Outside Interest Disclosure Requirements

You are required to:

1. Participate in COI training every four years,
2. Disclose your Outside Interests to the COI Program through the COI Program’s electronic disclosure system (https://uavpr.arizona.edu/COI/), and
3. If you have disclosed an Outside Interest, disclose each of your research projects through the COI Program’s electronic disclosure system.

Who is required to complete a disclosure?

You must complete a disclosure if you are an Investigator. You are an Investigator if you are responsible for the design, conduct, or reporting of research, regardless of your title or position. This includes being principal investigator, but also being a co-PI, co-investigator, project director or having any other senior or key personnel role. You can also be an Investigator if you are a student, postdoctoral researcher, volunteer, consultant, or have another role.

* The touchstone is whether you have independent responsibility for the design, conduct, or reporting of the research.
What information do I need to disclose?

You must disclose both your Outside Interests, as well of those of your immediate family members, which includes your spouse, dependent children, or domestic partner.

Outside Interests to be disclosed include Significant Financial Interests and Significant Personal Interests, which we will further explain in a moment.

It is important to provide as much information as you can! When you complete your disclosure, please provide as much information as possible.

- The more you tell us, the easier it is for us and our faculty committee to understand and properly assess the relationship between your research and your outside interests.
- Our faculty committee often sends insufficient disclosures back for more information, which can delay the start of your research.
- Providing complete information may prevent delays in the review of your disclosure.

<table>
<thead>
<tr>
<th>Disclosure</th>
<th>Might result in Delay</th>
<th>Might result in speedier COI Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outside Interest Disclosure - Description of Business Activity</td>
<td>Consulting</td>
<td>I use this entity for my private consulting business, which has clients in the pharmaceutical industry. My consulting activity focuses on medication management, which is distinct from my area of research at the University, which generally focuses on drug discovery.</td>
</tr>
<tr>
<td>Project Questionnaire - Description of the Role in Research</td>
<td>General PI Duties</td>
<td>As PI, my role in this study is primarily post-intervention follow-up with participants. I will not be directly involved in recruitment or consenting, although I will be primarily responsible for data analysis at the conclusion of the research.</td>
</tr>
<tr>
<td>Project Questionnaire - Enter or Upload a copy of the project Abstract</td>
<td>See PI's disclosure</td>
<td>[Copy and paste the full abstract]</td>
</tr>
<tr>
<td>Project Questionnaire - Enter or Upload a copy of the project Abstract</td>
<td>[Just pasted the Abstract]</td>
<td>[Pasted the abstract, and also included]</td>
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</tbody>
</table>

XYZ, Inc. (the entity in which I have an outside interest) manufactures medical devices that monitor insulin levels. I use this device on my patients and conduct educational lectures on my experience with this device on behalf of XYZ.

By contrast, this project focuses on whether ABC, manufactured by ORS, helps increase insulin levels in diabetic patients. This project seeks to measure the efficacy of ABC and not XYZ's medical device.
What are Significant Financial Interests?
1. Any income you receive from Intellectual Property rights, such as patents or copyrights (unless that income is paid through UA);
2. Any equity valued at over $5,000 in a public company;
3. Any equity at all in a private company, regardless of its value; and
4. Any outside compensation you receive that exceeds $5,000. Compensation includes your salary, as well as consulting fees, honoraria, paid authorship and other types of remuneration for services; if you receive compensation from, and hold equity in, a public company, these should be added together to determine if you cross the $5,000 threshold.
5. If your research is funded by, or if you have sought funding from a Public Health Service Agency (e.g., the National Institute of Health), you also must disclose any reimbursed or sponsored travel related to your institutional responsibilities, regardless of amount. (You do not have to report travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, a teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.)

What are Significant Personal Interests?
A Significant Personal Interest is any managerial, professional, or fiduciary position you or anyone in your immediate family hold in any outside entity whether or not compensated. This can include officer, director, and board positions.

What outside interests am I not required to disclose?
You do not have to disclose the following:
1. Salary, royalties, or other payments you get directly from the University of Arizona;
2. Investments in mutual funds or retirement accounts where you don’t control the underlying investments; and
3. Sponsored travel or income from teaching engagements and review panel participation when such funds are provided by a government agency; another US University; or an academic teaching hospital, medical center, or research institute affiliated with another US University.

What if I do not have any outside interests?
Anyone who meets the “Investigator” definition must comply with the disclosure requirements, whether or not you have an outside interest. This means submitting your disclosure and recertifying it annually.
When should I update my disclosure?
You should complete your initial disclosure within 30 days of hire. After that, you should update your disclosure annually every June, as well as within 30 days whenever you get a new disclosable interest or your disclosed interest changes.

In addition, if you have disclosed an outside interest, you must enter a disclosure for each of your research projects, either:
1. When prompted by an email for those research projects that are routed through sponsored projects services, or
2. For other projects, sufficiently in advance of starting your research to allow time for COI review (typically, 60 days in advance).

What happens if I don’t disclose?
If you do not disclose in a timely and complete manner, a number of possible consequences may occur.

- Awarded funds may be held.
- Proposals may be held or withdrawn.
- You will be non-compliant with policy and sponsor regulations.
- Your research may be subject to a retrospective review for bias.
- Your human subjects protocol may be withdrawn.

Where do COI obligations come from?
The University’s COI requirements are informed by, and structured to ensure compliance with, the conflict of interest requirements imposed by a variety of external sources. This includes, among others:

- PHS, NSF and other federal regulations;
- University Policy;
- Sponsor Requirements;
-Accreditors; and
- State Law.
What other related policies might I have to comply with?

This resource guide, along with the associated training and disclosure requirements, are designed to ensure your compliance with the University’s Individual Conflict of Interest in Research Policy. In addition to this policy, the University also has a number of other policies that may apply to you. These include:

- **Conflict of Commitment Policy**: applies to Full time (0.5+ FTE) appointed personnel who have outside professional commitments or employment;
- **Procurement and Contracting Services COI Policy**: applies to any university employee with a personal or pecuniary interest in an entity that may enter into a contract with (or otherwise be involved in a business decision of) the University;
- **Institutional COI Policy**: applies to University Administrators, which is defined to include any individual in a position of administrative leadership of a recognized University college, academic department, business, or other administrative unit, where a regular job requirement is to make institutional decisions on behalf of the University;
- **College of Medicine Interactions with Industry polices**:  
  - Tucson  
  - Phoenix; and
- **ABOR-Policy 3-901(B)** on technology transfers involving University employees. Contact Tech Launch Arizona for more information.

Helpful Resources

- **COI Disclosure Database**
- **Individual Conflict of Interest in Research Policy**
- **Conflict of Interest Program Homepage**
- **What is Conflict of Commitment and how is it different?**
- The COI Program is available to answer your questions and provide individual or group training. The easiest way to get in touch is our email address, COI@email.arizona.edu.
- We encourage you to visit the Research Gateway for our list of frequently asked questions about the following topics:
  - **Disclosures of Outside Interests**
  - **COI Disclosures for Human Subjects Research**
  - **Consulting Agreements**