



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Portal COI Module, you should continue to update your disclosure throughout the year to add, remove, or modify any outdated external interests as appropriate.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
- 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 has the responsible charge or oversight 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 Old 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, the 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 project.

What is “design, conduct, or reporting of research?”

Research design is the creation of the plan, the strategy, the methodology, the procedures, and the structure of conducting a research study. Anyone involved in creating, developing, or substantively contributing to those aspects of scientific research is subject to the regulations. Similarly, persons who materially influence the research questions pursued are subject to the regulations.



Conduct of research pertains to the direction, execution, or management of the study plan. It includes all aspects of carrying out a study, including subject recruitment, selection, enrollment, or retention; data or specimen collection, analysis or interpretation; maintenance of regulatory binders and other study documents; data and safety monitoring, study drug or device accountability, and management of study-related records.

Reporting of research includes the reporting and attribution of adverse events; the presenting of data/results; submitting information to the IRB (e.g., continuing review); completion of case report forms; and contributing to the presentation or publication of the research.

It is impossible to detail every component of what constitutes design, conduct, or reporting of research. **Some interpretation by PIs will be needed.** ODU expects all personnel to make a **good faith effort to meet the spirit of the COI training and disclosure requirements and to seek guidance from the Office of the Research AVP for Compliance, as needed.**

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 held by an Investigator and the 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 and the Investigator's Immediate Family Members, exceeds \$5,000 over a 12-month period.
- 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.
- Any venture or other capital financing.

Exclusions from the Significant Financial Interest Definition:

- Salary or supplementary payments paid by ODU or its affiliates.
- Income from mutual funds and/or retirement accounts so long as you do not have direct control over investment decisions.
- Income from seminars, lectures, teaching, service on advisory committees or review panels, for federal, state or local government agency, institution of higher education (as defined by 20 USC 1001(a)), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education;



- Reimbursed or sponsored travel by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic medical center, or a research institute that is affiliated with an Institution of higher education.
- Royalties, milestone payments, licensing fees, or other remuneration paid by the University, or its affiliates to the Investigator if the Investigator is currently employed or otherwise appointed by the University or the Old Dominion University Research Foundation.

WHO MUST COMPLETE AN ANNUAL DISCLOSURE?

ODU policy requires that research Investigators and Senior/Key Personnel annually disclose all significant financial interests and other opportunities for tangible personal benefit that are related to their institutional responsibilities. ODU's Research Portal Conflict of Interest (COI) module allows Investigators and Key Personnel to fulfill this obligation through the creation and submission of an Annual Disclosure and Travel Disclosures.

The core requirement met by the ODU Research Portal COI module is to assure that ODU is in compliance with all federal, state, and institutional regulations relating to conflict of interest. The online Disclosure form is completed:

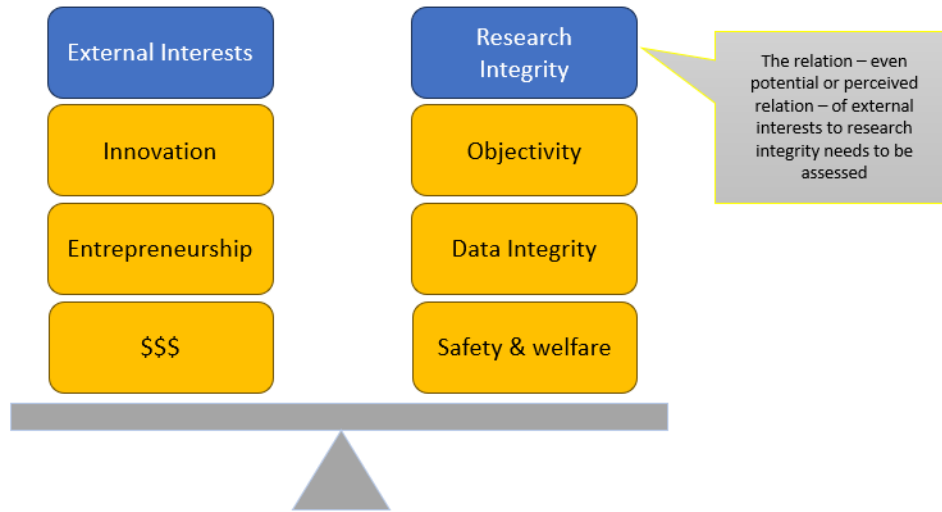
- To meet the requirement for annual conflict of interest disclosure (Annual Disclosure)
- To disclose all personal financial interests relating to a new project -- research or other proposal, Institutional Proposal, and/or award (Project Disclosure)
- To relate a new significant financial interest to existing projects (Updating Annual Disclosure)
- To report sponsored or reimbursed travel for compliance with Public Health Service (PHS) or Department of Energy (DOE) regulations (Travel Disclosure).

TIPS:

- Senior/Key Personnel are always considered Investigators by virtue of the definition of Key Personnel
- **Key Personnel are not administrative personnel or individuals who perform routine, pre-defined, or incidental tasks related to the project.**
- **Being paid off of a grant or contract does not necessarily make one a key personnel.**

WHY DO WE CARE ABOUT COI IN RESEARCH?

The risk that an individual's external financial interests may bias or compromise – or have the appearance of biasing or compromising – an individual's judgment, objectivity, or decision-making with respect to research design, conduct, or reporting.



WHAT MUST ODU DO TO COMPLY?

As a condition of federal funding, the University must establish procedures that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from Investigator Financial Conflicts of Interest (FCOIs; or COIs*)

Federal regulations require that the University:

1. Maintain a current, documented, and enforced COI policy.
2. Educate Investigators as to ODU’s COI policies and procedures.
3. Facilitate and ensure Investigator compliance with initial and ongoing COI disclosure requirements.
4. Identify and manage FCOIs.
5. Flow down sponsor COI requirements to subrecipients/collaborators.
6. Meet sponsor and other COI reporting requirements.

** We use the general term “COI” across the board to avoid confusion among various sponsors’ vernacular when it comes to COI terminology.*

KEY ASPECTS OF ODU’S COI REQUIREMENTS

- **Investigators** must disclose all SFIs related to their Institutional Responsibilities on an ongoing basis.
- **Institutions** determine whether an SFI could be a COI for each research activity in which an Investigator is involved.
- **Institutions** must eliminate, reduce, or manage COIs, and meet sponsor and other COI reporting requirements.

Please familiarize yourself with ODU’S Policy on Research COI, available here: [ODU Policy on Research COI](#)

RESEARCH SUBJECT TO ODU’S COI POLICY

- Proposals submitted to/research funded by:
 - Federal sponsors
 - Industry sponsors



- Other sponsors that have specific COI terms and conditions
- All research involving human participants and animals regardless of funding source

WHERE DO INVESTIGATORS DISCLOSE?

All Investigators disclose financial interests in ODU's Research Portal COI Module, including:

- ODU Investigators
- Subrecipient Investigators (if following ODU's policy)
- Consultants (if meeting the definition of "Investigator" per the project PI)

Training is a prerequisite to completing the annual COI disclosure and is required every 4 years. Once an individual has read through the training and acknowledges their comprehension of it, an individual does not need to review and acknowledge it again until the (4) years has expired unless otherwise directed to by the Office of Research AVP, COI Committee, or their supervisor. Following the required training completion and acknowledgement, you will find that there are **three related parts to the Annual Disclosure** associated with the **COI Module found within ODU's Research Portal**: Entity Disclosures Questionnaire (financial, outside commitments, and foreign entities), Entity-Project Declarations, and Acknowledgement. **Part I** is the Entity Disclosure Questionnaire, where the individual answers questions and discloses any significant financial interest, outside commitments, and foreign entity disclosures they or an immediate family member may have. **Part II** asks the individual to declare whether the financial, outside commitments, or foreign Entity Disclosures are related to their institutional responsibilities and university-affiliated research. **Part III** requires the Investigator to sign a statement certifying that each disclosure is true, complete, and accurate. The system will automatically date and timestamp each certification once completed. The COI Module will automatically link the individual's Entity Disclosures and Entity Declarations with their open sponsored projects.

Note: ***Open research projects*** are those that ***are active (within their period of performance) or inactive and in the process of closeout; meaning, the award may have ended but it is still being administratively processed and has not been deactivated and considered closed by the sponsor yet.*** Until a sponsored project is closed (deactivated), it is considered open. Closeout procedures may vary, although typically take up to 120 days of the expiration of the period of performance to reconcile financial expenditures associated with the award, return any funds due to the sponsor, make corrections, complete audits, submit required final reports, etc. An award may also be processing a No Cost Extension during this period as well to extend the period of performance. A current COI disclosure is required while sponsored awards are considered ***open***. Once the closeout processes of an awards have been completed, the award will be deactivated and considered closed.

Travel Disclosure: The COI Travel Disclosure allows individuals to report sponsored or reimbursed travel for compliance with Public Health Service (PHS) and Department of Energy (DOE) regulations (Travel Disclosure). Travel that is paid for, sponsored, reimbursed, or otherwise funded by outside activities may become a conflict. Travel may be considered a financial interest or a gift, depending on the circumstances. In making disclosures, it is important to disclose the name of the outside entity sponsoring the travel, its purpose, location (if foreign, include country) and value (including any registration fees, accommodations, transportation costs, etc.).

Professional societies, foreign institutions of higher education, for-profit entities and non-profit entities are a few examples of outside entities that require disclosures. Otherwise, travel paid for by the University, federal, state, or local government agencies, US higher education institutions, US academic teaching hospitals, US medical centers or research institutes affiliated with a US institution of higher education, generally do not need to be disclosed. Currently, only Investigators and Key Personnel with open PHS and DOE awards are required to submit Travel Disclosures.



WHAT MUST BE DISCLOSED?

Significant Financial Interests related to an Investigator's Institutional Responsibilities.

Significant Financial Interests held by an Investigator, or an Investigator's Immediate Family Members, that is reasonably related to their ODU responsibilities.

Immediate Family Members include: 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.

Investigators with PHS or DOE-funded research **must** also report travel that is paid for, sponsored, reimbursed, or otherwise funded by outside activities.

Institutional Responsibilities refer to an Investigator's professional responsibilities performed on behalf of Old Dominion University, which may include activities such as:

- Research
- Research consultation
- Teaching and advising
- Institutional committee memberships and other service
- Service on institutional panels

Disclosure of outside activities and interests that relate to one's Institutional Responsibilities (e.g., consulting activities in the realm of one's academic or research focus at ODU) must be disclosed.

WHEN DO INVESTIGATORS NEED TO DISCLOSE?

- **Before engaging in research proposed to or funded by sponsors subject to ODU's COI requirements**
 - A disclosure must be on file in ODU's Research Portal COI Module for each Investigator on a proposal **before** the proposal can be submitted to the sponsor by the institution, and/or for each PI and Co-Investigator on an IRB protocol before a protocol can be approved by ODU's Institutional Review Board (IRB).
- **Within 30 days of receiving or becoming aware of a new SFI**
 - SFIs must be disclosed in the ODU Research Portal COI Module within 30 days of acquisition, receipt of payment, etc.
 - Do NOT wait until annual disclosure time to update your disclosure with new SFIs.
- **At least annually by February 28th each year.**
 - If you have no new SFIs to disclose between annual COI disclosure cycle, the annual COI disclosure is sufficient. You must complete a COI disclosure annually, even if acknowledging no change, by carrying over your prior annual disclosure to the new reporting year.
 - The annual COI cycle runs between January and February of every year.
 - **The information collected is for the previous calendar year (January – December),** to align with the receipt of income forms/statements and preparation of taxes.

ONGOING DISCLOSURE REQUIREMENTS

Disclose **new SFIs within 30 days** of acquiring or becoming aware of them, and **at least annually**. Below is an example of an annual disclosure cycle with sample SFI's throughout the year and the reporting requirements related to each.

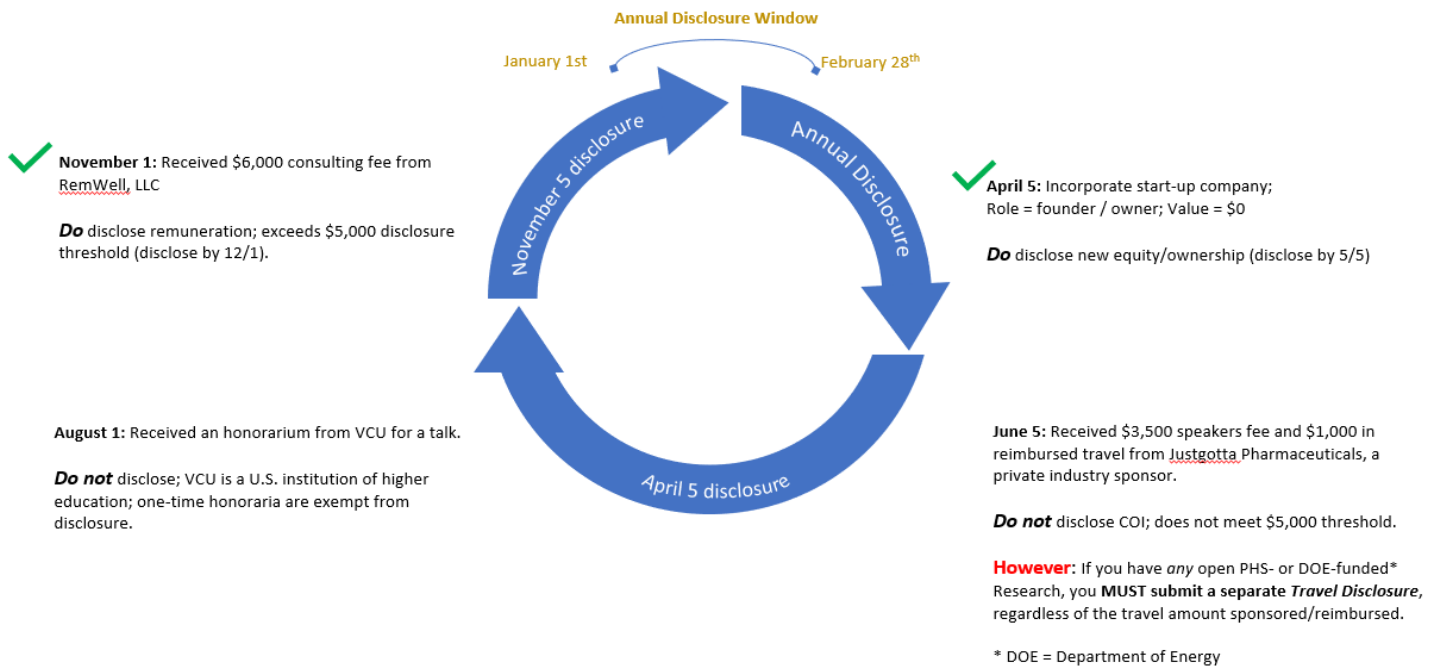
NOTIFICATION

Investigators will receive notification that the Annual COI Disclosure Reporting Window has opened as of January 1st of each year and that they have until the end of February to complete their disclosure. They will receive a reminder notification halfway through the Annual COI Disclosure Reporting Window if they have not completed it already. Those outstanding will receive reminders again with 1-week remaining and then again 2-days prior to the closing of the reporting window.

Note: The Investigator’s Chair/immediate supervisor is copied on the mid-point notifications. The ODU Research Foundation, ODU AVP for Compliance and the Investigator’s Dean/Vice President is copied on the 1-week and 2-days prior to the window closing notifications. A weekly digest is sent to the ODU Office of Research AVP for Compliance, the ODU VPR, and a copy to the ODU President’s Office of those who have expired.

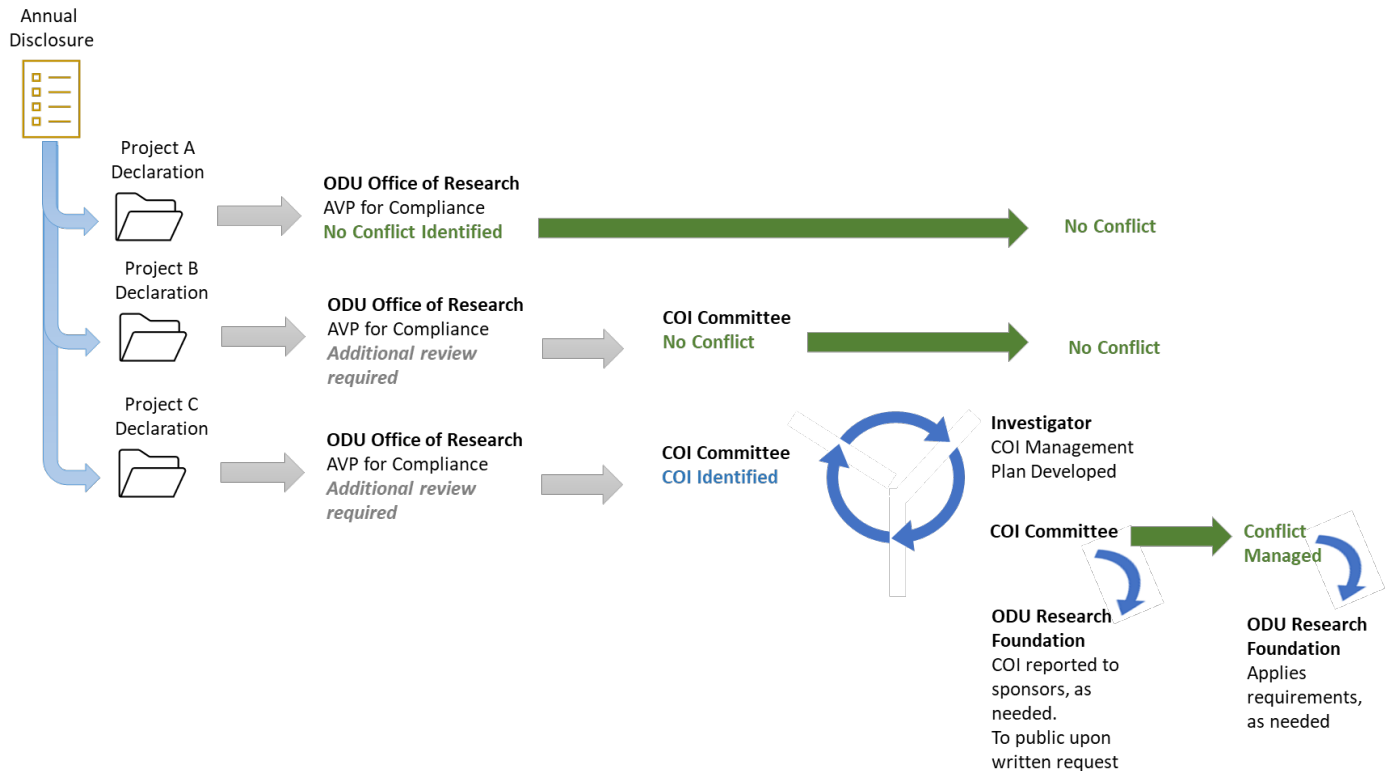
Annual Disclosure in February (Due by February 28th)

If you have no new SFIs through the year, the Annual Disclosure COI Carry-Over process will satisfy your annual requirement.



HOW ARE DISCLOSURES REVIEWED?

Disclosures/SFIs are reviewed in comparison to each *open* research project subject to ODU’s COI requirements. ODU’s Office of Research AVP for Compliance performs an initial review; if a potential or actual COI is identified, the review is referred to the COI Committee.



SIGNIFICANT FINANCIAL INTERESTS vs. CONFLICTS OF INTEREST

A Significant Financial Interest (SFI) is any financial interest meeting the definition that is related to your Institutional Responsibilities. These must be disclosed.

Institutions then review SFIs relative to research projects to identify any potential overlap or relationship. Not every disclosed SFI is a COI.

A Financial Conflict of Interest (FCOI or COI) is an SFI that could directly and significantly affect the design conduct or report of specific research activity. These must be managed, reduce or eliminated.

WHAT HAPPENS IF A COI IS IDENTIFIED?

If a COI is identified, the COI Committee will work with the Investigator to reduce, manage, or eliminate the COI.

Examples of management strategies include:

- Disclosure in publications
- Disclosure to colleagues and collaborators
- Disclosure to IRB and to research participants



- Reduced role in project
- Independent data review and/or monitoring

Some sponsors require that certain information relative to COIs be reported prior to expenditure of funds, which is done by the ODU Research Foundation. The ODU Research Foundation will notify Investigators prior to such reporting.

Certain COI information relative to PHS-funded research must be made available to the public upon request. ODU Research Foundation will notify Investigators prior to provision of such information.

WHAT IS CONSIDERED NONCOMPLIANCE RELATIVE TO COI?

Noncompliance includes failure to identify, review, or manage COIs as required by federal regulations and University policy. The following are considered instances of Investigator noncompliance:

- Failure to disclose information as required;
- Failure to submit an updated disclosure within 30 days of acquiring a new SFI;
- Submission of an incomplete, erroneous, or misleading initial, updated or annual disclosure;
- Failure to comply with COI management plan strategies established by the University;

Instances of non-compliance will be reviewed and disciplinary action taken, if needed, in accordance with applicable University policies and procedures.

****Relative to PHS-funded research, noncompliance may result in the need for ODU to perform a federally-required retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research****