
3. Agency for Healthcare Research and Quality (AHRQ)
4. Agency for Toxic Substances and Disease Registry (ATSDR)
5. Centers for Disease Control and Prevention (CDC)
6. Food and Drug Administration (FDA)
7. Health Resources and Services Administration (HRSA)
8. Indian Health Service (IHS)
- 9. National Institutes of Health (NIH)**
10. Substance Abuse and Mental Health Services Administration (SAMHSA)
11. Office of Global Affairs
12. Office of the Assistant Secretary for Health (OASH)
13. Office of the Assistant Secretary for Preparedness and Response (ASPR)

Six Basic Steps in the Financial Conflict of Interest Process

1. Complete a Certification
 - Who, when, what, and how to disclose
2. FCOI Certification Review
 - COI Office Review
 - COI Committee Review
3. COI Committee & Submission Dates
 - COI Committee
 - COIC Meeting dates
4. Management of the FCOI
 - FCOI Determination
 - Management Plan Examples
5. Changes/Updates to Financial Interests
 - When, what, and how?
6. Travel Disclosures

<http://www.uh.edu/research/compliance/coi/>

Step 1: Complete a Certification



- Who must complete a certification?

All academic staff members meeting the definition of Investigator. The term "Investigator" means **the Project Director or Principal Investigator, Co-Principal Investigators, and any other persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research activities funded or proposed for funding.** Therefore, the policy can apply to collaborators, consultants, postdoctoral fellows, graduate students, and others who meet the threshold for responsibility.

At a minimum, all individuals listed as an investigator or key personnel on a research project must file a certification, however it is the responsibility of the PI to determine if other research team members meet this threshold based on their role in the research.

Step 1: (continued)

- *When is certification required?*
 - Annually, by October 1 of each fiscal year, to cover the current fiscal year (Sept 1, 2014 – Aug 31, 2015)
 - Within 30 days in the case of any new acquisitions or discovery of new significant financial interests (see Step 5 for more information)
 - At the time of application for new funding if current financial interests could reasonably affect, or be affected by, the proposed research.

Step 1: (continued)

- What must be certified and disclosed?
 - All Significant Financial Interests (SFIs) that may appear to be related to your research or institutional responsibilities must be disclosed. Disclosure is required if such an interest is held by you, your spouse, or your dependent children.

IMPORTANT: Some non-federal funding agencies require compliance with the lower thresholds set forth by the PHS policy.



Step 1: (continued)



➤ Significant financial interests include:

- *Income* in excess of \$10,000 (\$5,000 for Public Health Service (PHS)-funded Investigators) from a *publicly-traded entity* during the last 12 months,
- *Stock* in a *publicly traded company* valued in excess of \$10,000 (\$5,000 for PHS-funded Investigators) at the time of disclosure,
- *A combination* of the above two items (stock and income) that exceeds \$10,000 (\$5,000 for PHS-funded Investigators) during the preceding 12 months,
- *Any amount of equity* (stock, stock options, or other ownership interest) in a *non-publicly traded entity*, such as a start-up company,
- *Income related to intellectual property* rights paid by any source other than the Investigator's current Institution within the next 12 months.
- *Income related to intellectual property* rights paid by the University of Houston **ONLY IF** the investigator/investigator's family has an *interest in the company licensing the technology*.

Step 1: (continued)



- Does NOT need to be disclosed:
 - Salary, royalties, or other remuneration paid to the Investigator from the Institution that currently employs the Investigator (exception: *Income related to intellectual property rights* paid by the Investigator's current Institution and the investigator/investigator's family has an interest in the company licensing the technology.),
 - Income from seminars, lectures, or teaching engagements sponsored by, a federal, state, or local government agency; a U.S. Institution of higher education; or a research institute affiliated with such, a medical center, or an academic teaching hospital,
 - Income for services (e.g., honoraria, advisory committees, and review panels) and travel expenses paid by a federal, state, or local government agency; a U.S. Institution of higher education; or a research institute affiliated with such, a medical center, or an academic teaching hospital,
 - Income from investments in mutual funds or retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles (for example, an interest in a pooled fund), or
 - Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Program Phase I applications and awards. [Note: Although disclosure is not required under the PHS regulations for Phase I, it is highly recommended so that potential conflicts are understood and a plan is in place to manage them prior to the submission of Phase II. Such financial interests should still be addressed in consent forms for human subjects.]

Step 1: (continued)

- *How to certify and disclose*
 - Fill out a Conflict of Interest Certification Form (available on the [DOR website](#))
 - If one or more of the screening questions on the certification form is answered “yes,” a disclosure form(s) is required and must be attached to your certification prior to obtaining acknowledgement signatures.
 - Obtain all required acknowledgement signatures from your Chair, Center Director, College Dean (in most cases).
 - Once all signatures have been obtained, documents can be uploaded to RD2K. All Department Business Administrators have access to RD2K. For individual access to upload your own documents, please contact the DOR, Research Information Center personnel.

Step 1: (continued)



- *Who should acknowledge and sign my form?*

You are:	Signatory 1	Signatory 2
Tenure track academic faculty appointments	Department Chair	College Dean
Non-tenure track research faculty appointments	Department Chair	Center Director
Staff & students employed by an academic department or college	Department Chair	College Dean
Staff & students employed by a Division of Research Center	Department Chair	Center Director
Tenure track academic faculty appointments affiliated with a Division of Research Center	Department Chair	College Dean
Non-tenure track research faculty appointments with a Division of Research Center	Center Director	VC/VP for Research and Technology Transfer
Department Chair	College Dean	Provost
Division of Research Center Directors	College Dean	VC/VP for Research and Technology Transfer
College Dean	Provost	VC/VP for Research and Technology Transfer

Step 1: (continued)

- *Types of Disclosure Forms*
 - Significant Financial Interest Disclosure Form (non-IP)
 - COI Intellectual Property Disclosure Form
 - Travel Disclosure Form (for PHS, and those agencies that follow PHS regulations, funded investigators only)

Step 2: FCOI Certification Review

- COI Office Review

- No outside Significant Financial Interests require disclosure by investigator?
 - An administrative review performed by the COIC office.
 - A memo/email is generated and sent acknowledging that the investigator has reported no potentially conflicting financial interests.
 - Archived by the COI Office.
- Certifications submitted with disclosures
 - First reviewed in the COI Office for completeness.
 - Office staff may request additional information or clarification from the investigator
 - Added to COI Committee Agenda
- COI Office checks to make sure all PHS investigators and key personnel have completed required online training for COI.
 - Online training is provided through CITI at www.citiprogram.org.
 - FCOI modules 1 and 2 must be completed prior to utilizing PHS funds and at least once every four years.

Step 2: (continued)

- *Conflict of Interest Committee (COIC) Review*

- Disclosures are placed on an agenda for review by the COIC.

- Primary and a secondary reviewers are assigned to review and present each disclosure to the full committee.
- Upon committee discussion, a determination is made regarding whether a perceived conflict between the significant financial interest and the investigator's institutional responsibilities exists.
- If a perceived or real conflict exists, a plan (or an updated plan, if necessary) to manage the conflict is required (see Basic Step 4).

Note: If not enough information is provided regarding the financial interest or how it may appear to conflict with the research or other institutional responsibilities, the disclosure will be tabled and a request for further clarification made. This will delay a final determination until the committee conducts additional review at a subsequent meeting.

Step 3: COI Committee and Submission Dates



- Meets Monthly (typically 4th Tuesday) – disclosures submitted at least 2 weeks prior will be placed on the meeting agenda
- The COIC Reviews Certifications and Disclosures on behalf of the Vice Chancellor/Vice President for Research and Technology Transfer, the Institutional Official (IO)
- It is comprised of members of multiple UH Colleges and Departments, appointed by the IO.
 - Includes a member from the Research and Scholarship committee, as well as a member external to UH.
- Ex officio membership are from UH General Counsel, the Office of Intellectual Property Management (OIPM) and the Compliance Office.
- May require additional information to make their determination
- Makes recommendation to IO about management plan, however IO provides final signature, along with Chair/Dean

Step 4: Management of the FCOI

Examples of Management Plans:

- Public disclosure of the conflict in publications and presentations
- Disclosure to human subjects participating in the research
- Disclosure to other research team members
- Appointment of an independent third party to monitor the research
- Modification of the research plan, with approval by the sponsor
- Change of personnel or personnel roles so that the individual in conflict does not participate in the part of the research that could be affected
- Reducing or eliminating the financial interest (e.g., sale of an equity interest)
- Severance of relationships that create financial conflicts

Step 5: Changes/Updates to Financial Interests

- The aims of newly proposed research projects must be taken into consideration, as potential conflicts must be reported and managed at the time of submission of the proposal.
- All investigators, throughout the year, must submit an updated and/or new certification and disclosure within 30 days of a change in the status of any significant financial interest or the addition of any significant financial interest.
 - For example:
 - Sale of stock previously disclosed
 - Receipt of additional compensation to that already disclosed
 - A new financial interest was obtained
 - A previously reported financial interest was eliminated

Step 6: Travel Disclosures

(for PHS-funded investigators **ONLY**)

- Third party sponsored/reimbursed travel (including from non-profit organizations), must be disclosed on the Travel Disclosure Form.
- Disclosure is **not** required for travel sponsored by or reimbursed by:
 - government agencies,
 - U.S. Institutions of higher education or a research institutes affiliated with such,
 - U.S. medical centers,
 - U.S. academic teaching hospitals.
- Travel disclosures must include, at a minimum:
 - the purpose of the trip,
 - the identity of the sponsor/organizer,
 - the destination,
 - the duration.
- The COIC will determine whether the travel constitutes an FCOI with PHS-funded research. If yes, a management plan will be required.
- If the investigator is PHS funded *and* receiving 3rd party reimbursement and/or sponsored travel, ***a Travel Disclosure form must be filed within 30 days of the return from the trip.***



Tips and Tricks for Certification and Disclosure

1. Reasonableness Standard – keep the key goal in mind. Do you have personal financial interests that conflict or may appear to conflict with or bias the design, conduct, or reporting your funded research/institutional duties?
2. Provide signatories with complete packet if further disclosure is required
3. Obtain all signatures prior to submission (including PI, Dean, Chair) – otherwise, will be sent back
4. Answer ALL questions as thoroughly as possible – otherwise, will be sent back
5. Upload entire packet in one submission to RD2K
6. Be as complete as possible in disclosures
7. Look at grant/contract language to see if the agency requires compliance with PHS FCOI requirements (ex: American Heart Association)

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Division of Research



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Contact Us

For Human Subjects, Animal Subjects, Conflict of Interest, Research Congruency, Responsible Conduct of Research:

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Compliance

The Office of Research Policies, Compliance and Committees is committed to the support and education of the UH research community in all areas of compliance with federal regulations concerning **human subjects**, **animal subjects**, **conflicts of interest**, **grant congruency**, and **responsible conduct of research**.

The Office of Contracts and Grants oversees **effort reporting** and **export controls**.

Upcoming deadlines

CPHS Committee 1: Friday, August 1, 2014

CPHS Committee 1, Expedited Review Subcommittee: Monday, July 18, 2014

CPHS Committee 2: Friday, August 8, 2014

CPHS Committee 2, Expedited Review Subcommittee: Friday, July 25, 2014

IACUC Committee: Monday, August 25, 2014

COI Committee: Monday, September 8, 2014

Related Links

[Animal Care Operations \(ACO\)](#)[DHHS Office of Research Integrity](#)[Environmental Health and Life Safety](#)

Compliance

[Human Subjects/CPHS](#)

[Animal Subjects/ACUC](#)

[Conflict of Interest Certification](#)

[Step 1: Complete a Certification](#)

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[Policy on Conflict of Interest for Academic Staff](#)

Conflict of Interest Certification



Review the 6 basic steps depicting the University of Houston's Financial Conflict of Interest process by **clicking each step** on the left side of the page

Occasionally, situations arise where an investigator may have an outside interest that could conflict or be perceived to conflict with his or her University of Houston research or other institutional responsibilities. To address these situations and to comply with federal

Related Links

[Policy on Conflict of Interest for Academic Staff](#)

[Conflict of Interest Forms](#)

[COI Institutional Reporting Requirements](#)

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Resources

- DOR Forms
 - Animal Care Operations
 - Closeouts
 - Conflict of Interest**
 - Contract Agreement
 - DOR Letters and Agreements
 - Export Controls
 - CPHS/IRB
 - Institutional Animal Care and Use Committee (IACUC)
 - Intellectual Property Forms
 - Internal Awards Forms
 - Post-Award Administration
 - Proposal Processing

- Training
- Systems
- SharePoint for DOR

Conflict of Interest Forms

	Modified:
updated FY2015 Certification of Compliance (see also Forms Instructions)	08/14/2014
new IP Disclosure Form	08/14/2014
updated Travel Disclosure (pdf)	08/14/2014
updated Significant Financial Interest Disclosure Subrecipient Letter Template	08/14/2014
	01/07/2014

See also Compliance: Conflict of Interest.

FY2015 FCOI Forms Instructions

[http://www.uh.edu/research/resources/dor-forms/coi-forms/DOR.ORPCC.C.06 FY2015 Forms Instructions.pdf](http://www.uh.edu/research/resources/dor-forms/coi-forms/DOR.ORPCC.C.06_FY2015_Forms_Instructions.pdf)

Certification form Example

<http://www.uh.edu/research/resources/dor-forms/coi-forms/DOR.ORPCC.C.01%20FCOI%20Certification.pdf>

SFI Disclosure form example

<http://www.uh.edu/research/resources/dor-forms/coi-forms/DOR.ORPCC.C.04%20SFI%20Disclosure.pdf>

IP Disclosure form example

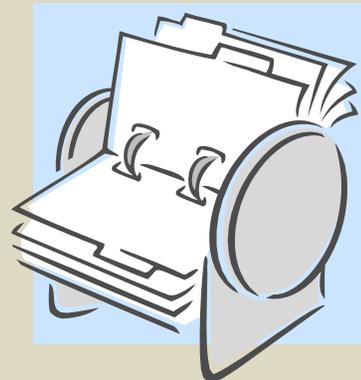
[http://www.uh.edu/research/resources/dor-forms/coi-forms/DOR.ORPCC.C.05_FY2015_IP_Disclosure Form.pdf](http://www.uh.edu/research/resources/dor-forms/coi-forms/DOR.ORPCC.C.05_FY2015_IP_Disclosure_Form.pdf)

Travel Disclosure form example

<http://www.uh.edu/research/resources/dor-forms/coi-forms/DOR.ORPCC.C.02%20COI%20Travel%20Disclosure.pdf>

Contacts

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Thank you for your time!

Helpful References

Department of Health and Human Services Code of Federal Regulations:

[42 CFR Part 50; 45 CFR Part 94](#)

[21 CFR Part 54](#)

[Conflict of Interest FAQs](#)

[National Science Foundation Award and Administration Guide. Chapter IV](#)

[University of Houston Manual of Administrative Policies and Procedures](#)
(MAPP 08.01.01)

[University of Houston System Administrative Memorandum \(SAM](#)
01.G.01)

[UH Division of Administration and Finance Travel Request](#)

[UH Faculty Handbook](#)

