OLD DOMINION UNIVERSITY University Policy

Policy #5201 INDIVIDUAL RESEARCH CONFLICT OF INTEREST AND COMMITMENT <u>Investigator</u> – Includes the Principal Investigator (PI), Co-Principal Investigator (Co-PI), Co-Investigator (Co-I), and any other key personnel, regardless of title or position, identified on the proposed project 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.

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 Counsel, 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 identified by the University.

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 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 <691.5eC /P <a3Tj&).5 (g).5 (BDC g).5 ()

- 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 nonpromotional engagements sponsored by governmental or nonprofit entities;
- Income from service on advisory committees or review panels for governmental or nonprofit entities;
- Royalties, milestone payments, licensing fees, or other remuneration paid by the

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.

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Investigators must provide information on the purpose of the trip, the identity of the sponsor/organizer, the destination, amount funded, duration, and relatedness to their Institutional Responsibilities. adl0.304 0 Td7]3 -3-3 ()11 [atat1.s

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;

vi. 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 Conflict 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 Conflict 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 via the Institutional Official. The Conflict 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, and research that proceeds without the imposition of conditions or restrictions when a conflict of interest exists. The ODU Research Foundation will then notify the sponsor in accordance with sponsor regulations and thereafter as required by the funding agency.

If it is identified that 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, implement a Conflict Management Plan, even if interim, if it is determined that the SFI is

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. <u>Subrecipient Compliance</u>

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 specific 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 42 CFR 50.604., and 42 CFR 50.605.

H. RESPONSIBLE OFFICER

Assistant Vice President for Research Compliance

I. RELATED INFORMATION

Board of Visitors Policy 1450 – Faculty Sanctions
University Policy 1001 – Development, Approval and Maintenance of University Policy
Policy, Procedures and Timeline for Responding to Allegations of Misconduct in Scientific
Research and Scholarly Activity
Policy on Financial Interests in Sponsored Programs

Policy Formulation Committee (PFC) & Res	sponsible Officer Approval to Proceed:		
/s/ Gregory A. Cutter	April 16, 2024		
Responsible Officer	Date		
Policy Review Committee (PRC) Approval to	o Proceed:		
/s/ Donna W. Meeks	January 23, 2024		
Chair, Policy Review Committee (PRC)	Date		
Executive Policy Review Committee (EPRC)	Approval to Proceed:		
/s/ Kenneth Fridley	April 22, 2024		
Responsible Oversight Executive	Date		
University Counsel Approval to Proceed:			
/s/ Allen T. Wilson	April 24, 2024		
University Counsel	Date		
Presidential Approval:			
/s/ Brian O. Hemphill, Ph.D.	April 26, 2024		
President	Date		
Policy Revision Dates: August 2, 2012;	October 1, 2020; April 26, 2024		
Scheduled Review Date: April 26, 2029			