



OLD DOMINION UNIVERSITY

University Policy

Policy # 5201

INDIVIDUAL RESEARCH CONFLICT OF INTEREST, AND COMMITMENT

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Responsible Oversight Executive: Vice President for Research

Date of Current Revision or Creation: October 1, 2020

A. PURPOSE

The purpose of this policy is to outline Old Dominion University's approach to identifying, reporting, evaluating, managing, and resolving actual and potential research conflicts of interests and commitment to ensure the integrity of the University's scholarship, research, sponsored programs, evaluation, and administration is not threatened.

B. AUTHORITY

[Code of Virginia Section 23.1-1301, as amended](#), grants authority to the Board of Visitors to make rules and policies concerning the institution. Section 7.01(a)(6) of the [Board of Visitors Bylaws](#) grants authority to the President to implement the policies and procedures of the Board relating to University operations.

C. DEFINITIONS

[Officers and Key Employees – For the purpose of this policy, this includes the President, all Vice Presidents, the Chief of Staff, Provost, Deans and vice deans, Associate Deans, General Council, Chief Financial Officer, the COI and Institutional COI committee chair, the chair of the Institutional Biosafety Committee, Institutional Review Board chairs, chairs of other similar committees that may be created in the future, and other Key Employees that the University may define from time to time.](#)

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.

Institutional Official – The individual at the University responsible for the solicitation and review of disclosures of significant financial interests from each Investigator who is participating in, or planning on participating in, research. For the purposes of this policy, the Institutional Official is the Vice President for Research, Office of Research.

Institutional Responsibilities – Institutional Responsibilities mean an Investigator's professional responsibilities on behalf of Old Dominion University, including teaching, research, clinical care, administrative, and other Old Dominion University activities and services.

Intellectual Property (IP) – Refers to property created or developed by an Investigator, including but not limited to, patents and inventions, copyrightable work, software, and trademarks.

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 Old Dominion University Research Foundation employee, or, under appropriate circumstances (e.g., NSF Graduate Fellowship), a graduate student. Co-PIs are key personnel who have responsibilities similar to 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.

Research Conflicts of Commitment (COC) – A potential or actual research conflict of commitment (COC) exists when time allocation creates a risk of divided loyalty between the University and an outside entity. This conflict arises when there is an uneven distribution of effort between University duties or institutional responsibilities (teaching, research), and external professional activities that involve an inordinate investment of time or is conducted at a time that interferes with the Investigator’s fulfillment of their duties.

University facility must be a University employee or Old Dominion University Research Foundation employee, or, under appropriate circumstances (e.g., NSF Graduate Fellowship), a graduate student. Co-PIs are key personnel who have responsibilities similar to 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.

Research Conflicts of Commitment (COC) – A potential or actual research conflict of commitment (COC) exists when time allocation creates a risk of divided loyalty between the University and an outside entity. This conflict arises when there is an uneven distribution of effort between University duties or institutional responsibilities (teaching, research), and external professional activities that involve an inordinate investment of time or is conducted at a time that interferes with the Investigator’s fulfillment of their duties.

Research Conflict of Interests (COI) - A potential or actual research conflict of interests (COI) exists when commitments and obligations to the successful conduct of a research project are likely to be compromised, or perceived to be compromised, by a person’s outside interests or commitments, especially financial. The COI is most relevant to an individual who is responsible for the design, conduct, reporting, and/or oversight of research activities or programs affiliated with the University or the Old Dominion University Research Foundation. These individuals may also be referred to as “investigators.” (Note: the requirements of this policy are separate from any requirements and obligations under the State and Local Government Conflict of Interests Act, Virginia Code § 2.2-3100 *et seq.*)

Research Conflict of Interests Committee (COIC) - The University COIC is responsible for the oversight and management of actual or potential research conflicts of interests and commitments and is authorized by the Vice President for Research to receive COI/COC disclosures and to review and manage the risks associated with the disclosed interests.

Significant Financial Interest (SFI) - 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.

The term SFI does not include:

- Salary or supplementary payments from the University or its affiliates;
- Income from seminars, lectures, or non-promotional engagements sponsored by governmental or non-profit entities;
- Income from service on advisory committees or review panels for governmental or non-profit entities;
- 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.

Subrecipient – For the purposes of this Policy, a Subrecipient is a legal entity that receives a subcontract from a pass-through entity to carry out a portion of a sponsored program. A Subrecipient has responsibility for programmatic decision-making; has its performance measured in relation to whether objectives of a programmatic scope of work were met; and is responsible for adherence to applicable sponsored program requirements specified in the sponsored award, as opposed to providing routine goods or services for the benefit of the pass-through entity.

D. SCOPE

This University Policy applies to an Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, and reporting of research or sponsored project activities conducted under the auspices of the University/ODU Research Foundation, which may include collaborators or consultants. The Policy applies from the time of submission of a funding proposal or Institutional Review Board (IRB) application and remains applicable through the life of the funding award or study, whichever is longer. [Financial interests of the University or Officers](#)

[and Key Employees of the University, acting within their authority on behalf of the institution, that may affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution are Institutional Conflicts of Interest \(“Institutional COI”\) and will be processed and reviewed under a separate policy.](#)

This Policy covers the avoidance, disclosure, management, and resolution of financial conflicts of interest, as well as conflicts of commitment regarding research at the University. This policy also includes the requirements necessary to conform to applicable federal law and regulations regarding financial conflicts of interest in federally funded research.

Phase I Small Business Technology Transfer (STTR) / Small Business Innovation Research (SBIR) applications and financial assistance awards are exempt from Department of [Energy \(DOE\)](#) and Public Health Service (PHS) disclosure requirements and are not governed by this policy.

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E. POLICY STATEMENT

Conflicts of interest in research may arise in situations where any Investigator’s personal, financial, or other interests could affect, or appear to affect, the conduct or reporting of their research activities. Having a conflict of interest does not imply improper conduct of research; rather, conflicts of interest must be identified and managed, reduced, or eliminated to not threaten the integrity of scientific investigations and the public’s trust in academic research.

Conflicts of commitment in research may arise in situations where an Investigator is allocated time to an outside activity that conflicts with their official university duties or conflicts with the terms of their research grants and contracts. A conflict may occur even when the investigator does not receive financial or material compensation.

Disclosure by Investigators of financial, personal, or professional relationships that raise a potential COI/COC or its perception is at the heart of the University’s COI/COC policy and is a prerequisite for determining whether a conflict, once recognized, can be managed or reduced or, in some cases, eliminated.

The Vice President for Research has final authority over this policy. Consistent with this responsibility, the Vice President for Research has designated primary authority to the Assistant Vice President for Research Compliance to serve as the University’s designated Institutional Official responsible for implementation and ensuring compliance with this policy and all applicable COI/COC laws, regulations, and external policies.

Oversight and enforcement of this policy is the responsibility of the University’s Office of Research, although the academic unit where the research is conducted, and if not the same, the unit where the Investigator has primary appointment, as made aware of and consulted on any enforcement actions or sanctions. The immediate supervisor of the Investigator services in both a supporting and advisory role to the Institutional Official or designee and the COIC. The supervisors of the Investigator is expected to be cognizant of the activities taking place in the unit and monitor the research as to potential and actual COI and COCs.

F. PROCEDURES

GENERAL RESEARCH CONFLICTS OF INTEREST AND COMMITMENT POLICY AND MANAGEMENT

The Research Conflict of Interests Committee (COIC) is responsible for the oversight and management of actual or potential research conflicts of interest and commitment on behalf of the University. Members of the COIC and the chair are appointed by the Provost. Membership consists of a broad spectrum of University faculty, staff members, and students involved in a cross-section of research disciplines, including two members proposed by the Faculty Senate, and administrators responsible for procurement. The COIC also includes representation from the University Office of Research, and the non-University community. Representatives from the ODU Research Foundation and the Office of University Counsel serve as *ex officio*, non-voting members. Voting membership of the Committee shall not exceed 15, and a quorum shall consist of 50% of the total voting membership. The COIC reports through its appointed chair to the Provost and Vice President for Research within 45 days of receiving a request to review a potential COI, COC, SFI, or Management Proposal.

1. Responsibilities of Investigators

Investigators on research projects are required to report to the Office of Research financial interests, outside professional activities, and any other interests or activities, as requested, including foreign engagements that could affect or appear to affect their research, including their Significant Financial Interests (SFI) that reasonably appear to be related to their professional expertise and Institutional Responsibilities. Investigators must make all disclosures as required by this policy.

Conflict of Interest (COI) and Conflict of Commitment (COC) reporting for research is completed annually and at various transactional points, as outlined below.

- a. Annual Reporting: Investigators must submit a COI/COC Disclosure annually during an announced open filing window. An annual disclosure must be submitted even if the individual has no outside interest or there have been no changes to the prior disclosure.
- b. Transactional Reporting: In addition to the annual COI/COC reporting requirement, Investigators must also comply with transactional COI/CO reporting requirements throughout the reporting year, and in accordance with the University's reporting procedure and time frames. Transactional COI/COC reporting includes submitting a COI/COC Disclosure or certifying the accuracy of an existing COI/COC Disclosure when:
 - i. Participating as an investigator on a new sponsored research proposal submission;
 - ii. Being added as a new Investigator to a n ongoing sponsored research project; and
 - iii. Within thirty days of discovering or requiring (e.g., through purchase, marriage, or inheritance) a new SFI.
- c. Investigators must complete the Financial Conflict of Interest training available online [as directed](#) from the Office of Research prior to engaging in sponsored research. Investigators must be re-trained every four years and whenever there is a substantive change to this policy. The Office of Research must also [direct the](#) re-training any Investigator who has been found to be non-compliant with National Science

Foundation (NSF), PHS COI regulations or the DOE COI Policy, and/or University's COI/COC Research Policy before engaging or continuing sponsored research.

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In addition to annual and Transactional Reporting, the Office of Research may, within its discretion, request that investigators submit or update their COI/COC Disclosures from time-to-time.

d. Report Sponsored or Reimbursed Travel

Investigators participating in PHS or DOE-funded Research are required to report on their annual COI Disclosure the occurrence of any Reportable Travel.

Any reimbursed or sponsored travel must be disclosed by Investigators. Exceptions to this reporting requirement are set forth in PHS COI regulation and the DOE COI Policy, and include when travel is reimbursed or sponsored by (1) a Federal, State, or local government agency; (2) an institution of higher education as defined at 20 U.S.C. 1001(a); (3) an academic teaching hospital; (4) a medical center, or (5) a research institution that is affiliated with an institution of higher education.

Investigators must provide informational on the purpose of the trip, the identity of the sponsor/organizer, the destination, amount funded, duration, and relatedness to their Institutional Responsibilities.

2. Responsibilities of the Office of Research and Old Dominion University Research Foundation

a. Review

The Institutional Official or designee within the Office of Research , as appropriate, shall:

Maintain and monitor an online COI/COC Disclosure system in collaboration with ODU Research Foundation. Additionally, the ODU Research Foundation's Incident Reporting Hotline allows confidential reporting on matters of concern at rfhotline@odu.edu.

- i. Maintain confidentiality for all COI/COC disclosures submitted by individuals involved in research activities, except on a need-to-know basis to provide institutional or internal oversight as authorized by this policy and to comply with requests from Federal, State, and Foundation funding agencies as required under terms of a grant, contract, or cooperative agreement, University policy, or law;
- ii. Review Investigator COI/COC disclosures and their research activity to reasonably determine whether an investigator has an actual or potential COI/COC and request and document additional details, including precise dollar figures or percentages for ownership interests or remuneration, if such details appear necessary to determine whether there is an impermissible Conflict of Interests;
- iii. If review indicates an actual or potential COI/COC or SFI exists, the disclosure is forwarded to the COIC for review, and if it is determined that the COI/COC or SFI requires management, they may take the following actions (among other options):

- a) Require specific type of administrative oversight or management condition/plan; or
 - b) Recommend the withdrawal of the proposal or suspension of the technology transfer agreement.
 - iv. Identify additional individuals to advise on complex or novel issues of actual, potential, or perceived research conflicts of interest, such as representatives from the academic units, ODU Research Foundation, Human Resources, Export Control, the Graduate School, or other relevant units. If there is a possible conflict of interest, the review will be referred to the individual's supervisor and appropriate administrative unit, as applicable;
 - v. Notify the Investigator and their academic unit director (e.g., Chair, Dean) that an actual or potential COI/COC or SFI exists and that a Management Plan is required.
- b. COI/COC Management

If it is determined that a conflict exists, a final written agreement to manage the conflict is established by the COIC in collaboration with the Investigator and the supervisor of the Investigator. The Management Plan is reviewed and signed by the Investigator, their supervisor or unit head and dean, and the Institutional Official or designee. Supervisors oversee the implementation of a Management Plan for Investigators who report to them, and Investigators are responsible for managing their conflict(s) in accordance with the terms of the Management Plan.

Examples of appropriate actions to resolve COI/COCs include:

- i. Public disclosure of SFIs in abstracts, publications, presentations, press releases, and applications or proposals for research funding;
- ii. Monitoring of research by independent reviewers or an oversight committee;
- iii. Selection of a non-conflicted PI;
- iv. Disqualification from participation in all or a portion of the funded research;
- v. Divestiture of SFIs;
- vi. Severance of relationships that create actual or potential conflicts;
- vii. Prospective discussions with the academic unit director of the time involved in any planned outside activities that may have the potential to conflict with, or appear to conflict with, commitments to the University;
- viii. Refusal by the University to enter into a research agreement if a COI/COC cannot be managed effectively;
- ix. Participation of one or more non-conflicted persons in the evaluation of research data and/or preparation of manuscripts;
- x. Partition a graduate student's work when that student is funded by a sponsor where the student's advisor has an economic interest

Final COI/COC Management Plans will be uploaded into the ODU Research Portal by the COIC. The Management Plan must be approved prior to the start or continuation of any research expenditures. Further:

The Institutional Official or designee will notify the ODU Research Foundation that COI/COCs involving Federal agency sponsors are being managed and will inform the

Research Foundation of any administrative mitigation strategies requiring additional support.

If the COI/COC and SFI cannot be managed, the Institutional Official or designee can recommend and initiate actions leading to sanctions for non-compliance with this policy or the approved management plan.

c. Annual Data Summary Report

- i. The Office of Research, in partnership with the ODU Research Foundation, will compile annual statistical reports that will summarize the number of COI/COC disclosures, including the number of Investigators whose conflicts were resolved or were not managed, reduced, or eliminated.
- ii. The Institutional Officer or designee will provide each dean of an academic college and other equivalent administrators with research investigators a COI/COC Annual Data Summary Report for the entire college.

d. Disclosure of Outside Income

The University requires the reporting of an SFI. Some units, however, may require disclosure of the actual dollar amount.

e. Reporting

- i. When applicable, the Institutional Official or designee will notify the ODU Research Foundation of any financial conflicts of interest or non-compliance that the University is unable to satisfactorily manage, reduce, or eliminate. The ODU Research Foundation will then notify the sponsor in accordance with sponsor regulations and thereafter as required by the funding agency.

If an Investigator fails to disclose a SFI in a timely manner or if for any reason the University fails to review a SFI, the University must, within 60 days, determine whether the SFI is related to the research, and whether it rises to the level of a financial COI. If found to be a financial COI, a Management Plan, even if interim, must be implemented. The Institutional Official or designee will notify the ODU Research Foundation via an interoffice memo of situation and that a financial COI report must be provided to the sponsoring PHS or DOE agency at this time.

- ii. In addition, a retrospective review must be completed within 120 days of the COIC's determination that a financial COI exists and that it was not identified or managed in a timely manner (hereafter "retrospective review criteria") to determine whether the research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research.

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iii. A financial COI could be identified or managed in an untimely manner in any of the following circumstances:

- a) An Investigator has failed to disclose a SFI that is determined by the COIC to constitute a financial COI;
- b) The University failed to review or manage a financial COI (e.g., not timely reported by a subrecipient or timely reviewed by the University); or
- c) An Investigator has failed to comply with a Management Plan.

iv. If bias is identified, a mitigation report must be developed that outlines a plan of action to eliminate or mitigate the effect of the bias. The Institutional Official or designee will notify the ODU Research Foundation of situation, ~~the results of that determination,~~ and the mitigation report must be submitted to PHS ~~and DOE~~ awarding agency. See Section F.5. for more information on Retrospective Review.

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f. Public Accessibility

Under PHS COI regulations and the DOE COI policy, the University is required to make available to the public, upon request, specific information regarding a financial COI identified for Investigators on PHS- or DOE-Funded Research. The University shall provide specific information relative to such public requests within five business days of the request and to the extent required by 42 CFR Part 50.605(a)(5).

3. Responsibilities of the Academic Affairs and Supervisors

- a. Both the Provost and the Vice President for Research receive the Management Plans that address reported research conflicts of interest and the Annual Data Summary Reports.
- b. The Institutional Official or designee has the discretionary authority to review plans to prevent or manage COI/COCs and to approve sanctions for non-compliance.
- c. Supervisors oversee the implementation of a Management Plan for Investigators who report to them, and Investigators are responsible for managing their conflict(s) in accordance with the terms of the Management Plan.

4. Enforcement and Non-Compliance

- a. The Institutional Official or designee is responsible for ensuring implementation of this policy and may suspend all relevant activities until the COI/COC and/or SFI is resolved, or other action deemed appropriate by the Institutional Official or designee is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to institutional policy.

b. Sanctions

Sanctions may be applied for non-compliance with the requirements of this policy or with management plans in the same way as for non-compliance with any other University policy, in accordance with the Policy 1450 on Faculty Sanctions, including a letter of reprimand, special monitoring of future work, removal from the particular project, probation, suspension, salary reduction, or initiation of steps leading to possible reduction in rank or termination of employment.

5. Retrospective Review

In cases of non-compliance, a retrospective review is required for later determined financial conflicts of interest. The review is not required to be submitted to the PHS or DOE-awarding agency unless bias is found.

Whenever a financial COI in PHS or DOE-funded research is not identified or managed in a timely manner, a retrospective review and, if appropriate, a mitigation report will be prepared and submitted to the extent required by 42 CFR Part 50.605(a)(3).

A retrospective review is not required if a COI is timely identified and managed. A COI is considered to have been timely identified and managed if the CMP is (1) implemented before the expenditure of project funds, or (2) is established within 60 days of an Investigator's timely disclosure of an SFI. Since University policy requires an Investigator to report an SFI within 30 days of discovering or acquiring the interest (e.g. through purchase, marriage, inheritance), the COI is timely managed if a management plan is implemented, at least on an interim basis, within 90 days of its discovery or acquisition by the Investigator during the course of an on-going project.

6. Subrecipient Compliance

If the University carries out the research through use of a Subrecipient, the University must require the Subrecipient to comply with either this policy or the Subrecipient's financial Conflict of Interests policy. If the latter, then the Subrecipient must certify that its policy complies with the PHS regulations. The Subrecipient agreement must specify deadlines for the Subrecipient to submit all SFI disclosures or reports of Conflict of Interests to the University so that the University can meet its own reporting obligations.

G. RECORDS RETENTION

Records of financial disclosures and any resulting action will be maintained by the University/ODU Research Foundation for at least three years from the date of submission of the final expenditures report or otherwise as required by 45 CFR 74.53 and 50.604.

H. INSTITUTIONAL OFFICER DESIGNEE

Assistant Vice President for Research Compliance

I. RELATED INFORMATION

[Board of Visitors Policy 1450 – Faculty Sanctions Policy, Procedures and Timeline for Responding to Allegations of Misconduct in Scientific Research and Scholarly Activity](#)
[Policy on Financial Interests in Sponsored Programs](#)
[Institutional Conflict of Interest - Future](#)