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Understanding the University's Revised Conflict of Interest Policy and Organizational Conflict of Interest Policy

University of Pittsburgh
Conflict of Interest Office

Presentation for FSDP
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Today's Agenda

- New COI website
- Licensed Start-up Companies
- IRB & IACUC Protocol COI Management
- COI Management Plans
- Consulting Agreement Addendum
- Organizational Conflicts of Interest
- Foreign Influence
- New COI Disclosure System



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COI Website

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Licensed Start-up Companies and Management/Operating Positions under Conflict of Interest Policy for Research, Policy #11-01-03

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What is a Licensed Start-up Company?

Licensed Start-up company (LSC) means a company that:

- (1) is legally recognized in the State or commonwealth of creation or incorporation;
- (2) is not publicly-traded;
- (3) has a license agreement or option agreement for a license covering University –owned Intellectual Property; and
- (4) has a portion of its equity or option for equity held by the University, a University Member, a member of the Immediate Family, or in trust for a member of the immediate Family.



What is a Management/Operating position?

Management Interest refers to positions of responsibility held by a University Member within an outside organization, whether paid or unpaid, that have authority to make decisions bearing on hiring, finance, investment, research, production, marketing, sales, and any other strategic business decisions, and carry a fiduciary obligation to act in the best interest of that outside organization. Unless they hold other positions in the company, members of the scientific advisory board and the chair of the scientific advisory board would ordinarily not be considered to have a Management Interest.



Examples of Management/Operating Positions

- Chief Operating Officer
- President
- Chief Financial Officer
- Chief Medical Officer
- Member of the Board of Directors or Board of Managers



Under Policy 11-01-03, a University Member:

- **MAY** hold a management or operating position or serve as an officer in a Licensed Start-up Company (“LSC”) with the advance approval of the Conflict of Interest Committee (“COIC”);
- **MAY** hold a consulting or employment relationship with an LSC with the advance approval of the COIC;
- **MAY** serve as PI on non-human-subject research that is sponsored by or of commercial interest to the LSC with advance approval of the Senior Vice Chancellor of Research upon the recommendation of the COIC.



Additional LSC matters that require advance COIC approval:

- New IP agreements and amendments to existing agreements
- New or additional grants of equity to University members
- Consulting or employment agreements with University members
- Corporate research agreements
- Research sub-contracts to or from the LSC
- Professional services agreements



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IRB & IACUC Protocol COI Management

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Managing COIs with Research

- **COI Committee** responsible for managing potential conflicts related to human subject, animal research, and PHS-funded bench research
- COI questions that appear on IRB/IACUC protocols apply to all investigators and research personnel
 - Questions vary for PHS-funded studies
 - PI is ultimately responsible for accuracy



Managing COIs with Research

- COI declarations on all protocols must be kept current
 - New outside interests must be reported on the protocol(s) through a modification
 - Modification will notify the COI Office and regulatory committee (IRB, IACUC) for review and processing



Potential Conflicts to Disclose

- Financial relationship with an entity that...
 - Sponsors the research
 - Owns technology being evaluated or developed
- Inventor or author of intellectual property being evaluated or developed with receipt of royalties or other proceeds



CMPs for Research: Standard vs. PI-Exclusion

- Refer to handout



Type of Research	HUMAN SUBJECT RESEARCH		ANIMAL AND BENCH RESEARCH	
	Yes	No	Yes	No
Equity in and/or cash remuneration from a public company in aggregate greater than \$5,000 but not greater than \$10,000	Standard	N/A	Standard	N/A
Equity in and/or cash remuneration from a public company in aggregate greater than \$10,000 but not greater than \$20,000	Standard	Standard	Standard	Standard
Equity in and/or cash remuneration from a public company in aggregate greater than \$20,000	PI-Exclusion	PI-Exclusion	Standard	Standard
Remuneration from a non-public company greater than \$5,000 but not greater than \$10,000	Standard	N/A	Standard	N/A
Remuneration from a non-public company greater than \$10,000 but not greater than \$20,000	Standard	Standard	Standard	Standard
Remuneration from a non-public company greater than \$20,000	PI-Exclusion	PI-Exclusion	Standard	Standard
Equity in a non-public company	PI-Exclusion	PI-Exclusion	Standard	Standard
Management or officer position in any company	PI-Exclusion	PI-Exclusion	Standard ^b	Standard ^b
Inventor or developer of intellectual property with receipt of royalties or other proceeds greater than \$5,000 but not greater than \$10,000	Standard ^c	N/A ^c	Standard	N/A
Inventor or developer of intellectual property with receipt of royalties or other proceeds greater than \$10,000	PI-Exclusion	PI-Exclusion	Standard	Standard
Reimbursed or sponsored travel from one entity greater than \$5,000 but not greater than \$10,000	Standard	N/A	Standard	N/A
Reimbursed or sponsored travel from one entity greater than \$10,000	PI-Exclusion	N/A	Standard	N/A
CMP Delivery Method	DocuSign	DocuSign	Email	Email

^aThe Public Health Service (PHS) includes the National Institutes of Health and several other federal agencies. [Visit the COI website](#) for a complete agency list and additional resources.

^bRequires prior approval from the Senior Vice Chancellor for Research upon recommendation of the COI Committee for conflicted investigator to remain as PI of research sponsored by or of commercial interest to a [Licensed Start-up Company](#) as defined in [University Policy 11-01-03](#). If approval is denied, the PI-Exclusion management plan applies.

^cA CMP is required for research subject to the [FDA COI regulations](#) involving the evaluation or further development of intellectual property invented by the investigator, even if s/he has not received any royalties or proceeds.



Human Subject Research PI-Exclusion

- Individuals with the following financial interests may not serve as PI of human subject research:
 - Equity in and/or cash remuneration from a public company (in aggregate) greater than \$20,000 per 12 month period
 - Remuneration from a non-public company greater than \$20,000 per 12 month period
 - Equity in a non-public company



Human Subject Research PI-Exclusion

- Individuals with the following financial interests may not serve as PI of human subject research:
 - Management or officer position in any company
 - Inventor or developer of intellectual property when receipt of royalties and/or other proceeds exceeds \$10,000 per 12 month period
 - Reimbursed or sponsored travel from one entity exceeding \$10,000 per 12 month period (for PHS-funded research only)



Animal and Bench Research PI-Exclusion

- Management or officer position in any University Licensed Start-up Company
 - Exception requires approval from the Senior Vice Chancellor for Research, upon recommendation from the COI Committee
- No other limitations



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COI Management Plans (CMPs)

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CMP: Human Subject with PI-Exclusion

- Investigator with the SFI cannot:
 - be involved in recruitment
 - obtain informed consent
 - engage in recording of research data
 - be involved in clinical assessments of study eligibility criteria and intervention outcomes



CMP: Human Subject with PI-Exclusion

- Investigator with the SFI cannot:
 - directly participate in data and safety monitoring activities
 - be the only person responsible for interpretation of study results



CMP: Human Subject with PI-Exclusion

- Investigator with the SFI:
 - must provide a list of individuals involved in the study to the COI Office so they are notified of the SFI
 - Replaces old paper notification forms
 - must ensure students have department chairperson or dean approval to be engaged in research



CMP: Human Subject with PI-Exclusion

- Investigator with the SFI must:
 - disclose SFI in any related abstracts, presentations, press releases, or publications
 - notify the COI Office of federal grants supporting the protocol
 - disclose SFI in the informed consent form



CMP: Animal and Bench Research

- Similar management plans to human subject, but with some alterations



Example 1

- Dr. Adams is the Chief Medical Officer of Pittsburgh Therapeutics, Inc., a University Licensed Start-up Company. He would like to be PI of both animal and human subject research at the University that is of commercial interest to and sponsored by the same company through a Corporate Research Agreement (CRA).
- **From a COI management perspective, what is required?**



Example 2

- Dr. Lincoln is evaluating a device owned by New Orthotics, Inc., a non-public company, under a human subject research protocol. It is not an FDA-covered clinical study. She consults for the company, which compensates her through equity plus cash remuneration of \$19,500 per 12 month period.
- **Can Dr. Lincoln serve as PI of this study?**



Example 3

- Dr. Jefferson receives equity in and cash compensation from a publicly-traded pharmaceutical company for consulting. The aggregate (total) compensation is \$8,000. He is conducting PHS-funded animal research on a drug of commercial interest to the pharmaceutical company.
- **Is a management plan required?**
- **Can Dr. Jefferson serve as PI of research that is of commercial interest to this company?**



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Consulting Activities

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Conflict of Interest Office

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Outside Activities

- **Outside Employment Policy 02-06-01**
 - Full-time faculty: *“time given to outside activities is not to exceed one day a week”*
 - Cannot conflict with responsibilities assigned within the University or lead to a conflict of interest
- **SOHS – Industry Relationships Policy**
 - Pharmaceutical, medical device, biotechnology, hospital equipment supply companies



Consulting Activity Approval

1. Obtain supervisor's approval
2. Send to COI@pitt.edu
3. Have company sign Addendum



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STANDARD ADDENDUM FOR PROFESSIONAL SERVICE AND CONSULTANT AGREEMENTS WITH UNIVERSITY OF PITTSBURGH FACULTY, STAFF, AND STUDENTS

WHEREAS _____ (“Consultant”) has entered into an agreement to provide professional or consultant services to _____ (“Company”) dated _____ (“the Agreement”);

WHEREAS, Company acknowledges that Consultant is employed by, or is enrolled as a student, at the University of Pittsburgh (“Pitt”), and is therefore required to comply with Pitt’s policies at all times, including but not limited to its policies on Intellectual Property, Conflicts of Interest, and Outside Employment, as amended from time to time (“Pitt Policies”); and

WHEREAS, Company and Consultant agree that the terms set forth in this Addendum, either independently or in conjunction with Pitt Policies, shall govern Consultant’s activities and shall supersede any conflicting terms in the Agreement; and

THEREFORE, be it resolved that both Company and Consultant acknowledge and agree to the following:

- Use of Pitt Resources for Consulting Activities.** Consultant may only use Pitt resources in the performance of his or her obligations under the Agreement as permitted by Pitt policy.
- Conflict with Existing or Future Pitt Obligations.** Nothing in the Agreement shall interfere with Consultant’s ability to satisfy existing or future obligations at Pitt, including but not limited to research or teaching assignments, regardless of the source of sponsorship, if any.
- Consultant not Acting as an Agent of Pitt.** Company acknowledges that, while performing services for Company, Consultant is not acting as an agent or representative of Pitt for any purpose and has no authority to act for or bind Pitt. Accordingly, any obligations pertaining to any confidential or other information provided to Consultant by Company only apply to Consultant, and not to Pitt.
- Use of Pitt Name, Trademarks or Logos.** Company may only use the Pitt Name to identify the Consultant as a Pitt employee or student. All other use must be approved in advance, in writing, by Pitt’s Innovation Institute or Communications Office, as applicable. For purposes of this Agreement, the term “Pitt Name” includes, but is not limited to, the name, trademarks or logos of Pitt or any of its schools or departments, labs or centers.
- Intellectual Property.** Company and Consultant specifically acknowledge that Consultant cannot assign, convey, license to or vest in Company or any Company Affiliate (collectively referred to as Company), any rights in any intellectual property whatsoever, whether or not patentable or copyrightable, that conflict with Pitt’s rights in or to such intellectual property. Consultant and Company acknowledge that, notwithstanding anything to the contrary in any Pitt policy, Pitt permits Consultant to assign to Company all or a portion of Consultant’s right, title and interest to inventions, works of authorship, know-how, ideas and information (“Intellectual Property”) created by Consultant in performance of the approved services under the Agreement, provided that such Intellectual Property: (1) does not constitute or infringe upon any Intellectual Property, or any modifications or derivative works thereof, that is owned in whole or in part by Pitt (Pitt Intellectual Property”); (2) is not made, conceived, reverse engineered or reduced to practice using any Pitt Intellectual Property or any Pitt Resources; and (3) is not the subject of a research agreement between Company and Pitt.

For clarity, Consultant may not use or assign any Pitt Intellectual Property or use any Pitt Resources to perform any services or provide any deliverables to Company, except pursuant to and in accordance with a separate written agreement between Company and Pitt.

7. **Disclosures.** Company agrees that as an employee or student at Pitt, Consultant must disclose the terms of the Agreement to Pitt, including compensation. Additionally, Consultant must make financial disclosures to research funding agencies, journals and the public, as may be required by policy and/or applicable law.

8. **Marketing.** In accordance with the Industry Relationships Policy, as applicable to Consultants who are faculty, staff or students in Pitt’s Schools of the Health Sciences, Consultant’s services shall not be used for marketing or promotional purposes. Notwithstanding, Consultant’s contributions of evidence-based scientific information may be used to inform Company’s commercial strategies and initiatives.

9. **Incorporation by Reference.** Consultant and Company agree that this Addendum and the terms herein are incorporated into the Agreement by reference, and each party shall be legally bound hereto.

IN WITNESS WHEREOF, the Parties hereto have caused this Addendum to be duly executed and effective as of the last date of execution.

Company	Consultant
By: _____	By: _____
Name: _____	Date: _____
Title: _____	
Date: _____	



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Organizational Conflicts of Interest

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Purpose of OCI Rules

1. Prevent the contractor from holding conflicting roles that may bias contractor's judgment.
2. Prevent unfair competitive advantage in government contract bidding process

*OCIs arise when there is a risk of **bias** or **unfair competition** in the bidding on or performance of federal government contracts*



**BIASED
GROUND RULES**

Look back to work that was performed under prior government contracts

What work did the organization or one of its members do before the solicitation was issued?

Did the contractor help establish the parameters of the new contract?

**UNEQUAL
ACCESS TO
INFORMATION**

Look back to work that was performed under prior government contracts

To what non-public information did the contractor have access before the solicitation was issued?

Did the contractor have access to non-public information that can help it win the new contract?

**IMPAIRED
OBJECTIVITY**

Look ahead to work that will be performed under the proposed government contract

What work will the contractor be doing under the contract?

If they win the new contract, will the contractor be evaluating its own work?



OCI IMPUTATION

The interests of an individual within an organization are *imputed* to the rest of the organization



Preventing and Addressing OCI

1. Request COI assistance as soon as possible
2. OCIs must be addressed at the **proposal stage**
3. If an OCI is identified, a **mitigation plan** is required.
4. Government contract officers have the final say about whether an OCI will prevent an organization from being awarded a contract



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Foreign Influence

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Foreign Influence Concerns:

- January 18, 2019 Memo from Rob A. Rutenbar, Senior Vice Chancellor for Research

Reminders:

- Disclose Conflicts of Interests annually and as new covered interests arise [Policy 11-01-03]
- Disclose foreign engagements, including consulting arrangements or IP terms, during unit-based approvals for your outside activities[Policy 02-06-01].



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Conflict of Interest Disclosure

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New Disclosure System Coming Soon!



Contacts

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