

Financial Conflict of Interest in Research Policy (FCOI Policy)

July 2024



UNIVERSITY OF
OREGON

Office of the Vice President
for Research and Innovation

Overview



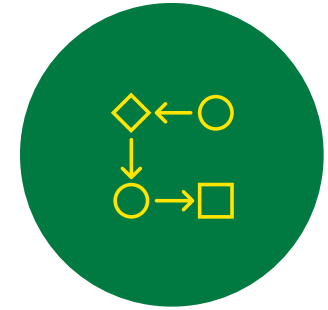
FCOI Policy



Common Activities
Requiring Disclosure



How to Submit a
Disclosure



Management Plan
Process





What Is A Financial Conflict of Interest in Research?

- Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research, as determined by the university.
- SFI further defined on next slide.
- The [Financial Conflict of Interest in Research](#) (FCOI) Policy applies to:
 - Project director or principal investigator (PI)
 - Any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Sponsored Research
 - Can include but is not limited to professorial faculty, research associates, emeritus faculty, research collaborators, post-doctoral students, graduate students, visiting scientists, and individuals with courtesy appointments, external collaborators, or outside consultants, regardless of whether paid or unpaid.
- Researchers are required to disclose activities for themselves, their spouse, and/or their dependent children annually, within 30 days of acquiring a new activity or interest, and within 30 days of a change in an existing activity or interest.
- Researchers must complete Financial Conflict of Interest in Research training every 3 years.
- Researchers submit disclosures in the [Research Administration Portal](#) (RAP).





Significant Financial Interest (SFI)

A financial interest consisting of one or more of the following interests of the researcher (and those of the researcher's spouse and dependent children) that reasonably appears to be related to the researcher's institutional responsibilities:

- \$5,000 in remuneration from a publicly traded entity in the 12 months preceding disclosure and the value of *any* equity interest. Remuneration can include salary, consulting fees, honoraria, paid authorship. Equity interest includes any stock, stock option, or ownership interest.
- \$5,000 in remuneration from a non-publicly traded entity in the 12 months preceding disclosure and the value of *any* equity interest. Remuneration can include salary, consulting fees, honoraria, paid authorship. Equity interest includes any stock, stock option, or ownership interest.
- *Any* intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Reimbursed or sponsored travel that is paid on behalf of and not reimbursed to the investigator that exceeds \$5,000 per individual entity when aggregated and that is related to the investigator's institutional responsibilities.





A Significant Financial Interest (SFI) Is Not...

Significant Financial Interest does not include:

- Salary, royalties, or other remuneration paid by the UO, including intellectual property rights assigned to the UO
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles
- Payment from a federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute affiliated with an institution of higher education for:
 - Seminars, lectures, or teaching engagements
 - Service on advisory committees or review panels





FCOI Policy

A Significant Financial Interest does not necessarily mean there is a financial conflict of interest with the sponsored research.





Required Training

- The [FCOI Policy](#) and federal funding agencies require all researchers responsible for the design, conduct, and reporting of sponsored research to complete financial conflict of interest training.
- Training is good for 3 years.
- UO uses the [Collaborative Institutional Training Initiative \(CITI\)](#) to deliver the training. The course is called COI Researcher. [Learn more about the required training](#), such as adding the COI Researcher course and affiliating your CITI account with the UO.
- Training completion dates migrate from CITI to the [Research Administration Portal \(RAP\)](#) each night.
- Completed training required before RAP will allow researcher to submit disclosure.





Congruence with Documents Submitted to Sponsors

- UO required to annually disclose researchers' external commitments to funding agencies.
- UO required to notify funding agency within 30 days of any disclosure failure.
- In current/pending support documents, biosketches, and Digital Persistent Identifiers (DPIs), PIs must disclose:
 - Organizational affiliations and employment
 - External positions and appointments
 - Foreign government-sponsored talent recruitment programs (prohibited from being party to [malign foreign talent recruitment program](#))
 - Honorary titles, degrees, and lab space at other institutions, especially if foreign
 - ***Even if there is no monetary value***
- ***Disclosures must match what is reported annually to Conflict of Interest Office via Research Administration Portal***
 - What's often missed: Honorific titles, unpaid appointments, unpaid board service, outside activities generating <\$5,000/year since they may not be subject to UO's [FCOI Policy](#)
- ***When in doubt, disclose, disclose, disclose!***





Common Examples of Outside Activities That Require Disclosure

A research associate holds a courtesy appointment at another university to access lab space and advise students.

Why This Requires Disclosure:

Because the researcher has access to lab space, it should be disclosed to the sponsor in a biosketch, current/pending support document, and Digital Persistent Identifier.

Although the researcher may not be receiving monetary funds, they should report the appointment to the UO via the RAP. The appointment may not be subject to the UO's [FCOI Policy](#), but disclosures across institutions must match.





Common Examples of Outside Activities That Require Disclosure

As an independent consultant, a researcher consults for a company to develop curricular supports in math for elementary students with limited English proficiency. The researcher received \$6,500 last year for their work.

Why This Requires Disclosure:

Under the [FCOI Policy](#), remuneration of more than \$5,000 in the previous 12 months from a non-publicly traded or publicly traded entity is considered a Significant Financial Interest and must be disclosed.





Common Examples of Outside Activities That Require Disclosure

A research assistant is listed as a patent inventor on a patent held by the University of California Berkely, their previous institution. They receive quarterly royalties from the licensing of the patent.

Why This Requires Disclosure:

Intellectual property rights and interests of *any* value are a Significant Financial Interest upon receipt of the income.

If UC-Berkely were paying the researcher for a seminar, lecture, teaching engagement, or service on review panels or advisory committee, this would not be a SFI and would not need to be disclosed.





Common Examples of Outside Activities That Require Disclosure

Remember: As a UO employee, you are also subject to the UO's [Conflict of Interest, Conflict of Commitment, and Outside Activities Policy](#) (COI/COC Policy).

You may be required to disclose outside activities and interests under the COI/COC Policy. Learn more about [what must be disclosed under the COI/COC Policy](#).

Unsure if your outside activity requires disclosure?

Ask us!

coi@uoregon.edu





How to Disclose an Outside Activity

- Disclosures must be submitted annually, even if a researcher has nothing to disclose; within 30 days of a change in an outside activity or interest; and within 30 days of acquiring a new outside activity or interest.
- Disclosures are submitted through the [Research Administration Portal](https://coi.rap.uoregon.edu) (RAP) at coi.rap.uoregon.edu. You will be prompted to enter your Duck ID.





How to Disclose an Outside Activity

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COI Stage

Dashboard Facilities IACUC IRB COI

Hello, David Condon
Switch User

Page for David Condon

My Inbox My Reviews

My Inbox

Filter by ID Enter text to search + Add Filter X Clear All

ID	Name	Date Created	Date Modified	State	Coordinator
DP00000433	Disclosure Profile for David Condon	4/20/2023 8:55 PM	2/21/2024 4:18 PM	Action Required	David Condon

2 items

page 1 of 1

25 / page





How to Disclose an Outside Activity

Note: Training Must Be Current



COI Stage UNIVERSITY OF OREGON Office of the Vice President for Research and Innovation Hello, David Condon Switch User

Dashboard Facilities IACUC IRB COI Disclosures Requests Certifications Plans Triggering Events Reports Meetings Help Center

COI > Disclosures > Disclosure Profile for David Condon Help

Action Required

Disclosure profile last completed: 10/25/2022
Training last completed: 12/8/2023
Training expiration date: 12/8/2026

Complete Disclosure Profile Update

Disclosure Profile for David Condon

Instruction Center	
Action Required	Reason
Click "Edit Disclosure Profile" and add disclosure information as needed or affirm you have nothing to declare. Click "Complete Disclosure Profile Update" button when update completed.	Disclosure profile has never been submitted
Click "Edit Disclosure Profile" and add disclosure information as needed or affirm you have nothing to declare. Click "Complete Disclosure Profile Update" button when update completed.	Review and update of your disclosure required.
Click "Edit Disclosure Profile" and add disclosure information as needed or affirm you have nothing to declare. Click "Complete Disclosure Profile Update" button when update completed.	Review and update of your disclosure required

Edit Disclosure Profile

Disclosures History

i You have not disclosed any interests. Reference the Instruction Center to take the appropriate steps of completing a disclosure update.





How to Disclose an Outside Activity

☰ Validate Compare <<

Instructions and Policies

Entity Disclosure Information

Complete Disclosure Profile

Go to forms menu Print Help

The UO has two distinct policies that require disclosures of certain types of outside financial interests and outside activities to prevent or manage conflicts of interest and conflicts of commitment. This RAP COI module solicits information from UO employees to help ensure compliance with both policies.

The *Conflict of Interest, Conflict of Commitment, and Outside Activities Policy* ("COI/COC policy") **applies to all UO employees**. This policy is tied to Oregon State ethics laws, and was developed to support the UO mission and its employees while ensuring compliance with Oregon State statutes. For more information about what must be disclosed under this policy, consult the [policy](#) and visit the UO's [website on Conflicts of Interest and Commitment](#).

- All employees are expected to be familiar with this policy and when possible, disclose outside activities and interests and secure approval in advance of obtaining the interest or engaging in the outside activity.
- Employees should complete and update their disclosure profile through this RAP COI module for activities or interests that do or may require disclosure and approval under the policy, even if they are unsure about whether or not disclosure is required.

The *Financial Conflict of Interest in Research Policy* ("FCOI policy") **applies only to sponsored researchers – specifically those who are identified as responsible for the design, conduct, or reporting of sponsored research at the proposal or award stage ("FCOI Investigators")**. This [policy](#) is tied to federal financial conflict of interest in research regulations, which have specific training and reporting requirements.

- If you are identified as a FCOI Investigator on a sponsored project, and your training is expired, you must complete COI training using the COI Researcher course through [CITI](#); this training is required by federal FCOI regulations and focuses on the requirements of the federal FCOI regulations.
- If you are a FCOI Investigator, you must disclose significant financial interests (SFIs) in accordance with federal FCOI regulations and UO's FCOI policy. If you are a FCOI Investigator, this RAP COI module will solicit information from you to help ensure your compliance with **both** the FCOI and COI/COC policy. For more information about what must be disclosed under both COI policies, visit the UO's [website on Conflicts of Interest and Commitment](#).

* I certify that I have read and understood the information presented to me above

Exit

Save

Continue





How to Disclose an Outside Activity

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Validate Compare <<

Instructions and Policies

Entity Disclosure Information

Complete Disclosure Profile

Editing: DP00004442 Go to forms menu Print Help

Entity Disclosure Information

1. * Do you have any financial interests and/or outside activities related to your UO duties/responsibilities to report?
(Please refer to help text here) ?

Yes No [Clear](#)

2. Entity disclosures:

[+ Add](#)

Entity	Foreign Entity?	Relation to Discloser	Disclosure Types	Total Value	Total Time Commitment (Days)	Last Modified
There are no items to display						

Exit Save Continue →





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Validating... Compare

Instructions and Policies

Entity Disclosure Information

Complete Disclosure Profile

Editing: DPO

Entity Disclosure

1. * Do you have... (Please refer to...)
 Yes No

2. Entity disclosure

+ Add

Entity Foreign Entity

There are no

General Information

1. Entity: ?

[Text Input Field]

or

If you cannot find the entity in the above list, enter the details here:

[None] [Text Input Field]

2. * Relation to discloser: ?

Self
 Spouse
 Dependent Child

3. * Disclosure types:

Name	Description
Equity or Ownership	Stock, stock options, or ownership interest. Venture capital or capital financing investments supporting your

* Required

OK OK and Add Another Cancel





How to Disclose an Outside Activity

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Editing: DPO

Entity Disclosure

1. * Do you have (Please refer to the instructions) Yes No

2. Entity disclosure

+ Add

Entity Foreign Entity

There are no

3. * Disclosure types:

Name	Description
<input type="checkbox"/> Equity or Ownership Interests	Stock, stock options, or ownership interest. Venture capital or capital financing investments supporting your outside activities and/or interests must be entered as entities for this disclosure type.
<input type="checkbox"/> Consulting or Other Professional Services	Includes scientific advisory board, expert witness services, provision of professional expertise to an outside entity in a consulting or other professional services capacity
<input type="checkbox"/> Editorial Services	Journal services, scientific editor services
<input type="checkbox"/> Intellectual Property Rights	Patent, copyright, license, trademark, or royalties paid directly to individual
<input type="checkbox"/> Divestiture and Cash Pay-out	Sale of equity or membership
<input type="checkbox"/> Sponsored Travel	Travel which is paid on behalf of the individual or reimbursed to the individual
<input type="checkbox"/> Board Service	Service on the board of directors or board of trustees for an outside nonprofit or for-profit organization
<input type="checkbox"/> Outside Employment	Employment external to your institution

* Required

OK OK and Add Another Cancel





How to Disclose an Outside Activity

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Editing: DPO

Entity Disclosure

1. * Do you have (Please refer to) Yes No

2. Entity disclosure

Entity Foreign Entity
There are no

Outside Employment

Employment external to your institution _____

1. * Estimated compensation in the past 12 months: (If uncompensated, enter 0) ?

2. * What is the FTE (full-time equivalent) percent? ?

3. Additional information that would help clarify this disclosure: ?

* Required

OK OK and Add Another Cancel





How to Disclose an Outside Activity

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Validate Compare

Instructions and Policies

Entity Disclosure Information

Complete Disclosure Profile

Editing: DPO

Entity Disclosure

1. * Do you have... (Please refer to...)
 Yes No

2. Entity disclosure

Entity Foreign Entity
There are no

4. Related documents:

There are no items to display

5. * Do you expect this activity or interest will continue in the future?
 Yes No [Clear](#)

* Required





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Hello, [Erin Moore](#) ▾

Validate Compare <<

Instructions and Policies

Entity Disclosure Information

Complete Disclosure Profile

Editing: DP00004442

Go to forms menu Print Help

Complete Disclosure Profile

Click the Complete Disclosure Profile Update button to satisfy the following:

Disclosure profile has never been submitted

Review and update of your disclosure required.

Complete Disclosure Profile Update

Exit Save **Finish**



How to Disclose an Outside Activity

COI/COC & Export... **Complete Disclosure Profile Update** Mandy Gettler (she/her/hers)

O UNIV
OR

Validate Complete

Instructions and Policies

Entity Disclosure Information

Complete Disclosure Profile

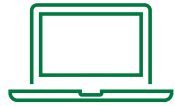
By completing this disclosure profile update you are verifying that all disclosure information is accurate and current.

I certify that I understand what is required of me as an Investigator in the University of Oregon community participating in the design, conduct and reporting of research. I further certify that I have declared all Significant Financial Interests reasonably related to my Institutional Responsibilities on this form.

I understand that this Disclosure is required to obtain funding from the U.S. Government. I certify to the best of my knowledge and belief that the information contained in this Disclosure Statement is true, complete, and accurate. I understand that any false, fictitious, or fraudulent information, misrepresentations, half-truths, or omissions of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims, or otherwise. (18 U.S.C. §§ 1001 and 287, and 31 U.S.C. 3729-3730 and 3801-3812). I further understand and agree that (1) the statements and representations made herein are material to U.S. Government's funding decision, and (2) I have a responsibility to update the disclosures during the period of performance of the award should circumstances change which impact the responses provided above.

OK Cancel





How to Disclose an Outside Activity

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Hello, [David Condon](#) [Switch User](#)

COI Stage

Dashboard Facilities IACUC IRB COI

Disclosures Requests Certifications Plans Triggering Events Reports Meetings Help Center

COI > Disclosures > Disclosure Profile for David Condon [Help](#)

No Action Required

Disclosure Profile for David Condon

Instruction Center	
Action Required	Reason
If you have new or updated information to add to your Disclosure Profile, click "Edit Disclosure Profile" and add/edit disclosure information as needed. Click "Complete Disclosure Profile Update" button when update completed.	Discloser's disclosure profile is within the grace period. No action required unless the discloser has new or updated information to add to their disclosure profile.

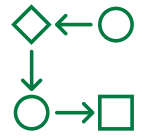
[Edit Disclosure Profile](#)

Disclosures [History](#)

i You have not disclosed any interests. Reference the Instruction Center to take the appropriate steps of completing a disclosure update.

Disclosure profile last completed: 7/2/2024
Training last completed: 12/8/2023
Training expiration date: 12/8/2026

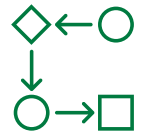




What Happens With Your Disclosure

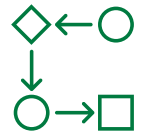
- Conflict of Interest Office reviews disclosures within 3 business days. Disclosures are compared against documents in EPCS to determine whether a researcher's SFI presents a financial conflict of interest.
- If no conflict is identified, researcher will not hear from our office. COI Office notifies Sponsored Project Services that award action can proceed.
- If a conflict is identified, researcher will receive an email with next steps: the management plan.
- Disclosures in which a conflict is identified are subject to public records requests. Some responses to disclosure questions request amounts of compensation. It is OK to provide a range estimate.





Management Plan Process





Management Plan Process

- Conflict of Interest in Research Committee (COIRC) oversees management plan process and recommends plan steps to mitigate financial conflict of interest with the sponsored research.
- Employee can always view track changes and comments in the Sharepoint document.
- Management plans are subject to public records requests. Steps in a management plan must be shared with the sponsor.



Links

- [FCOI Policy](#)
- [Research Administration Portal \(RAP\)](#)
You will be prompted to enter your Duck ID.
- [FAQs](#)
- [COI Office website](#)



Definitions

- **Conflict of Interest in Research** means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research, as determined by the university.
- **Declaration** means an Investigator's formal or explicit statement disclosing Significant Financial Interests to the university.
- **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.
- **Investigator** means the project director or principal Investigator, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Sponsored Research. Investigator can include but is not limited to: professorial faculty, research associates, emeritus faculty, research collaborators, post-doctoral students, graduate students, visiting scientists, and individuals with courtesy appointments, external collaborators, or outside consultants, regardless of whether paid or unpaid. The term Investigator does not usually apply to, but does not preclude, departmental grant administrators or financial staff.
- **Institutional responsibilities** means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, 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.
- **Management Plan** means the prospective plan for COIR mitigation.
- **Mitigation Report** means a retrospective report for COIR mitigation compliant with Sponsor's requirements.
- **NIH Standards** means the U.S. Department of Health and Human Services (DHHS) regulations on Promoting Objectivity in Research (42 CFR Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR Part 94).
- **Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). It includes any activity for which research funding is awarded through grant, award, fellowship, training, project, or research resources award.





COI Office

coi@uoregon.edu

[Our Website](#)



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