



# Institutional Conflicts of Interest in Research - INTERIM

**Policy Type:** Administrative

**Responsible Office:** Office of the Vice President of Research and Innovation

**Initial Policy Approved:** 06/08/2015

**Initial Policy Approved:** New-Interim

## Policy Statement and Purpose

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Institutional conflicts of interest are of concern when competing financial interests create the potential for inappropriate influence over research activities at Virginia Commonwealth University (VCU). Such influence can emanate from individuals among VCU leadership who hold positions of trust, as well as within the university itself, its entities, and holdings. At VCU, financial interests of Covered Members and University entities, as defined by this policy, will be annually disclosed and updated throughout the year. The financial interests of Covered Members and University entities will be reviewed for institutional conflicts of interests related to research and appropriately addressed. Reporting of financial interests by Covered Members and University entities enables the identification, management, or mitigation of institutional financial conflicts of interest in research that present a significant risk of an actual or perceived lack of objectivity, especially in human subjects research. The Office of the Vice President for Research and Innovation (OVPRI) has the responsibility for overseeing the process for reporting, reviewing, managing and monitoring institutional conflicts of interest in research that may arise from the business relationships of Covered Members with outside entities.

Failure to report or promptly update applicable financial interests and comply with management plans may subject a Covered Member to actions that include: removal from the contract, grant, or cooperative agreement and/or disciplinary action in accordance with applicable University procedure.

Noncompliance with this policy may result in disciplinary action up to and including termination. VCU supports an environment free from retaliation. Retaliation against any individual who brings forth a good faith concern, asks a clarifying question, or participates in an investigation is prohibited.

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## **Who Should Know This Policy**

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All University members are responsible for reading this policy and familiarizing themselves with its contents and provisions.

## **Definitions**

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### **Activities Affecting or Involving Research**

For purposes of this policy, activities affecting or involving research include, but are not limited to, the following:

- administrative influence over the design and conduct of research;
- the use of University resources that have an impact on or result from research activities including decisions involving expenditures, purchasing, investments, equity and technology transfer, and the execution of contracts and grants;
- the licensing of intellectual property that was discovered at or owned by the University;
- development and commercialization of intellectual property under an approved exception from the state’s prohibited contract provision for research, and
- evaluation, promotion, and the assignment of job responsibilities in the supervision of faculty and staff in research.

### **Covered Members**

This Policy covers all personnel who hold certain positions wherein they make decisions for the University that may affect or involve research, especially human subjects research.

Covered Members include but are not limited to:

1. Personnel who hold senior academic or administrative positions within the University, such as the President, Provost, Vice Presidents, Associate and Assistant Vice Presidents, Deans, Associate and Assistant Deans, Department and Division Chairs, Directors, including Institute and Center Directors,
2. Members of research review boards (IRB and IACUC), members of the Researcher and Institutional Conflict of Interests Committees, and other research ethics and compliance committee members, as appropriate,
3. Members identified as having influence or authority over University purchasing and disbursements, and,
4. Members identified as having influence or authority over research-related compliance matters.

Covered Members are identified through their role or title and will specifically receive notification about the annual reporting requirement. Members of VCU Governing Boards and affiliated foundations are not Covered Members according to this policy since they, by virtue of their role, are subject to conflict of interest reporting and management processes established within the Boards they represent.

### **Financial Interests of Covered Members**

Financial Interests of Covered members include anything of monetary value held by a Covered Member or a Covered Member’s immediate family member, including, but not limited to:

- gifts to Covered Members from a business, government, organization or others exceeding \$10,000;
- salary, wages, or payments in excess of \$10,000 from an outside firm or business;
- business interests of Covered Members in excess of \$10,000;
- ownership interests in excess of 3% of the total equity in each outside firm or business;
- license or revenue in excess of \$10,000 from Institutional technology, and
- contracts for institutional consulting services or business partnerships.

Financial Interest does not include salary, reimbursement, or travel payment originating from VCU. Financial interests also do not include grants or contracts processed by the VCU Office of Sponsored Programs.

### **Financial Interests of the University**

Financial interests of the University include:

- Gifts or pledges to the University of \$100,000 or greater from any entity or person, including real estate.
- Payments to the University which exceed \$100,000 (either per transaction or in the aggregate). Payments include royalties from the licensing of intellectual property owned by the University.
- Equity, ownership or financial interests held by the University in where such interests have a) a value in excess of \$50,000 in publicly traded companies, or b) a value of any amount in a non-publicly traded entity.
- Financial Interests of Covered Members responsible for the oversight of research.

### **Gift**

A gift to the University is differentiated from sponsored research projects or grants. Gifts are awards that are given with few or no conditions specified. Gifts may be provided to establish an endowment or to provide direct support for existing programs.

### **Human Subjects Research**

Human subjects research includes all research meeting the definition of 'research' performed with 'human subjects' as defined in the Federal Common Rule (45CFR, Part 46 and 21CFR Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation. In the event that the Common rule definitions of 'human subject' or 'research' are modified through rulemaking, any such revisions shall apply for the purposes of this policy.

### **Institutional Conflict of Interests**

An Institutional Conflict of Interests (ICOI) is a situation in which the Financial Interests of the University or Financial Interests of Covered Members, might affect or reasonably appear to affect institutional Activities Affecting or Involving Research.

### **Institutional Conflicts of Interest Committee (ICOIC)**

The Institutional Conflict of Interests Committee is a standing Committee of the University, composed of faculty, administrative personnel, and ex-officio members, as needed, and convened, with an appointed Chair, under the authority of the Vice President for Research and Innovation ("VPRI"). ICOIC membership will include individuals who are basic scientists and clinical faculty. The charge of the ICOIC is to review reports involving potential Institutional Conflicts of Interest in research, determine whether an Institutional Conflict of Interest exists, and recommend a plan for managing, reducing, or eliminating the conflict to the VPRI. ICOIC members will recuse themselves from review of cases in which they have a financial interest. In addition, ICOIC members must adhere to signed confidentiality agreements.

The ICOIC works in collaboration with the Researcher Conflict of Interests Committee and the Audit and Compliance Services, which implements the Statement of Economic Interests reporting process.

## **Contacts**

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The Office of the Vice President for Research and Innovation officially interprets this policy. The Office of the Vice President for Research and Innovation is responsible for obtaining approval for any revisions as required by the policy Creating and Maintaining Policies and Procedures through the appropriate governance structures. Compliance with this policy is the responsibility of the Vice President for Research and Innovation or designee. Please direct policy questions to the Director of the Office of Research Integrity and Ethics.

## **Policy Specifics and Procedures**

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Described below are the procedures for reporting, review, response, and monitoring of Institutional Conflicts of Interests in Research. University members are responsible for complying with all applicable laws and university policies that address ethical conduct and other types of conflicts of interest

### **1. Identifying Financial Interests:**

University departments will provide reports of financial interests to the Office of Research Integrity and Ethics as requested when the financial interests constitute Financial Interests of Covered Members or Financial Interests of the University as defined in this policy:

- **Audit and Compliance Services**  
Audit and Compliance Services will share, on a regular basis, reported Financial Interests of Covered Members. Reporting of financial interests by Covered Members occurs at least annually according to procedures and processes required by VCU. Covered Members must report changes in financial interests within 30 days of their occurrence.
- **VCU Innovation Gateway**  
VCU Innovation Gateway will report licensing of University-owned and licensed intellectual property.
- The Office of Development and Alumni Relations will report Gifts to the University.

### **2. Review of Reported Financial Interests:**

The Office of Research Integrity and Ethics will evaluate the reports submitted by university departments, and report potential Institutional Conflicts of Interest to the ICOIC for review.

- **Review Considerations for Identifying ICOI**  
Reviews will consider whether the financial or fiduciary interests reported in accordance with this policy may affect, or have the potential to appear to affect, any of the following:
  - safety of human research subjects;
  - welfare of animal subjects;
  - integrity of research;
  - appropriate allocation of research resources;
  - objectivity in business and contracting decisions for research purposes.

### **3. Response recommendations regarding identified Institutional Conflicts of Interest:**

The ICOI review of a specific case may result in one of three types of recommendations:

**No ICOI:**

Cases referred to the ICOIC may conclude with a finding of no actual, potential, or perceived ICOI.

**Manageable ICOI:**

For identified conflicts considered by the ICOIC to be manageable, it will recommend a management plan. Possible management plan components may include, but are not limited to:

- 1) effective recusal from decision-making regarding the proposed arrangement by the financially interested Covered Member;
- 2) reduction in the magnitude of the financial interest held by the Covered Member and/or specified University Foundation (generally to below the thresholds outlined above);
- 3) disclosure of the financial interest in relevant publications, presentations, human subject consent forms, clinical procedure or other consent forms, educational material, etc.; and,
- 4) oversight by an individual or committee who do not hold financial or non-financial interests related to the project.

**Unmanageable ICOI:**

In cases determined to involve an unmanageable ICOI, the ICOI committee will require elimination of conflicting financial interests in order to initiate the proposed research activity. The ICOI committee and the Institution should give precedence to activities that carry out Institutional missions over conflicting financial interests, to the extent that research integrity remains protected.

### **4. Notification of Manageable and Unmanageable Institutional Conflicts of Interest:**

The ICOIC will communicate its decision and management plan, as relevant, to the following, depending on the nature of the financial interest:

- the Covered Member whose interest was at issue,
- the Office of the Vice President of Research and Innovation,
- the Dean of the School for the Covered Member whose interest was at issue. Should the Dean have the ICOI, the next higher level of supervision receives the management plan,
- the Vice President for Development if the institutional conflict is related to receipt of a gift,
- the President of VCU,
- the senior staff member responsible for managing the University entity's financial interest,

- the Office of Sponsored Programs (OSP) which shall ensure that the sponsor is notified of the institutional conflict of interests and its management plan, as applicable,
- the appropriate research review unit.

For institutional conflicts of interest deemed to be unmanageable, the ICOIC will be in communication with affected individuals and/or entities.

## **5. Monitoring the Management of Institutional Conflicts of Interest:**

The ICOIC will appoint one or more non-conflicted persons to monitor the approved management plan, on a pre-arranged basis. Those monitoring will hold a commensurate university position as the conflicted Covered Member. Monitoring results and corrective action plans, if any, must be reported to the respective Dean (or higher) and the ICOIC. For conflicts arising from financial interests in VCU entities, the senior administrator responsible for the conflicted institutional entity will report to the ICOIC on adherence to the management plan on a pre-arranged basis.

## **6. Appealing an ICOI Determination**

A request to appeal an ICOIC determination should be directed to the Vice President for Research and Innovation within 14 days of receiving notice of the ICOI determination.

The VPRI may convene an ad hoc committee to review the appeal and issue a recommendation to the VPRI. The VPRI will render a decision within 10 work days, and the decision of the VPRI will be final.

## **7. Public Reporting of Institutional Financial Interests**

Public reporting of managed ICOI will be congruent with the public reporting of researcher financial conflicts of interest.

## **Forms**

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Electronic reporting systems are associated with this policy and procedure.

## **Related Documents**

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### **Standards**

- [VCU Code of Conduct](#)
- [AAHRPP Standards I-6.A and I.6.B, http://www.aahrpp.org/apply/resources/procedures-and-standards](http://www.aahrpp.org/apply/resources/procedures-and-standards)

### **Policies on Individual Conflicts of Interest (Financial)**

- [Conflict of Interests in Research Policy](#)
- Procedures for Compliance with the Virginia State and Local Government Conflict of Interest Act Prohibited Contracts Exception

**Policies on Individual Conflicts of Commitment (Instruction, Scholarship, and Service)**

- [Misconduct in Research and Scholarly Activities](#)
- [Outside Professional Activity and Employment, Research and Continuing Education Policy](#)
- [Policy for Managing Undue Influence in Research Committees and Groups](#)
- [Responsible Conduct in Research and Scholarship Policy](#)

**Institutional Policies involving Financial Interest**

- [Policy on Corporate-Sponsored Research Agreements](#)

**Revision History** \_\_\_\_\_

None – New Policy

**FAQs** \_\_\_\_\_

There are no FAQs associated with this policy and procedures.