RES-008

Institutional Conflict of Interest in Human Subjects Research

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Contact Office Vice President for Research (Office of the)

Oversight Executive
Vice President for Research

Applies To Academic Division and the Medical Center.

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Reason for Policy

Institutional conflict of interest are of concern when financial interests create the potential for inappropriate influence over research activities at the University of Virginia (UVA). This is particularly important when the research involves human subjects. Such influence might originate from individuals among UVA leadership who hold positions of trust, as well as within the university itself, its entities, and holdings. At UVA, financial interests of covered members and University units, as defined by this policy, will be annually disclosed and updated throughout the year. The financial interests of covered members and University units will be reviewed for institutional conflict of interest related to human subjects research and appropriately addressed.

Reporting of financial interests by covered members and University units enables the identification, management, or mitigation of institutional financial conflict of interest in research that present a significant risk of an actual or perceived lack of objectivity in human subjects research.

The goals of this policy are to set forth a definition of institutional conflict of interest (ICOI), establish an Institutional Conflict of Interest Committee, and identification of roles and responsibilities associated with ICOI.

Definition of Terms

Activities Affecting or Involving Human Subjects Research

Description

These include, but are not limited to, the following:

- Administrative influence over the design, conduct, analysis, or reporting 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.
- Research and development or commercialization of intellectual property under an approved exception pursuant to the Virginia State and Local Government Conflict of Interests Act at VA Code §2.2-3106 (C)(8) for an employee's personal interest in a contract for research and development or commercialization of intellectual property between the University and a business in which the employee has an interest.
- Evaluation, promotion, and the assignment of job responsibilities in the supervision of faculty, trainees, and staff engaged in research.

Covered Members

Description

All personnel who hold certain positions wherein they make decisions for the Academic Division and the Medical Center 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 including, but not limited to: the president, provost, vice presidents, associate and assistant vice presidents, deans, associate and assistant deans, institute and center directors, the chief executive officer of the Medical Center; and
2. Members of research review boards (IRBs, members of the UVA Conflict of Interest Committee, and other research ethics and compliance committee members, as appropriate).

Note: Board Members of University-Associated Organizations are not included as covered members because by virtue of their role, they are subject to conflict of interest reporting and management processes established within the Boards they represent.

Financial Interests of Covered Members

Description

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.
- Salary, wages, or payments from an outside firm or business.
- Ownership interests in an outside firm or business.
- License or revenue from Institutional technology.

Financial interest does not include salary, reimbursement, or travel payment originating from UVA; or grants or contracts processed by the UVA Office of Sponsored Programs. Specific reporting thresholds are identified and may be updated from time to time in the specific financial interests reporting systems used by covered members.

Financial Interests of the University

Description

Includes:

1. Gifts or pledges to the University of $100,000 or greater from any entity or person, including real estate.
2. Royalty payments to the University which exceed $100,000 (either per transaction or in the aggregate) from the licensing of University intellectual property.
3. Equity, ownership, or financial interests held by the University where such interests have: a) a value in excess of $100,000 in publicly traded companies; or b) a value of any amount in a non-publicly traded entity.

Gifts

Description

Pledges, outright contributions received from private sources, or activities supported by an external party (i.e., donor) in exchange for which no goods or services are expected, implied or forthcoming to the donor, and in which no proprietary interests are to be retained by the donor. Gifts are subject to minimal or no restrictions.

Human Subjects Research

Description

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 Interest (ICOI)

Description

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.

Policy Statement

The mission of the University of Virginia is to act in the service of the Commonwealth of Virginia, the nation, and the world through research, teaching, and patient care. Relationships with the commercial sector can support the University’s core mission and should be aligned with the University’s fundamental shared values of honor, integrity, trust, and respect. Relationships between the University, including its institutional officials, and commercial entities should not compromise the University’s core mission and values. Addressing institutional conflict of interest is especially important in the realm of human subjects research to protect human research participants and the integrity of the research.

1. **Institutional Conflict of Interest Committee (ICOIC):**
   The Institutional Conflict of Interest 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 (VPR). ICOIC membership will include faculty, one or more from a clinical department.

   The ICOIC will review reports involving potential institutional conflict of interest in research; determine whether an institutional conflict of interest exists; and recommend to the VPR a plan for managing, reducing, or eliminating the conflict. ICOIC members will recuse themselves from reviewing cases in which they have a financial interest.

   Additionally, ICOIC members must adhere to signed confidentiality agreements. The ICOIC works in collaboration with the Research Conflict of Interest Committee and the University's Human Resources Impact and Decision Support Group which implements the Virginia Statement of Economic Interests reporting process.

2. **Responsibilities:**
   The ***Office of the Vice President for Research (VPR)*** is responsible for:
   - Oversight of the process for reporting, reviewing, managing, and monitoring institutional conflict of interest in research that may arise from the business relationships of covered members and University units with outside entities.
   - Identification of covered members through their role or title and notification to them of the annual reporting requirement.
   - Initiation of revisions to this policy as necessary and obtaining approval for the revisions.
   - Interpretation of this policy.
   - Facilitation of compliance with this policy.

3. **Compliance with Policy:**
   Failure to comply with the requirements of this policy (as determined by the appropriate dean, director, supervisor, or conflict of interest committee) are considered misconduct on the part of a covered member and may be subject to disciplinary action up to and including termination in accordance with relevant University policies.

   Violations include but are not limited to situations in which a covered member:
   - Knows of a situation that places them in a potential or actual conflict of interest but fails to disclose it fully.
   - Discloses a potential or actual conflict of interest but fails to abide fully by the required plan for avoiding or managing the conflict.

   UVA 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.

   Direct questions about this policy to the Office of the Vice President for Research.

Procedures

Described below are the procedures for reporting, review, response, and monitoring of institutional conflict of interest in human subjects research. University members are responsible for complying with all applicable laws and University policies that address ethical conduct and other types of conflict of interest. In particular, University members with individual financial interest must be aware of and comply with the Virginia State and Local Government Conflict of Interests Act and policy, RES-005, Financial Conflicts of Interest for Research Investigators.

1. **Identifying Financial Interests:**
   Financial interest of covered members will be reported via the UVA Financial Interest Reporting System and/or via the Virginia Statement of Economic Interests reporting as coordinated by the UVA HR IMPACT and Decision Support Group. Both systems require reporting on an annual basis. Covered members must report changes in financial interests within 30 days of their occurrence. Data from both systems are available to the Office of the Vice President for Research. Newly hired covered members must report financial interests within 30 days of employment.

   The UVA Licensing & Ventures Group will report (1) licensing of University-owned and licensed intellectual property to the Office of the Vice President for Research and (2) when the University acquires equity as a result of technology licensing or other economic development activities.

   External Relations will report gifts made to the University to the Office of the Vice President for Research.

2. **Review of Reported Financial Interests:**
   The Office of the Vice President for Research will evaluate the reports submitted and report potential institutional conflict 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
     - Integrity of research
     - Appropriate allocation of research resources
     - Objectivity in business and contracting decisions for research purposes
3. **Response Recommendations Regarding Identified Institutional Conflict of Interest:**
   The ICOI review of a specific case may result in one of three types of recommendations:
   a. No ICOI: Cases referred to the ICOIC may conclude with a finding of no actual, potential, or perceived ICOI.
   b. 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 (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.
      4. Oversight by an individual or committee who do not hold financial or non-financial interests related to the project.

c. Unmanageable ICOI: In cases determined to involve an unmanageable ICOI, the ICOI committee will require elimination of conflicting financial interests to initiate the proposed research activity. The ICOIC and the institution gives 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 Conflict of Interest:**
   The ICOIC will communicate its recommendation and management plan, as relevant, to the following, depending on the nature of the financial interest:
   - the Institutional Review Board,
   - the covered member whose interest was at issue,
   - the Office of the Vice President of Research,
   - the dean of the school for the covered member whose interest was at issue. If the dean has the ICOI, the next higher level of supervision receives the management plan,
   - the senior vice president for external relations if the institutional conflict is related to receipt of a gift,
   - the president of the University,
   - the senior staff member responsible for managing the University unit's financial interest,
   - the Office of Sponsored Programs (OSP) which, if required, notifies the sponsor of the institutional conflict of interest and the conflict management plan.

   For institutional conflict of interest deemed to be unmanageable, the ICOIC will communicate with affected individuals and/or University units.

5. **Monitoring the Management of Institutional Conflict of Interest:**
   The ICOIC will appoint one or more will appoint one or more non-conflicted persons to monitor the approved management plan, on a pre-arranged basis. Those monitoring will hold a University position commensurate or senior to 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 of University units, the senior administrator responsible for that unit will report to the ICOIC on adherence to the management plan on a pre-arranged basis.
6. **Appealing an ICOIC Determination:**
   Direct a request to appeal an ICOIC determination to the vice president for research (VPR) within 14 days of receiving notice of the ICOI determination. The VPR may convene an ad hoc committee to review the appeal and issue a recommendation to the VPR. The VPR will render a decision within 10 working days, and the decision of the VPR will be final.
7. **Public Reporting of Institutional Financial Interests:**
   Public reporting of a managed ICOI will be congruent with the public reporting of researcher financial conflicts of interest.

Related Information

FIN-001: Classification of Awards to the University as either a Gift or a Sponsored Program
RES-005: Financial Conflicts of Interest for Research Investigators
Virginia State and Local Government Conflict of Interests Act: (§2.2-3100 et seq.)

Major Category Research Administration

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Approved By Executive Vice President and Chief Operating Officer

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