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## FINANCIAL CONFLICT OF INTEREST IN RESEARCH: TRAINING FOR INVESTIGATORS

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New federal requirements came into effect on August 24, 2012 regarding the University of Oregon's obligation to identify and manage Financial Conflicts of Interest in Research. The University has updated its Financial Conflict of Interest in Research Policy, and correspondingly, Research Compliance Services has revised our procedures related to Conflict of Interest in Research to ensure that the University is in compliance with these new federal regulations.

One key requirement of the new University of Oregon Policy and revised regulations is that all Investigators, including those who are receiving subawards, must complete training on Financial Conflicts of Interest in Research before applying for, or engaging in, any sponsored activity. The following training module will take approximately 5-10 minutes to complete and covers all the information you will need regarding Financial Conflicts of Interest in Research and sponsored activities as a member of the research community at University of Oregon.

### **FINANCIAL CONFLICTS OF INTEREST IN RESEARCH**

Investigators' objectivity is the foundation for advancing the frontiers of knowledge and the basis for obtaining and maintaining public trust in research. The University of Oregon encourages outreach and connections with private industry, including creating start-up businesses or licensing technologies and other products of research where the Investigator has a financial interest that relates, or may appear to relate, to his/her research. At the same time, these activities may create potential, perceived or apparent financial conflicts of interest in research. The University of Oregon's Policy on Financial Conflict of Interest in Research defines Conflict of Interest in Research (COIR) to mean a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research, as determined by the University.

Broadly, a COIR can be described to occur where a private financial interest related to the sponsored activity has the potential, or direct ability, through action or inaction, to influence the outcome of those activities, or where the outcomes of the research has the potential or direct ability to influence the private financial interests of the Investigator.

Financial interests in, financial activities with, or positions of influence that direct financial activities of entities external to the University must be disclosed and managed in a way that ensures objectivity of the research and teaching process and the safety of human research participants as required by the research sponsor and federal regulations.

### **WHY DO I NEED TO COMPLETE THIS TRAINING**

As part of the University of Oregon's research community, you will need to complete this training to be compliant with newly revised federal regulations regarding sponsored research as well as University Policy.

The purpose of this training is to:

- Provide you with an understanding of the University of Oregon's policy on COI in research
- Describe your responsibilities as an investigator as it relates to COI in research
- Explain what qualifies as a Significant Financial Interest
- Describe what to expect after you have submitted your SFI Declaration
- Provide you with related regulations and additional resources

The training consists of six informational sections, followed by a Certification Page. Please read each page and click the box at the bottom of each page when completed. When you have completed your review of the following material, by clicking CERTIFY, you acknowledge that you have participated in this training exercise, understand the associated content and your obligations as a researcher, and certify its completion.

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**I. WHAT IS UNIVERSITY OF OREGON'S POLICY ON FINANCIAL CONFLICT OF INTEREST IN RESEARCH?**

The University of Oregon's Financial Conflict of Interest in Research policy exists to ensure that the design, conduct, or reporting of research will be free from real or potential influence by any related Investigator's Significant Financial Interests, which are determined by the university to constitute a Conflict of Interest in Research (COIR).

The policy requires that any Investigator engaged or planning to be engaged in research (e.g., submitting a proposal, receiving a subaward) must declare all Significant Financial Interests that could reasonably appear to be related to his/her Institutional Responsibilities at the institution/company that is receiving the award. Section III of this training module contains a detailed explanation of Significant Financial Interest (SFI).

The policy states that the University will determine whether a Significant Financial Interest represents a Conflict of Interest in Research. Per the policy, the University will manage that COIR as required by all applicable federal, state and sponsor requirements.

The policy also states that the University will comply with all applicable sponsor or federal requirements in reporting COIR, coordinating with subrecipients and addressing instances of non-compliance with University policy and sponsor regulations.

For further detail, please review the full University of Oregon Financial Conflicts of Interest in Research policy:

<http://policies.uoregon.edu/policy/by/1/09-research/financial-conflict-interest-disclosure-and-management-investigators-external>

I have read and understand Section I.

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II. **WHAT ARE MY RESPONSIBILITIES?**

All Investigators engaged in or planning to be engaged in research at the UO either directly or through a subaward have specific responsibilities in complying with the UO policy which are detailed below.

**IDENTIFY INVESTIGATORS**

During the proposal development process, the Principal Investigator must identify all Investigators, on that proposed project.

The term Investigator includes the principal investigator, or any other personnel, regardless of title or position, responsible for the design, conduct or reporting of research. This designation typically does not include staff that do not have independent decision making authority regarding the design or conduct of the research and does not include departmental grant administrators, as those personnel report on financial status but not on the research per se.

**DECLARE SIGNIFICANT FINANCIAL INTERESTS**

As a University of Oregon Investigator, you are required to submit a SFI Declaration, formally and explicitly stating all Significant Financial Interests to the University that reasonably appear to relate to your Institutional Responsibilities. Institutional Responsibilities include your professional responsibilities on behalf of your institution or organization, which may include activities such as research, research consultation, teaching, graduate student mentorship and advising, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards

**COMPLETE SFI DECLARATIONS ON TIME**

You must complete a SFI Declaration at least annually (once every 365 days) AND within thirty days of discovering or acquiring a new Significant Financial Interest (e.g., through purchase, marriage, or inheritance). You must also ensure your annual SFI Declaration is current prior to the execution of any subagreement from the University of Oregon to your institution.

I have read and understand Section II.

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**III. WHAT IS A SIGNIFICANT FINANCIAL INTEREST?**

You should understand what qualifies as a Significant Financial Interest (SFI) that requires declaration to the University.

A financial interest is anything of monetary value (whether that value can be easily determined or not), that belongs to you, your spouse, your domestic partner, or your dependent children. Your financial interest becomes a Significant Financial Interest requiring declaration if it reasonably appears to be related to your Institutional Responsibilities. Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution/company receiving the subaward, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

SFIs (financial interests related to institutional responsibilities) include the following which apply to you, your spouse/domestic partner, and/or your dependent children:

- Income from a publicly-traded entity\* (e.g., stock in a corporation that can be traded on a public stock exchange) during the previous 365 days and/or hold any equity interest in the entity, the combined value of which exceeds \$5,000.
- ANY equity interest in a non-publicly traded entity\* (e.g., shares or percentage ownership interest in a business that does not have shares traded on a public stock exchange).
- Receipt of more than \$5,000 compensation (income, consulting, and land trade) from a non-publicly traded entity\* during the previous 365 days.
- Income of any dollar amount from intellectual property rights and interests (such as patents, copyrights, royalties, licensing fees) during the previous 365 days.
- Reimbursement for travel, or any travel costs sponsored by an entity\* (other than a U.S. government, academic medical center or higher education institution) if costs for that travel, when aggregated, exceed \$5,000 per sponsoring entity\* in the previous 365 days.

\*The use of entity above excludes the institution/company that is receiving the subaward.

Any Significant Financial Interests potentially related to an Investigator's Institutional responsibilities should be declared. In some cases, a relation will be obvious (such as a financial interest in a pharmaceutical company for which the Investigator evaluates potential drugs); in many cases the relation will be less obvious. In such instances, the Investigator should declare this SFI to the University, as the compliance burden shifts to the University to determine whether the SFI is reasonably related to the Investigator's Institutional Responsibilities, reducing the Investigator's risk for noncompliance. However, financial interests that are wholly unrelated to an Investigator's Institutional responsibilities (e.g., a financial interest in a local dry cleaning business and the Investigator conducts educational outcomes research) do not need to be declared.

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**WHAT IS A NOT A SIGNIFICANT FINANCIAL INTEREST (SFI)?**

You do not need to declare the following types of financial interests:

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- Travel reimbursed or sponsored by a federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education;
- Payment from a federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education for seminars, lectures, teaching engagements or service on advisory committees or review panels;
- Equity interests or income from investment vehicles, such as mutual funds and retirement accounts, in which you, your spouse, domestic partner or dependent child/ren do not directly control the investment decisions made in these vehicles.
- Income from service on advisory committees or review panels for a federal, state, or local government agency, or an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- **Special Note:** Investigators are required to disclose all financial interests received from a foreign institution of higher education or the government of another country.

I have read and understand Section III.

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IV. **WHAT CAN I EXPECT AFTER I SUBMIT MY DECLARATION?**

If you declared any Significant Financial Interests, The University of Oregon's Research Compliance Services (RCS) office, with input from with the University's Conflict of Interest in Research Committee (COIR Committee), will review the Significant Financial Interest against your sponsored subagreement research activities and determine whether your SFI presents a potential or actual conflict of interest in research. (Please note: simply having a Significant Financial Interest does not necessarily mean a Conflict of Interest in Research exists).

If RCS and the University's COIR Committee determine that a SFI constitutes a COIR pertaining to a specific sponsored subagreement project, you may be asked for further clarifying information to support the development of a Management Plan.

A Management Plan is designed to create action steps to manage, reduce, or eliminate any actual or perceived Financial Conflict of Interest in Research as it relates to a specific sponsored project. Generally, Management Plans set up additional oversight mechanisms to disentangle the Investigator's private interests from the design, conduct, or reporting of research and to assure that research is conducted in a manner not to affect the interests of the Investigator.

Furthermore, Management Plans may include notice requirements to allow informed decision making. For example, a Management Plan may require a brief statement of the Investigator's interests relating to the research in the informed consent for participants or in public presentations of research data that relate to the Investigator's interests.

An initial draft Management Plan will be developed by Research Compliance Services and will be reviewed and discussed by the COIR Committee in its regular meeting. If your SFI requires a Management Plan, you will be invited to participate in the COIR Committee meeting in which you will have an opportunity to provide further information or make suggestions on steps to include in your Management Plan. The Management Plan then is finalized and approved by the Designated Institutional Official. You are responsible for complying with all aspects and provisions of the Management Plan.

**IMPORTANT NOTE: MANAGEMENT PLAN COMPLIANCE**

All required Management Plans must be developed and approved prior to fully executing a sponsored subagreement and prior to expending any sponsored funds on a specific subagreement or within 60 days of a newly disclosed SFI, as required. In instances of non-compliance, Investigators are required to work with the University until the issue is fully resolved in accordance with all applicable sponsor and federal requirements.

I have read and understand Section IV.

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V. **RELEVANT SPONSOR REGULATIONS & ADDITIONAL RESOURCES**

The following are additional resources available to Investigators to understand financial Conflict of Interest in research, the UO policy and processes and applicable external regulations.

**ADDITIONAL RESOURCES**

PHS policy: [http://grants.nih.gov/grants/compliance/42\\_cfr\\_50\\_subpart\\_f.htm](http://grants.nih.gov/grants/compliance/42_cfr_50_subpart_f.htm)

NIH FCOI policy: <http://grants.nih.gov/grants/policy/coi/>

Office of Research Integrity: <http://ori.dhhs.gov/education/products/RCRintro/c05/0c5.html>

**UNIVERSITY OF OREGON**

University of Oregon Interim policy: <http://policies.uoregon.edu/policy/by/1/09-research/financial-conflict-interest-disclosure-and-management-investigators-external>

If you have further questions regarding financial Conflict of Interest in research, please feel free to contact the Research Compliance Services at [ResearchCompliance@uoregon.edu](mailto:ResearchCompliance@uoregon.edu).

I have read and understand Section V.



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VI. **SELF TRAINING CERTIFICATION**

- I certify that I have read this presented material and shall comply with the University of Oregon's financial Conflict of Interest in Research policy and associated procedures, including my responsibilities as an Investigator, as required under applicable federal and sponsor regulations and University of Oregon policy.
  
- I shall submit a declaration within 30 days of acquiring or having any new Significant Financial Interests.

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Investigator Name

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Investigator Institution

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Investigator Signature

Date

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