

OLD DOMINION UNIVERSITY
University Policies and Procedures

5331 - FINANCIAL INTERESTS IN SPONSORED PROGRAMS

1. Summary

In order to protect the integrity/objectivity of certain federally sponsored programs, all Old Dominion University investigators who have financial interests that in some manner might influence or appear to influence the conduct of those projects must: a) inform the Office of Research of this fact at the time of proposal submission, and b) prior to acceptance of the awards, develop acceptable strategies to manage those conflicts.

2. Purpose

This policy and procedures to implement it are designed to minimize the probability that the objectivity of activities at this institution sponsored by certain federal agencies will be adversely affected by personal financial interests of individuals involved in the design, conduct or reporting of such projects.

Financial interests may potentially conflict with research interests in diverse ways. For example, a financial interest might be increased by: a) the demonstration that a material has potential commercial applications, b) the demonstration that a material owned by a financial competitor does not have certain properties; or c) a failure to investigate appropriately the properties of a material owned by a financial competitor. If an investigator has a financial interest, there is a potential for the design, conduct, or reporting of research to be biased in favor of, or against, a particular research outcome.

3. Applicability

This policy applies to each person at Old Dominion University who is responsible for the design, conduct or reporting of research or educational projects that are proposed for, or awarded, funding by a federal agency requiring a process to manage relevant significant financial interests, and will be followed in relation to each proposal to and award from these agencies.

4. Definitions

“Significant financial interest” means anything of monetary value, including but not limited to salary or other payment for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include salary, royalties or other remuneration from Old Dominion University; income from seminars,

lectures or teaching engagements sponsored by public or non-profit entities; income from services on advisory committees or review panels for public or non-profit entities; or financial interests in business enterprises or entities if the value of such interests do not exceed \$5,000 in a calendar year, or represent more than a 5% ownership of any one enterprise or entity when aggregated for the investigator and the investigator's spouse and dependent children.

“Relevant Significant Interest” means a significant financial interest that would reasonably appear to be directly and significantly affected by the sponsored program which is being considered.

5. Procedures

Promulgating the University Policy on Financial Interests in Sponsored Programs

Old Dominion University will make this policy readily available to investigators¹ and potential investigators in print copy or as an electronic file. Print copies of this policy will be available to investigators and potential investigators from the Office of Research where they may also receive application forms to prepare proposals to be submitted to most federal agencies requiring the documentation referred to in this policy. The internal approval form for sponsored program applications (the Blue Sheet) will include a statement that the principal investigator has read and is familiar with the Old Dominion University Policy on Financial Interests in Sponsored Programs, and will include a query on any relevant significant financial interests that might compromise the objectivity of the research.

It is the responsibility of the principal investigator² to identify other individuals involved in the design, conduct or reporting of the research to be funded by a federal agency requiring the documentation referred to in this policy. Each investigator so identified must attest to the absence of a relevant significant financial interest or disclose the existence of any relevant significant financial interest. Each investigator who discloses a significant financial interest will notify the principal investigator that a disclosure has been made.

Disclosure Process

The principal investigator of each sponsored program prepared for submission by Old Dominion University to a federal agency requiring the documentation referred to in this policy shall prepare or have prepared by each investigator participating in the project a statement disclosing the absence or presence of any relevant significant financial interest. The documentation shall be submitted with the proposal while it is undergoing internal review prior to submittal by Old Dominion University or the Old Dominion University Research Foundation to the sponsoring agency. The statement reports the existence of each significant financial interest:

- a) that would reasonably appear to be directly and significantly affected by the research

or educational activities funded or proposed for funding; and/or

- b) in entities whose financial interests would reasonably appear to be directly and significantly affected by such activities.

If a significant financial interest that might compromise the objectivity of the project is present for any investigator involved with the proposal, a disclosure, consisting of a description of the applicable significant financial interest(s) and the identity of entities affected, shall be submitted to the Office of Research with the proposal. The disclosure made by an investigator may be sealed for privacy. Institutional officials shall rely upon these disclosures to identify all applicable significant financial interests of investigators. During the period that the proposal is under review, and throughout the life of the project if an award is made, each investigator participating in a project subject to this policy shall submit an updated disclosure of relevant significant financial interests annually, and also whenever there is a change in relevant significant financial interests.

The Office of Research will maintain the disclosures and records pertaining to each funded award for at least three years beyond the termination of completion of the award, or until resolution of any action by a federal agency involving the records, whichever is longer. Documents pertaining to disclosure of a significant financial interest shall be treated as privileged communications that are a part of the individual's personnel file so long as they are under university control. Disclosure documents may be subject to Virginia Freedom of Information statutes; each such request will have to be decided on a case-by-case basis.

Disclosures will be reviewed by the vice president for research prior to submission of the proposal to the potential federal sponsor. The vice president will, upon request, work with investigators to assist in their full identification of relevant significant financial interests. If there is a declared relevant significant financial interest, the proposal and the disclosure must subsequently be referred to a Committee on Financial Interests in Sponsored Programs for approval of a conflict management strategy.

Managing a Relevant Significant Financial Interest

If a disclosure of a relevant significant financial interest is made, a strategy for managing, reducing, or eliminating the actual or potential conflicts that the significant financial interest causes must be adopted prior to acceptance of the award by Old Dominion University. The investigator making the disclosure shall submit a proposed strategy in a timely manner to the Committee on Financial Interests in Sponsored Programs through the Office of Research. The Committee on Financial Interests in Sponsored Programs has the authority to approve or not approve a management strategy to ensure objectivity in the project. The principal investigator and any other investigator with a relevant significant financial interest shall record in writing their mutual agreement on a management strategy approved by the Committee on Financial Interests in Sponsored Programs and deliver it to the Office of Research prior to acceptance by Old Dominion University of the affected award. The agreed

management strategy will become part of the sponsored program record maintained by Old Dominion University.

Strategies for management of an actual or potential conflict of financial interest might include: (a) public disclosure and notification of affected entities of a significant financial interest; (b) monitoring of research by independent reviewers; (c) modification of the research plan; (d) disqualification of an investigator or investigators from participation in all or a portion of the research funded by a federal agency; (e) divestiture of significant financial interests; (f) severance of relationships that create actual or potential conflicts; or (g) informing the awarding agency that the proposal has been withdrawn by Old Dominion University.

It is the intent of this policy that relevant significant financial interests be disclosed, reviewed, and managed within the normal time frame for application, review, and award by federal research sponsors. Investigators are encouraged to disclose relevant significant financial interest and propose management plans to the Committee on Financial Interests in Sponsored Programs in advance of application, and it is in the best interest of investigators to do so. For example, management of a financial conflict might require review of experimental data by independent reviewers. Such a review might be incorporated into the research plan and budget of a proposal. Should such a review be necessary, but not incorporated into the proposal, an investigator might need to withdraw an application in order to incorporate such a review in a revised proposal to be submitted subsequently. This policy does not anticipate that Old Dominion University will provide significant resources to assure objectivity in research conducted by investigators with relevant significant financial interests.

If a management strategy satisfactory to the principal investigator and all other involved investigators is not approved by the Committee on Financial Interests in Sponsored Programs, the principal investigator or other involved investigators may appeal the matter to the vice president for research for resolution.

6. Committees

The Committee on Financial Interests in Sponsored Programs will consist of three members of the teaching and research faculty recommended by the vice president for research, and appointed by the provost and vice president for academic affairs. These faculty members will be selected from disciplines in which research is sponsored by federal agencies, and will serve staggered terms for a period of three years. The research administrator from the Office of Research will serve as non-voting staff to the committee, and will convene the committee as needed.

7. Implementation

This policy shall come into effect June 28, 1995, and remain in effect until modified or

rescinded. It is anticipated that this policy and procedures will be reviewed after they have been in force for three years, and that the policy and procedures will be expanded to encompass other scholarly activities in which objectivity may be compromised by a financial interest. It may also be modified in response to modifications of the applicable federal regulations and guidelines.

8. Enforcement

Compliance with this policy shall be considered an acceptable practice in proposing, carrying out or reporting results from research and scholarly activity. Failure of investigators to comply with this policy, including, but not limited to, completely and accurately disclosing relevant significant financial interests and/or complying with provisions of any approved strategy for managing relevant significant financial interests shall be deemed a violation of Old Dominion University's Policy and Procedures for Responding to Allegations of Misconduct in Scientific Research and Scholarly Activity and shall be treated in accordance with that document.

9. Other Regulations

The Virginia State and Local Government Conflict of Interest Act (Code of Virginia, Section 2.1-639.1-.24) defines several prohibited conflicts of interest for state employees. One, which arises when an employee of Old Dominion University or a member of the immediate family has a "personal interest" (as defined in the Act) in a firm or business which contracts with Old Dominion University for certain categories of research and development contracts, may be exempted from the Act provided that the potential conflict of interest is appropriately disclosed and the contact is approved in writing by the vice president for research. Old Dominion University has promulgated a Conflict of Interest Policy that supplements the statutes of the Commonwealth of Virginia. The Conflict of Interest Policy also requires disclosure of a potential conflict of interest to the appropriate dean and specifies penalties for willful violation of the policy. This Policy on Financial Interests in Sponsored Programs is unrelated to, and in no way supersedes, the Virginia State and Local Government Conflict of Interest Act or the Conflict of Interest Policy.

10. Certifications

The vice president for research shall make such certifications to federal agencies as are required by regulation in regard to this policy and its implementation.

Each investigator is expected to read and understand this Policy on Financial Interests in Sponsored Programs, to make all disclosures required by it, and to comply with any conditions or restrictions imposed by Old Dominion University to manage, reduce or eliminate actual or potential conflicts of interest. Each investigator named in a proposal will complete and submit to the principal investigator a memorandum affirming the presence or absence of a relevant significant financial interest.

Each principal investigator should be aware that federal agency proposal forms may require the principal investigator to execute a certification, which is subject to criminal penalties for falsification, in regard to matters referred to in this policy.

Responsibility: Provost and Vice President for Academic Affairs

Authorization: Roseann Runte, President

Date: May 15, 1995

1. "Investigator" means the principal investigator and any other person at Old Dominion University who is responsible for the design, conduct or reporting of research funded, or proposed for such funding, by a federal agency having requirements for management of relevant significant financial interests. In the context of relevant significant financial interests which are reported, "investigator" includes the investigator's spouse and dependent children.
2. "Principal Investigator," or alternatively, "Program Director," mean the individual at Old Dominion University responsible for the conduct of the sponsored program. See the policy on Qualifications for Service as a Principal Investigator.