

ODU My COI Quick Reference Guide for COI Disclosures

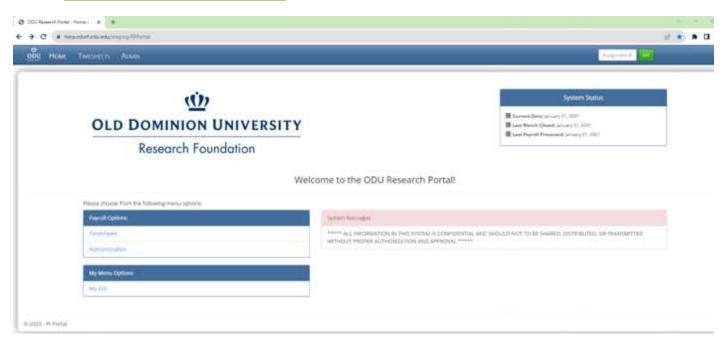
How to submit an **Annual COI Disclosure**

1 My COI Portal - Access and Annual Renewal COI

1.1 ODU Research Portal

To access the ODU Research Portal, you must have an ODU Midas ID or Guest Account. Once you have your Midas ID or Guest Account, you can navigate to the web address below:

https://hera.odurf.odu.edu/RFPortal



Click on My COI Disclosures underneath My Menu Options:



Now you will see your respective My Conflict of Interest (COI) Disclosures Dashboard:

My Conflict of Interest (COI) Disclosures





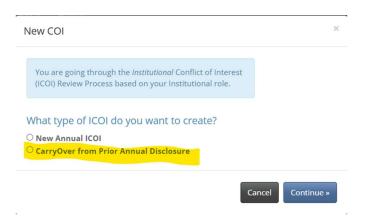
Your respective Dashboard may be empty or have a previously entered annual COI disclosure.

1.2 To Complete Your Annual Renewal

- 1.2.1 If you have a previously entered COI Disclosure:
- 1.2.1.1 Click **+New RCOI** as highlighted below in the screen capture.



1.2.1.2 Once you do that, it will prompt you to 'Create a new disclosure' or 'Carry-over from the prior year.' Go ahead and click 'Carry-over from prior year' as seen below.



- 1.2.1.3 It will do just that, carry-over everything from your prior year disclosure. If there are any updates you need to make, you can do so now. REMEMBER: You are reporting for the prior 12-month period. If you don't have any updates or changes, click 'Next Step.'
- 1.2.1.4 If you don't have any disclosures and/or active research projects, there will be a message that indicates that because of this, there are no potential or actual conflicts of interest. Go ahead and click 'Next Step' in this instance, which should bring you to the last part of the process, the acknowledgement and signature page. Read the acknowledgement, check the box, enter your name, and click 'Submit.'
- 1.2.1.5 If you do have a disclosure(s) and an active project, it will bring you to Part II: Declarations where you will review each project and identify the relationship of your disclosed financial interest and each of your projects. You can make updates here to your relationships if appropriate.



Once you have completed Part II, click 'Next Step", which should bring you to the last part of the process, the acknowledgement and signature page.

- 1.2.1.6 Read the acknowledgement, check the box, enter your name, and click 'Submit.'
- 1.2.2 If you don't have a previously entered COI Disclosure, go ahead and follow the instructions beginning with 1.3 below to start a New COI disclosure.

1.3 Start a New COI

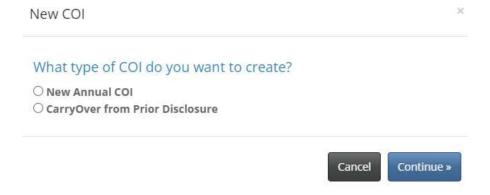
In the event you have not had to complete a COI disclosure in the past but now need to complete these steps.

To fill out a New COI, click on the plus sign at the top right of the Dashboard next to New COI.

My Conflict of Interest (COI) Disclosures



You will then see an option for selecting 'New Annual COI' or 'Carryover from Prior Disclosure'. For most everyone who have not completed a COI on the Portal before, you would click on 'Annual COI'. Once a selection is made, hit Continue.



You will then see the COI Training (Part 1). You must review the following information and then check the Acknowledgement box at the bottom of the screen before you hit Continue. Once you check the box, select Continue.





ODU Significant Financial Interests Disclosure Reporting

PART 1: COI TRAINING

A conflict of interest (COI) disclosure must be completed annually (by February 28th of each year) and within 30 days of discovering or acquiring a new financial interest and/or sponsored travel. Your disclosure should cover the prior 12 months. After you complete your annual disclosure in the ODU Research Portal COI Module, you should continue to update your disclosure throughout the year to add, remove, or modify any outdated external interests as appropriate. This disclosure form contains a brief training module that is required to be acknowledged once every four (4) years, or unless otherwise directed by the Office of Research AVP for Compliance, COI Committee (COIC), or supervisor. The training module contains helpful definitions and guidelines for understanding conflicts of interest, your responsibilities, and how to complete this disclosure.

PURPOSE

The ODU COI disclosure process was developed to promote objectivity and transparency in research and other professional activities by ODU faculty and associated personnel. At the end of this training section, you will understand

- The federal COI requirements that guide ODU's research
- COI policy and processes
- Coll policy and processes
 Who is subject to research COI requirements
 The term "Significant Financial Interest" (SFI)
 Where and when SFIs must be disclosed
 How SFIs are reviewed at ODU
 The term "Financial Conflict of Interest" (FCOI)
 How FCOIs are managed

- How FCOIs may be reported to sponsors and to the public Implications for noncompliance with research COI requirements

DEFINITIONS

Investigator » includes the Principal Investigator (PI), Co-Principal Investigator (Co-PI), Co-Investigator (Co-I), and any other key personnel, regardless of title or position, who is responsible for the design, conduct, or reporting of research. The PI for any research activity conducted at a University facility must be a University employee or (Id Dominion University Research Foundation (RF) employee, or, under appropriate circumstances (e.g., NSF Graduate Fellowship), graduate student, post-doc, research assistants. Co-PIs are key personnel who have responsibilities like that of a PI on research projects. While the PI has ultimate responsibility for the conduct of a research project. Co-PI is also obligated to ensure the project is conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research. Note: The PI determines who is an investigator on a

Immediate Family Member » A spouse and any other person residing in the same household as the investigator who is a dependent of the investigator or of whom the investigator is a dependent

Significant Financial Interest » A significant financial interest means the receipt by an Investigator or an Investigator's Immediate Family Member of anything of monetary value, including but not limited to the following, provided they appear to be reasonably related to the Investigator's Institutional Responsibilities:

- Non-publicly traded entity: if the value of any remuneration received from any foreign or domestic, non-publicly-traded entity over a 12-month period, when aggregated, exceeds \$5,000, or when the Investigator or the
- Investigator's immediate family Members holds any equity interest.

 Publicly traded entity. Any equity interest, including stock options in any foreign or domestic publicly-traded entity beld by an Investigator's immediate family members, that, when aggregated, exceeds 5% ownership interest in any single entity or a current value of \$5,000, as determined through reference to public prices, recent financing events, or other reasonable measures of fair market value.

 Salary, consulting fees, honoraria, royalties, and other payments received directly from a single outside entity that, when aggregated for the Investigator's Immediate Family Members, exceeds \$5,000 over
- Any sponsored or reimbursed travel related to Institutional Responsibilities, regardless of dollar amount
- . Any income received from rights in Intellectual Property (e.g., patents, copyrights), as measured over a 12-month basis

University Policy on Research Conflicts of Interest

Acknowledgement

☐ I have read and understand the training and policies above

1.4 Fill out Part 1: COI Disclosure Questionnaire

There are 17 questions within the COI Disclosure Questionnaire. All 17 questions are required to have a response. If YES is selected for a question, there will be additional sub-questions related to the main question. If NO is selected for a question, you can move on to the next question. There is also an area at the bottom of the questionnaire to attach supporting documentation.



Part 1: COI Disclosure Questionnaire

Question (1 of 17)

O YES O NO

Do you currently have, or have you had in the past 12 months, any active academic, professional or institutional appointments at an organization other than ODU/ODURF?

Consistent with federal sponsor requirements, please mark "yes" if you have held any titled academic, professional or institutional appointments, regardless of whether renumeration is received and whether the appointment is full time, part-time, or voluntary (including adjunct, visiting, courtesy, or honorary). Do not include serving as an invited guest lecturer or external reviewer/examiner (e.g. of a student dissertation/thesis) if there is/was no ongoing commitment or relationship.

Note: if you have been at ODU/ ODURF < 12 months, limit your response to reflect appointments that have been active since your ODU / ODURF start date.

Question (2 of 17)

○ YES ○ NO

Do you or a family member currently own a business?

Question (3 of 17)

O YES O NO

Do you have access to research/laboratory space, equipment, facilities, or the services of research support staff, including student assistants, at a location other than ODU that is not associated with an ODU/ODURF sponsored program or other ODU/ODURF research agreement?

Question (4 of 17)

O YES O NO

During the period of your employment at ODU, have you been named as an inventor on any patent or patent application other than those submitted on ODU's behalf by the ODURF?

If you select YES for a question, you will be required to answer the sub-questions for each External Entity that you are associated with outside of ODU. For example, if you are associated with External Entity 1 and External Entity 2, you will need to add 2 Entries of sub-questions to complete the overall Question.



Question (1 of 17)

O YES O NO

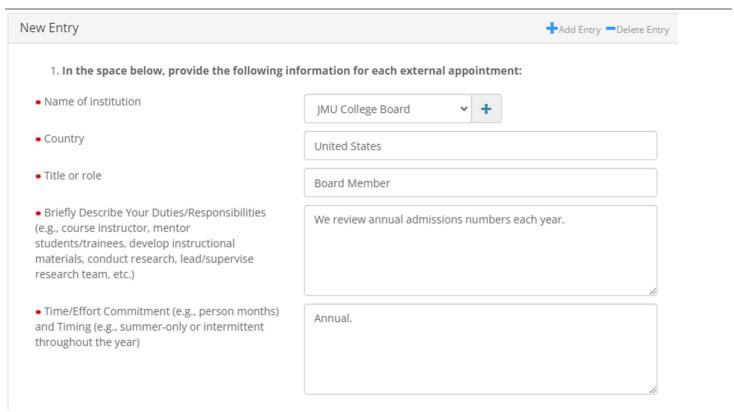
Do you currently have, or have you had in the past 12 months, any active academic, professional or institutional appointments at an organization other than ODU/ODURF?

Consistent with federal sponsor requirements, please mark "yes" if you have held any titled academic, professional or institutional appointments, regardless of whether renumeration is received and whether the appointment is full time, part-time, or voluntary (including adjunct, visiting, courtesy, or honorary). Do not include serving as an invited guest lecturer or external reviewer/examiner (e.g. of a student dissertation/thesis) if there is/was no ongoing commitment or relationship.

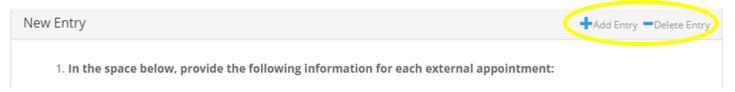
Note: if you have been at ODU/ ODURF < 12 months, limit your response to reflect appointments that have been active since your ODU / ODURF start date.

Entry #1 1. In the space below, provide the following information for each external appointment: Name of institution Restaurant X Country Germany • Title or role Board Member • Briefly Describe Your Duties/Responsibilities I am on the board of directors. We reviewed financials each year. (e.g., course instructor, mentor students/trainees, develop instructional materials, conduct research, lead/supervise research team, etc.) • Time/Effort Commitment (e.g., person months) Monthly and Timing (e.g., summer-only or intermittent throughout the year)





You can add as many Entries as needed. You also have the ability to Delete Entries as well.



Once you have completed all 17 Questions, you will need to upload any Supporting Documents. You can do that in the Supporting Documents section near the bottom of the page by selecting **Choose File**, finding the file, and double clicking on that file, and then clicking **Upload Attachment**.







After you have uploaded your supporting documentation, you have the option to **Save and Submit Later**, OR go to **Next Step**, OR **Cancel**.



If you hit Save and Submit Later, you will then be taken back to the My COI Disclosures Dashboard.

My Conflict of Interest (COI) Disclosures



The Dashboard contains additional data about your respective COI Disclosure including:

- Version # (V#)
- Disclosure Type
- Disclosure Status
- Created On
- Submitted On
- Review Status
- Disposition
- CMP Status
- COI Expires On
- COI Action(s)
- Training Expires On



To **Edit and Submit** your COI for Review, click on the word **Edit** underneath COI Action(s) in the Dashboard. Scroll down to the bottom of the page after you have updated each of the Questions that needed more information. Select **Next Step.**

1.5 Fill out Part II: Project Declarations

After completing Part 1 and hitting **Next Step**, you will then see Part II: Project Declarations. All the active projects, including those in which the period of performance has ended but are actively being closed out (inactive), within the ODU Research Portal that you are assigned to will automatically be displayed on the screen. If you are not assigned to any projects, then the screen will say "You are not assigned to any projects and therefore this step is not required. Click Next Step to go to the next page."

Part II: Project Declarations

Instructions: Please identify your relationship with each entity and provide additional supporting comments as needed.

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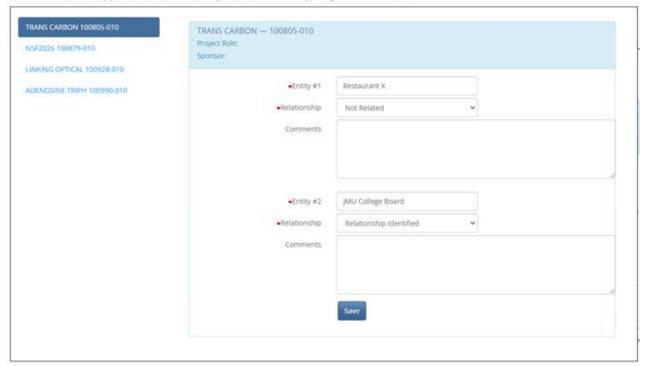
For each Project and respective Entity that you are associated with, you will need to fill out the Relationship and add any relevant comments and then hit **Save**. The relationship options are as follows:

- **Not Related** i.e., your outside engagement in activity/financial interest is not related to your research project and academic or professional expertise.
- **No Conflict Exists** i.e., situations where any financial interest held by an Investigator or an Investigator's family is below the threshold for Significant Financial Interest and where the situation suggests no actual, potential, or perceived Conflict of Interest. These situations may continue without special safeguards or oversight.
- **Potential Relationship** i.e., your outside activities or interests present a potential or perceived Conflicts of Interest with your research project and academic or professional expertise, which may represent Conflict of Interest, but in many cases would be permitted to go forward after disclosure with a Management Plan.
- **Relationship Identified** i.e., actual Conflict of Interest with your outside activities or interests, which may be permitted to go forward after disclosure only with an appropriate Management Plan to eliminate the conflict, safeguard against prejudice toward University activities, and provide continuing oversight.



Part II: Project Declarations

Instructions: Please identify your relationship with each entity and provide additional supporting comments as needed.



Once you have completed the updates for each Project and hit **Save** for each Project, then you will see green check marks next to each project as well as a **Next Step** button appear at the bottom right of the screen. Hit **Next Step** to move on.

Part II: Project Declarations

 $Instructions: Please\ identify\ your\ relationship\ with\ each\ entity\ and\ provide\ additional\ supporting\ comments\ as\ needed.$

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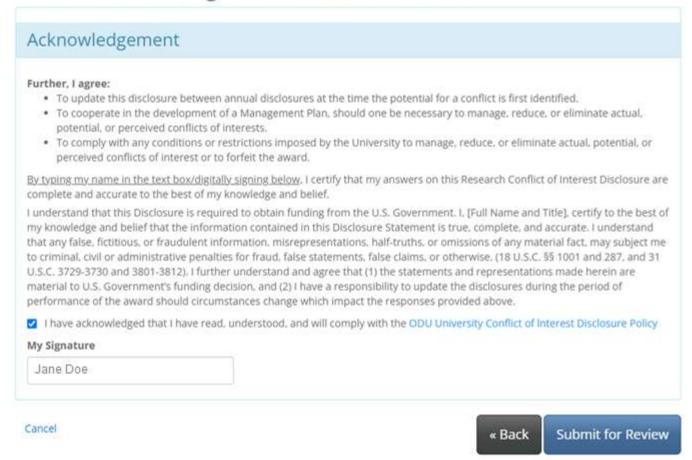
Next Step »

1.6 Part III: Acknowledgement and Certification

Once you hit **Next Step** on Part II, it will take you to Part III: Acknowledgement and Certification. Here you will review and digitally sign the Acknowledgement page for your respective Conflict of Interest Disclosure.



Part III: Acknowledgement and Certification



You must select the Check Box and write your Name in the Signature Box. Then select **Submit for Review.** Once you select **Submit for Review**, your COI Disclosure will be submitted, and you will be taken back to the My COI Disclosures Dashboard.

My Conflict of Interest (COI) Disclosures



At the Dashboard, you will see that you now have a Submitted On Date, an updated Disposition and an option to View your respective COI. Your COI Disclosure will be locked for editing until it has been reviewed and processed by the ODU AVP for Compliance, Secured Research and Regulated Activities Office (SRRO), and/or the COI Committee. Your COI Disclosure may be returned to you if more information is requested by the ODU AVP for Compliance or the COI Committee. Once it has been reviewed and processed, you will have the ability to update your disclosure. **Update** gives you the option to create a new version (copy) of the original and make changes as needed so that there is a historical tracking of changes. If you update your disclosure, your



respective COI Disclosure will then be locked and again move through the necessary reviews. You will be able to see the **Review Status** in the middle of the Dashboard.

