



Institutional Conflicts of Interest in Research

Policy Type: Administrative

Responsible Office: Office of Research Integrity and Ethics, Office of the Vice President of Research and Innovation

Initial Policy Approved: 06/08/2015

Current Revision Approved: 01/17/2019

Policy Statement and Purpose

An institutional conflict of interest (ICOI) in research is a situation in which the financial interests of the university or its covered members might reasonably appear to influence or bias institutional activities involving research. Such influence or bias, or appearance of either, can be exerted by individuals among VCU leadership or emanate through university entities and holdings. An unmanaged ICOI in research may have consequences ranging from public mistrust of the university and its research to risk or harm to participants in human subjects research. This policy requires that financial interests of university entities and covered members are reported and that conflicting interests are evaluated and appropriately resolved or managed.

Noncompliance with this policy may result in disciplinary action up to and including termination. VCU supports an environment free from retaliation. Retaliation against any employee 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

All university members involved in activities affecting or involving research are responsible for knowing this policy and familiarizing themselves with its contents and provisions.

Definitions

Activities affecting or involving research

Activities affecting or involving research include, but are not limited to, the following:

- Administrative influence over resource allocation, procurement, or the design, conduct, or reporting of research
- Having influence or authority over evaluating, promoting, or assigning job responsibilities in the supervision of faculty and staff in research

Activity and Interest Reporting System (AIRS)

The AIRS is a secure Research Administration Management System (RAMS) for the reporting of confidential financial and non-financial interests and third party relationships.

Conflict of Interest (COI) in Research Program

The COI in research program, based in the Office of Research Integrity and Ethics:

- Administers activities related to ICOI (and individual COI) in research
- Reviews reports from university entities and reported interests in the AIRS in order to identify and manage ICOI in research
- Makes expedited ICOI dispositions, refers complex cases to the ICOI Committee (ICOIC) for full review, and implements management plans resulting from expedited or ICOIC review
- Communicates with relevant individuals and/or entities about ICOI management and oversees management plan adherence

Covered members

Covered members hold certain positions wherein they make decisions for the university that may affect or involve research, particularly human subjects research.

Covered members include, but are not limited to, leadership personnel who engage in activities affecting or involving research and hold senior academic or administrative positions within the university (i.e. provosts, vice presidents, deans, department and division chairs, and institute and center directors).

Covered members are identified through their role or title. 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 or foundations 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 from a business, organization, or individual that owns or controls products being studied or tested in research that meet or exceed \$10,000 in the 12 month period preceding ICOI review
- Salary or other payments for services (e.g. consulting fees, honoraria, or remuneration for holding a position in a company) from an outside entity or business that meet or exceed \$10,000 in the 12 month period preceding ICOI review
- Business ownership interests of covered members that meet or exceed \$10,000
- Equity interests (e.g. stocks, stock options, or corporate bonds) that meet or exceed 5% of the total equity in each publicly traded entity or any interest in a non-publicly traded entity (e.g. a start-up company)
- License-related payments, including royalties and milestone payments, from intellectual property owned by the university that meets or exceeds \$10,000 in the 12 month period preceding ICOI review

Financial interests of the university

Financial interests of the university include:

- Gifts to the university from an entity or person that meet or exceed \$100,000 in the 12 month period preceding ICOI review
- License-related payments, including royalties and milestone payments, from licensed intellectual property owned by the university that meet or exceed \$100,000 in the 12 month period preceding ICOI review
- Equity interests held in a non-publicly traded entity, such as a start-up company.
- Purchases or procurements that meet or exceed \$50,000 (either per transaction or in the aggregate) in the 12 month period preceding ICOI review

Financial interests of the university do not include investments. Outside professional asset management firms independent of the university manage the university's investment portfolios. The separation between, and independence of, the university's investment decisions and its activities affecting or involving research minimize the risk of institutional conflict of interest in this area.

Gift

Gifts are donations to the university 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 (45 CFR Part 46) and 21 CFR Part 56, regardless of the source of research funding or whether the research is otherwise subject to federal regulation.

Immediate family

Immediate family means the covered member's spouse and any person who resides in the same household and is a dependent of the covered member.

Institutional Conflict of Interest (ICOI) in Research

An ICOI in research is a situation in which the financial interests of the university or its covered members might reasonably appear to affect institutional activities involving research.

Institutional Conflict of Interest Committee (ICOIC)

The ICOIC is a standing or ad hoc 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). The charge of the ICOIC is to review referred cases involving potential ICOI in research, determine whether an ICOI in research exists, and develop a plan for managing, reducing, or eliminating the conflict. The ICOIC works in collaboration with the Conflict of Interest in Research Committee (COIC) and the COI in research program.

State-prohibited contract exception

Under the Code of Virginia *State and Local Government Conflict of Interests Act*, a VCU employee is prohibited from having an interest in a contract with VCU other than their own employment contract. Exceptions for research and development contracts may be enacted pursuant to meeting the provisions under the Act, in addition to having a finalized management plan.

Contacts

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. Please direct policy questions to the COI in research program in the Office of Research Integrity and Ethics within the Office of the Vice President for Research and Innovation.

Policy Specifics and Procedures

1. Reporting financial interests

Reporting by covered members:

- If the covered member is a researcher, they are to report their own financial interests as well as those held by any member of their immediate family in the AIRS.
- If the covered member is not a researcher and financial interests are not reported in the AIRS, the Integrity and Compliance Office will provide the covered member's annual financial interest disclosure, upon request by the COI in research program, as designated by the Code of Virginia *State and Local Government Conflict of Interests Act*.

Reporting by university entities:

University entities must provide annual reports, at a minimum, to the COI in research program upon request.

- VCU Innovation Gateway - reports license-related payments from university-owned intellectual property and equity interests held by the university that meet or exceed the financial interest threshold
- Office of Development and Alumni Relations - reports gifts to the university that meet or exceed the financial interest threshold
- Office of Procurement Services - reports research-relevant procurements by the university that meet or exceed the financial interest threshold

2. Review of reported financial interests and disposition

The COI in research program will review and analyze reports from university entities and reported interests in the AIRS in order to determine whether the financial interests reasonably appear to affect the safety of human research subjects, welfare of animal research subjects, integrity of the research, appropriate allocation of research resources, and/or objectivity in contracting and purchasing decisions.

The COI in research program is authorized to make expedited dispositions of 'no ICOI' or 'ICOI' or refer cases to the COIC or ICOIC for further review and disposition. The COIC handles referred ICOI reviews that are related to individual researchers and the ICOIC handles referred reviews that are highly complex or involve multiple university entities. The COI in research program will notify relevant parties about a 'no ICOI' disposition, as appropriate.

Committee members will recuse themselves from review of cases in which they have a financial interest or relationship that could appear to bias the member. Committee members are required to adhere to applicable rules of privacy and confidentiality pertaining to ICOI review.

3. Management of ICOI in research

The determination of a manageable ICOI by the COI in research program, COIC, or ICOIC requires a management plan, which will correspondingly be developed by the COI in research program, COIC or ICOIC. Possible management plan components may include, but are not limited to:

- Disclosure of the ICOI in research in relevant publications, presentations, informed consent forms, and press releases, as appropriate
- Disclosure to study personnel, students, trainees, and professional colleagues
- Recusal of the conflicted covered member from decision-making regarding applicable grants, contracts, procurements, or other activities affecting or involving research
- Reduction in the magnitude of the financial interest held by the covered member and/or specified university entity (generally to below the thresholds outlined above)
- Agreement to end the fiduciary relationship with the company sponsoring the research before the research commences and not to hold such an interest for a period of two or

more years following completion of any related research conducted at or under the auspices of the institution

- Internal or external oversight by an individual or committee with no conflicting interests related to the project, which may include referring human subjects research review to an external Institutional Review Board

If a covered member has a personal interest in a research and development contract with VCU, the ICOIC will consider whether an exception to the state-prohibited contract provision under the Code of Virginia is warranted.

In cases determined to involve an unmanageable ICOI, the nature of the conflict will be referred to the VPRI for further consideration. The ICOIC will give precedence to activities that carry out institutional missions over conflicting financial interests to the extent that research integrity remains protected. However, ultimately disallowing the research to be conducted at VCU is a possible outcome.

4. Notification of ICOI in research

The covered member with the conflicting interest or the senior administrator responsible for managing the university entity's conflicting interest will be notified by the COI in research program about the ICOI in research disposition and management plan, will be asked to review the plan and sign agreement to adhere to it. The disposition and management plan will be reported to the following, as appropriate, depending on the nature of the financial interest:

- Department chair and/or dean of the covered member (if either the department chair or dean have the ICOI, the individual in the next higher level of supervision will be notified)
- VPRI
- Office of Sponsored Programs (OSP), which will ensure that the sponsor is notified of the ICOI and its management plan, as applicable
- Applicable research review unit, such as the IRB or IACUC, which may augment, but not diminish, the management plan in the interest of subject protections.
- President of VCU

5. Appealing an ICOI in research determination

A request to appeal an ICOI in research determination should be directed to the VPRI within five business days of receiving notice of the ICOI determination.

The VPRI will call for reconsideration by the COIC, ICOIC, or an ad hoc committee, if deemed appropriate and if additional supporting information has become available since the first review. The VPRI will render a decision within 10 business days. The decision of the VPRI is final and cannot be appealed.

6. Monitoring the management of ICOI in research

As described in the management plan, the covered member or the senior administrator overseeing a university entity with an ICOI is responsible for ensuring that the management plan is followed. An annual update, at a minimum, on the fulfillment of the management plan must be provided to the COI in research program on request. Results of management plan monitoring and corrective action, if any, will be reported to the respective dean (or higher) and the VPRI, as applicable.

7. Reporting of ICOI in research status

The COI in research program prepares an annual summary report, at a minimum, of ICOI analyses and dispositions based on data received. The report is submitted to senior representatives of those entities, the COIC, the ICOIC, and, if relevant, the VPRI or designee, and/or applicable research review units, as appropriate.

Forms

There are no forms associated with this policy and procedures.

Related Documents

1. AAHRPP Standards I-6.A and I.6.B
<http://www.aahrpp.org/apply/resources/procedures-and-standards>
2. VCU Policy: [Conflicts of Interest in Research Policy](#)
3. VCU Policy: [Research Exception for the Virginia Conflict of Interest Act Prohibited Contracts](#)
4. VCU Policy: [Outside Professional Activity and Employment, Research, and Continuing Education](#)
5. VCU Policy: [Corporate Research Agreements](#)
6. VCU Policy: [Relationships with University-Related Foundations](#)
7. VCU Policy: [Investment](#)

Revision History

This policy supersedes the following archived policies:

Approval/Revision Date
06/08/2015

Title
Institutional Conflicts of Interest in Research - INTERIM

FAQ

1. How is institutional conflict of interest in research different than a conflict of interest held by an individual researcher?

An individual researcher may have a conflict of interest that could compromise decision making during the design, conduct, or reporting of the research. Unlike a conflicted individual researcher who has direct contact with the research, an institutional conflict of interest is more difficult to identify. Even though an ICOI involves financial interests of university entities and covered members who are not directly involved in the research, an unmanaged ICOI may nonetheless affect, or reasonably appear to affect, objectivity in the conduct, review, oversight, or reporting of research.