

**DRAFT**

**UNIVERSITY OF VIRGINIA FINANCIAL CONFLICT OF INTEREST  
POLICY**

For Office Use Only:

<b>DATE:</b> MM/DD/YY	<b>Policy ID:</b> TBD	<b>Status:</b> Active
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**Contact Office:** VICE PRESIDENT FOR RESEARCH and GRADUATE STUDIES

**Oversight Executive:**

**Applies to:** Research Investigators

**Reason for Policy:** The University of Virginia supports research programs and is a public steward of funds supporting such programs. The University is committed to conducting the highest quality research. This commitment in turn requires an unwavering commitment to research objectivity, a fundamental value in scientific research. Fulfilling this commitment requires that appropriate safeguards be in place to prevent researchers from using their positions for purposes that are, or appear to be, influenced by private gain for themselves or their family. The mere fact that an investigator has a conflict of interest is not a violation of this policy, nor should it alone entail any reprobation of the investigator. The purpose of this policy is to inform investigators about their obligations concerning financial interests that could influence their research, and to ensure a reasonable expectation that the design, conduct and reporting of research will be unbiased by any conflicting financial interest of the investigator.

This policy is intended to provide uniform University requirements concerning financial conflicts of interest related to investigators. Any policy promulgated by any Department, Center, or other administrative entity within the University concerning research and conflicts of interest that conflicts with this policy is superseded by this policy. This policy does not, however, preclude individual units from adopting additional, more stringent, requirements that may be necessitated due to the conditions or circumstances specific or unique to a unit's mission. In such instance, it is the responsibility of the Department Chair, or equivalent unit administrator, to notify the University of Virginia Conflicts of Interest Committee of such additional measures it has adopted.

This policy is intended to incorporate by reference and supplement the requirements embodied in the federal regulation on Objectivity in Research, Virginia state laws on financial conflicts of interest, and any other relevant laws. Investigators have a duty to review carefully these federal regulations and state laws to assure that they have met state and federal requirements with regard to financial disclosures. State laws on financial conflicts and disclosure requirements may be found in Section 2.2-3100 et seq. of the Code of Virginia. See <http://legis.state.va.us/Laws/Code of Va.htm>. Federal Requirements are included in 42 CFR Part 50, Subpart F, and 45 CFR Part 94. For more detailed information and links to these regulations and federal policies on financial conflicts of interest related to human subject research, consult the NIH Office of Extramural Research at <http://grants2.nih.gov/grants/policy/coi> and (<http://grants.nih.gov/grants/policy/coifaq.htm>)

**Definitions:**

**Dependent** means a son, daughter, father, mother, brother, sister or other person, whether or not related by blood or marriage, if such person receives from the investigator, or provides to the investigator more than one-half of the dependent's financial support.

**Investigator** means the principal investigator, co-investigator, and any other key personnel, meaning individuals who are essential to the conduct of the research, who are not easily replaced, and who are responsible for or participate in the design, conduct, or reporting of research or proposed research for such funding.

**Immediate Family** means: (i) a spouse; (ii) children; and, (iii) 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.

**Public Health Service Act** or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

**Research** means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.

**Significant financial interest** means anything of aggregate monetary value of more than \$10,000<sup>1</sup> in annual income (or expected income) or more than 3% ownership interest. This includes, but is not limited to: salary or other payments for services (e.g., consulting fees or honoraria); equity interests or any asset valuation (e.g, stocks, stock options or other ownership interests or option for ownership); personal liability incurred or assumed on behalf of a business; ownership interests in a business or in real or personal property; or intellectual property rights or income derived from such rights (e.g., patents and licensing fees, copyrights and royalties); a financial interest in which the value cannot be readily determined; or any other financial interest that the investigator believes may interfere with his or her ability to protect participants.

**Policy Statement:** A conflict of interest exists under this policy when an investigator or member of his or her immediate family has a significant financial interest which is reasonably related to the investigator's research. Investigators must disclose all financial conflicts of interest to the University, which may then take any appropriate steps to manage, reduce, or eliminate the conflict of interest.

The specifics of the financial interests and their relation to the specific proposed research activity may differ considerably, making a single response unlikely. Nor will it be possible to guarantee that research will be possible in any and all cases of financial conflict of interest. In extreme situations, such as the involvement of investigators with significant financial interests in experiments with human participants, there will be a rebuttal presumption that such activities may not proceed.

The University shall maintain a Financial Conflict of Interest Committee, whose purpose is to facilitate uniform institutional guidance and management of financial arrangements related to research that may pose a conflict of interest. It is the responsibility of the committee to judge which financial interests require management.

Further, the Conflict of Interest Committee will develop the procedures for disclosure, review, management and reporting. The procedures will include those necessary for approval of the Board of Visitors or the President (when required).

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<sup>1</sup> Note a \$10,000 interest is defined as that amount derived from one arrangement or the total of smaller amounts resulting from arrangements with the entity.

**Related information:** U.Va. Objectivity in Research Policy at <http://www.virginia.edu/researchandpublicservice/research/researchpol/objectivity.html>;  
Policy XV.A.1 of the U.Va. Financial and Administrative Policies and Procedures on Conflict of Interests.

**Background: Approval Date:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

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[U.Va. Policy Home Page](#)

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