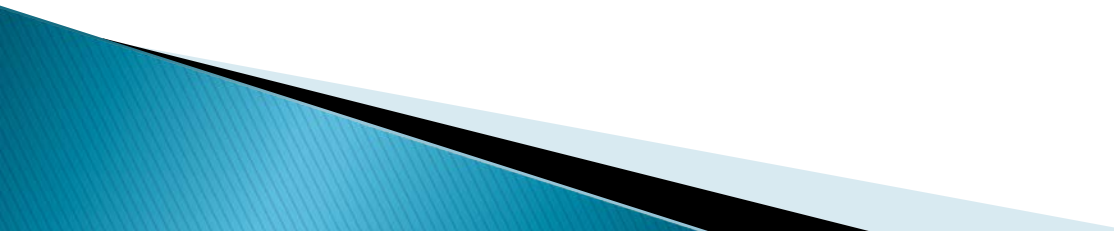


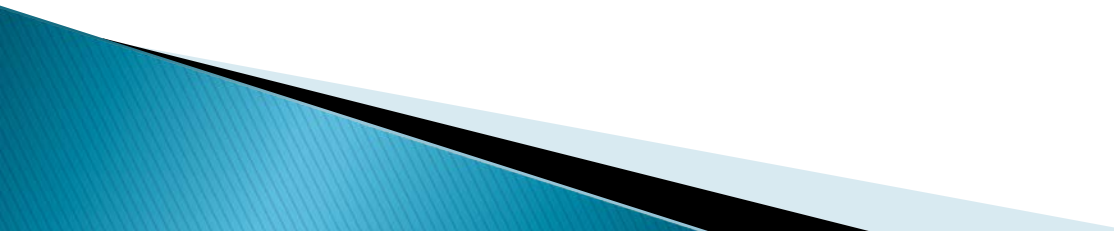
Conflict of Interest (COI) Management



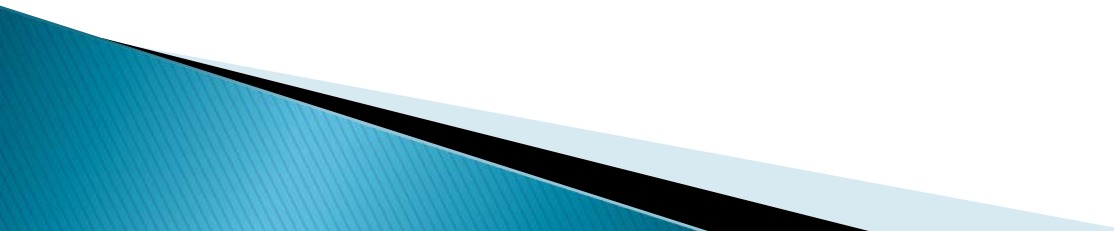
About the COI office:

- ▶ Responsible for the oversight and management of potential COIs of the University's employees and the institution itself
 - ▶ Chair: Dr. Craig Wilcox
 - Reports to George Huber, JD, Vice Provost of Research Conduct and Compliance
- 

Evaluation of Potential Conflicts

- ▶ Human research
 - ▶ Animal research
 - ▶ rDNA research
 - ▶ Decedent research
 - ▶ Human stem cell research
 - ▶ Consulting and purchasing conflicts
- 

What is a COI?

- ▶ **COI:** Commitments or obligations to the University or professional norms are likely to be compromised or perceived to be, by outside commitments
 - ▶ **Financial COI:** a significant financial interest that could directly and significantly affect the design, conduct or reporting of PHS funded research
- 

What is a Significant Financial Interest?

- ▶ **SFI**: financial interest (i.e., anything of monetary value, whether or not the value is readily ascertainable) consisting of one or more of the following interests of the Investigator (and Members of the Immediate Family) that reasonably appear to be related to the Investigator's institutional responsibilities

Threshold for SFI

\$5,000 for the aggregate of annual remuneration and equity in a publicly-traded entity

or

\$5,000 in annual remuneration or zero equity in a non-publicly-traded entity

Threshold for SFI

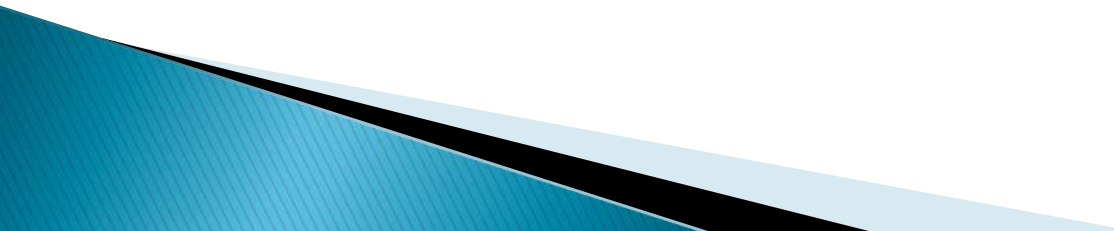
\$5,000 – \$10,000: Department chair determines existence of FCOI, proposes a Conflict Management Plan (CMP)

SFIs > \$10,000: COI Committee determines existence of FCOI exists, defines the CMP in consultation with the department chair

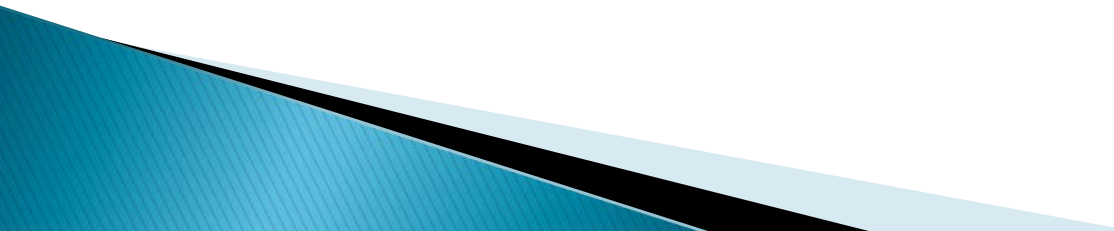
Conflicts and Investigators

- ▶ Investigators are not permitted to select the IRB reviewer for their research studies
- ▶ Must identify conflicts through OSIRIS and have them reviewed by COI Office
- ▶ Must comply with COI management plans, including notification of subjects. Standard plan is available at <http://www.coi.pitt.edu/Forms/StandardCOIMgmtPlan-HSR.htm>

COI and IRB Members

- ▶ Faculty and staff must complete COI super form through HSConnect
<https://www.hsconnect.pitt.edu>
 - ▶ Unaffiliated members review policy at orientation and sign statement of understanding
 - ▶ Policy reviewed annually
- 

COI and IRB Members

- ▶ Listed investigator;
 - ▶ Significant Financial Interest in the sponsor of the research or the technology being evaluated; or
 - ▶ Any other conflict that might be perceived to inhibit a fair and unbiased review of the research
- 

COI disclosed, now what?

- ▶ Please step out
 - Cannot review a research study in which there is a conflict of interest
 - Cannot participate in deliberations or decisions related to research in which there is a conflict of interest
- ▶ Can be REAL or PERCEIVED

OSIRIS Section 7.3 (Non-PHS)

7.3 Is this study funded in part or whole by a PHS Agency? ([click here for list of PHS Agencies](#))

* Yes No [Clear](#)

Does any investigator* involved in this study (select all that apply):

Name

- Have equity in a **publicly-traded entity** that either sponsors** this research or owns the technology being evaluated or developed that exceeds a **5% ownership interest** or a current value of **\$10,000**?
- Have equity in a **non-publicly-traded entity** that either sponsors this research or owns the technology being evaluated or developed?
- Receive salary, consulting fees, honoraria, royalties or other remuneration from an entity that either sponsors this research or owns the technology being evaluated or developed that is expected to exceed **\$10,000** during the past or next 12 months?
- Have rights as either the author or inventor of **intellectual property** being evaluated or developed in this research that is protected by copyright, the subject of an issued patent, or that has been optioned or licensed to an entity?
- Have a financial relationship with a **Licensed Start-up Company** overseen by the COI Committee that has an option or license to utilize the technology being evaluated or developed in this research?
- Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed?
- None** of the above options apply and there are no other financial conflicts of interest in the conduct of this research.

***Investigator** means the PI, co-investigators, and any other member of the study team, regardless of title, who participates in the design, conduct, or reporting of this research, as well as his/her spouse, registered domestic partner, dependents, or other members of his/her household. **The PI is responsible for ensuring that s/he and all other relevant members of the study team review the above questions describing Significant Financial Interests.**

**through the provision of funds, drugs, devices, or other support for this research

OSIRIS Section 7.3 (PHS)

7.3 Is this study funded in part or whole by a PHS Agency? ([click here for list of PHS Agencies](#))

* Yes No [Clear](#)

Does any investigator* involved in this study (select all that apply):

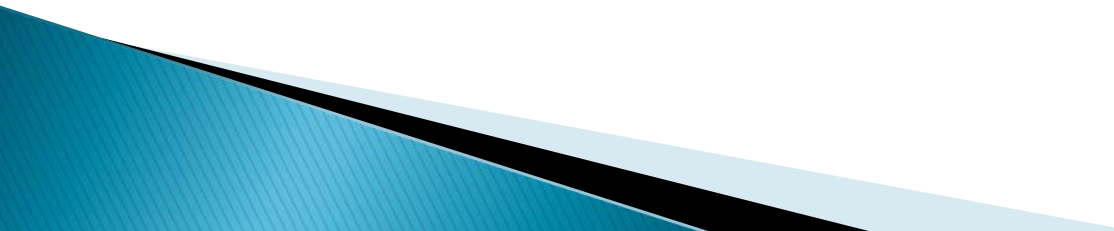
- | Name |
|---|
| <input type="checkbox"/> Have a financial interest (aggregated value of equity and remuneration** during the past or next twelve months) in a publicly-traded entity that either sponsors*** this research or owns the technology being evaluated or developed that exceeds \$5,000 but not \$10,000 ? |
| <input type="checkbox"/> Have a financial interest (aggregated value of equity and remuneration during the past or next twelve months) in a publicly-traded entity that either sponsors this research or owns the technology being evaluated or developed that exceeds \$10,000 ? |
| <input type="checkbox"/> Receive remuneration (during the past or next twelve months) from a non-publicly traded entity that either sponsors this research or owns the technology being evaluated or developed that exceeds \$5,000 but not \$10,000 ? |
| <input type="checkbox"/> Receive remuneration (during the past or next twelve months) from a non-publicly traded entity that either sponsors this research or owns the technology being evaluated or developed that exceeds \$10,000 ? |
| <input type="checkbox"/> Have equity in a non-publicly traded entity that either sponsors this research or owns the technology being evaluated or developed? |
| <input type="checkbox"/> Receive reimbursement or sponsorship of travel expenses (for one trip or a series of trips during the past or next twelve months) by an outside entity that either sponsors this research or owns the technology being evaluated or developed that exceeds \$5,000 ? |
| <input type="checkbox"/> Have rights as either the author or inventor of intellectual property being evaluated or developed in this research that is protected by copyright, the subject of an issued patent, or that has been optioned or licensed to an entity? |
| <input type="checkbox"/> Have a financial relationship with a Licensed Start-up Company overseen by the COI Committee that has an option or license to utilize the technology being evaluated or developed in this research? |
| <input type="checkbox"/> Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed? |
| <input type="checkbox"/> None of the above options apply and there are no other financial conflicts of interest in the conduct of this research. |

***Investigator** means the PI, co-investigators, and any other member of the study team, regardless of title, who participates in the design, conduct, or reporting of this research, as well as his/her spouse, registered domestic partner, dependents, or other members of his/her household. **The PI is responsible for ensuring that s/he and all other relevant members of the study team review the above questions describing Significant Financial Interests.**

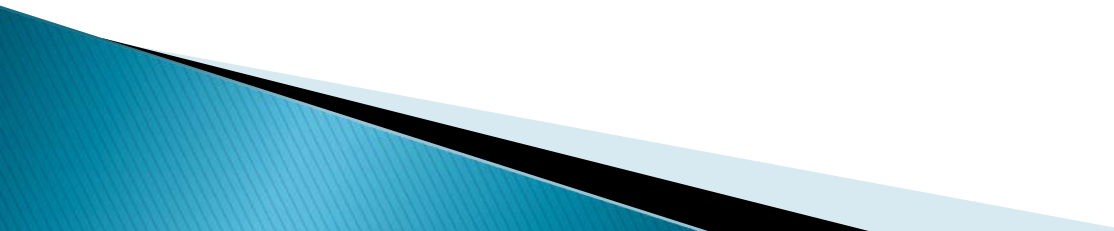
**such as salary, consulting fees, honoraria, or paid authorship

***through the provision of funds, drugs, devices, or other support for this research

Training Requirements

- ▶ PHS Funding: Investigators and key personnel must complete the CITI COI course
 - ▶ Other funding: Investigators using external research funds or have disclosed outside financial interest and do not work on any PHS-funded projects can complete either CITI or ISER COI course
- 

Questions you might be asked:

- ▶ What is a conflict of interest?
 - ▶ Who is required to disclose a conflict
 - ▶ How are conflicts managed?
 - ▶ Do subjects need to be notified of an investigator's conflict?
 - ▶ Can you review a protocol if you're conflicted?
- 

Questions?

Specialized education
available upon request:

askirb@pitt.edu