University of Virginia School of Medicine
Policy on Conflict of Interest and Conflict of Commitment

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Applies to:

All full- or part-time faculty with primary appointments in the University of Virginia School of Medicine (with rank of Lecturer or above, including Instructors, Assistant Professors, Associate Professors and Professors), as well as all individuals responsible for the design, conduct, or reporting of research and School of Medicine research core directors.

This policy also applies to Trainees and non-faculty employees, with respect to interactions with vendors and other corporate representatives, as described in the Policy Statement.

Definitions

Conflict of Commitment (COC). A conflict arising when time expended on Outside Activities such as consulting or entrepreneurial activities interferes with a Covered Person’s ability to meet his or her Institutional Responsibilities. (SOM faculty may, with approval of their chair, contract with outside entities for consulting or other external professional activities as described in SOM Policy on External Consulting and Professional Activities, referenced herein.)

Conflict of Interest (COI). A situation occurring when the professional, commercial, or Financial Interests or activities of a Covered Person outside the University have the potential to or actually influence his or her professional obligations to the University – including but not limited to, research, educational activities, clinical practice, and procurement.

Covered Persons. Includes the following: (1) full- or part-time faculty with appointments in the University of Virginia School of Medicine (Lecturer, Instructor, Assistant Professor, Associate Professor, Professor); (2) all individuals responsible for the design, conduct, or reporting of research; and (3) School of Medicine research core directors.

Dependent. Any person who receives more than one-half of his or her financial support from another individual.
Financial Interest. Anything of monetary value including, but not limited to: ownership of stocks, bonds, stock options, partnership or other equity interests, rights to patent or royalty payments, consulting fees, speaking fees, salary, loans, gifts, lectureship fees, compensation for serving on boards of directors, scientific and other advisory boards, or other remuneration. Financial Interests do not include stock owned through mutual funds.

Immediate Family. One’s spouse and dependent children.

Institutional Responsibilities. An Investigator’s professional activities on behalf of the Institution, which may include research, research consultancies, teaching, clinical practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator. The principal investigator and any other person who is responsible for the design, conduct, or reporting of sponsored research, or for a proposal seeking such funding.

Outside Activities. These include any self-employment, any participation in business partnerships, or any employment or consulting arrangements with entities other than UVa that relate to a Covered Person’s Institutional Responsibilities. Outside Activities may be either compensated or uncompensated.

Research. A systematic investigation designed to develop or contribute to generalizable knowledge, including basic and applied research, clinical trials, and product development.

SOM Faculty. For annual disclosure, this includes all faculty with primary appointments in the University of Virginia School of Medicine (appointments with rank of Lecturer or above including: Instructors, Assistant Professors, Associate Professors and Professors). With respect to this policy, the Financial Interest of the individual SOM Faculty includes his or her Immediate Family.

Trainee. Enrolled UVa students, residents, fellows, postdocs, or visiting scholars receiving short-term training.

UVa Start-up Companies. Privately held, for-profit companies that are based on intellectual property developed at UVa or involve equity stakes by Covered Persons.

Reason for this policy

The University of Virginia School of Medicine (SOM) encourages the discovery and dissemination of new knowledge via sponsored research, consulting, entrepreneurship, and other endeavors that are consistent with the missions of the University and that may benefit society. It is of utmost importance that these efforts be conducted with integrity, avoid the appearance of bias, use institutional resources appropriately, and maintain public trust.

Occasionally, the interests or commitments of Covered Persons have the potential to conflict with those of the University – situations that are regulated at federal, state, and institutional levels. This policy is designed to educate SOM faculty on actual and apparent Conflicts of Interest and Conflicts of Commitment, to foster a culture of disclosing one’s external financial interests and activities, and to create appropriate administrative procedures for the review and management of such conflicts.
Policy Statement

Covered Persons shall not conduct Outside Activities that interfere with their Institutional Responsibilities.

Except as approved by the SOM, remuneration for the conduct of a Covered Person’s academic responsibilities and Outside Activities shall only be received through the University or its affiliated organizations.

Covered Persons shall conduct University business, training, patient care, or research only under circumstances in which a reasonable person would conclude that the integrity of their performance of these activities has not been compromised by a conflict of interest.

The right or responsibility of Covered Persons to freely publish or present publicly their research findings shall not be constrained as a result of a financial incentive or contractual agreement with a non-UVa party.

SOM resources such as facilities, equipment, computer networks, and personnel shall not be used by Covered Persons for the financial benefit of external entities, unless authorized by the institution (except for incidental use of internet and phone systems as governed by the Virginia Department of Human Resource Management Policy on Use of Electronic Communications and Social Media).

Covered Persons shall disclose financial and commitment relationships with organizations outside of the University that relate to their Institutional Responsibilities, as described herein.

Covered Persons who have an existing (over the past 12 months) or anticipated (over the coming year) Financial Interest in interventional research involving human subjects that exceeds $10,000 in annual income or 3% ownership may participate in its conduct only upon requesting and receiving institutional approval.

Covered Persons and SOM trainees must comply with the requirements of Medical Center Policy 0008, “Gifts, Gratuities, and Interactions with Vendors,” in connection with any services they perform within or for the benefit of the Medical Center or the School of Medicine.

Procedures

Financial Interests that must be disclosed to the SOM

Covered Persons shall disclose the following Financial Interests in organizations outside of the University that relate to their Institutional Responsibilities:

- any reimbursed or sponsored travel related to Institutional Responsibilities during the previous year;
- $5,000 or more in total remuneration and/or $5,000 or more equity interest (i.e. stock ownership) in a publicly traded entity;
- $5,000 or more in remuneration from a non-publicly traded entity during the previous year; and
- any equity interest in a non-publicly traded entity, including a UVa Start-up Company.

Disclosure must be made annually. Additionally, disclosures must be made within 30 days of establishment of new Financial Interests that occur between annual declarations, or within 30 days of initiating their employment at the SOM.
Financial Interests that are exempt from disclosure to the SOM

Covered Persons are not required to disclose:

- income from seminars, lectures, or teaching engagements sponsored by a federal or local government agency, institution of higher learning, or research institute or medical center associated with an institution of higher learning;
- consulting activities and income associated with the review of grant/contract proposals or advisory panels on behalf of a federal, state, or local government, or an institution of higher education/academic medical center/academic research institute;
- reimbursed or sponsored travel paid by a federal, state, or local government, or an institution of higher education/academic medical center/academic research institute;
- income from agreements to which UVa is a party (including sponsored awards);
- income from financial instruments that are not controlled by the Covered Person (e.g., mutual funds); or
- income from the University of Virginia Licensing & Ventures Group or University Physicians Group.

Disclosure of Financial Interests to the SOM and other University offices

Covered Persons shall disclose their Financial Interests as described below:

- Disclosure to the School of Medicine. All Covered Persons are required to disclose annually all Financial Interests that relate to their Institutional Responsibilities using the SOM on-line disclosure system (https://www.web.virginia.edu/uvacoi). New Financial Interests must be disclosed within 30 days. Newly appointed Covered Persons must disclose their Financial Interests within 30 days of their initial appointment. Whenever an application for external research funding is submitted, the principal investigator must certify on the Proposal Approval Form that he or she and all project Investigators, including subcontractors, have disclosed their Financial Interests.

- Disclosure to the Institutional Review Board. Principal investigators engaging in human subjects research at UVa are required to ensure disclosure of the Financial Interests of all study personnel to the Institutional Review Board, when proposing a new protocol or when a new Financial Interest arises during the course of an IRB-approved study that might be perceived to influence the outcome of that study. These reports are required in addition to the annual disclosures described above.

- Disclosure to the University and Commonwealth under the Virginia State and Local Government Conflict of Interests Act. Individuals who have received a waiver of conflict of interest under the state COI statute, institutional leaders, and certain administrators must disclose annually their current Financial Interests to the Commonwealth. These annual financial reports are requested by and returned to UVa Human Resources and forwarded to the Office of the Secretary of the Commonwealth and are subject to the Freedom of Information Act. Also under this law (cf. §2.2-3110.5), the UVa Vice President for Management and Budget requires disclosure by Covered Persons of their Financial Interests in companies that may contract with the University. Neither of these replaces the financial disclosures required by this policy, nor are they described further in this document.

Together, these reports satisfy the requirements of this policy, the Virginia State and Local Government Conflict of Interests Act, and federal regulations.
Review of SOM Financial Disclosures

Review of conflicts of commitment. Department chairs will review the financial disclosures of their faculty for potential Conflict of Commitment. The dean or designee will review the disclosures of chairs. If the review suggests that a Conflict of Commitment exists, the reviewer shall discuss the conflict with the faculty member and take steps to assure either elimination or management of the conflict. If the reviewer is unable to guarantee its elimination or management, he or she should consult with the dean’s designee. The dean will make a final determination on the disposition of all Conflicts of Commitment.

SOM and institutional review of conflicts of interest. Disclosures of Financial Interests will be reviewed by staff of the SOM Conflict of Interest Committee (“SOM COI”). Financial Interests that are considered de minimis will not be pursued further. SOM COI staff will determine which Financial Interests relate to newly funded or ongoing research projects on which that individual participates (such that the Financial Interest could be affected by the research or is in an entity whose financial interest could be affected by the research), or to the individual’s clinical or training activities. Those related Financial Interests will be reviewed further and managed as follows:

- Research. Financial Interests related to research activities will be referred to and reviewed by the UVa Conflicts of Interest Committee (“UVa COI”), which will determine whether a Conflict of Interest exists. The Covered Person should first meet with SOM COI staff to identify the sources of the Financial Interest, confirm the relationship between the financial interest and the individual’s research, determine whether the Financial Interest could directly and significantly affect the design, conduct, or reporting of that research, and develop an appropriate management plan to be presented to the UVa COI staff. SOM COI may gather additional information to inform this process and the deliberations of the UVa COI. Recommendations of the UVa COI will be forwarded to the Vice President for Research, per UVa Conflict of Interest policy (referenced below). The UVa COI will coordinate with the Institutional Review Board concerning Financial Interests associated with human subjects research. For financial Conflicts of Interest that involve federal research awards, the UVa COI will notify the Vice President for Research, Office of Sponsored Programs, and Office of Grants and Contracts that potential conflicts have been reported and addressed. Follow up with research sponsors, including required reports, will be submitted through one or more of these offices.

- Medical Center Procurement (MCP). MCP will review the financial disclosures of SOM Faculty serving on the Procurement-Related Selection Committees or the Pharmacy and Therapeutics Committee, to ensure compliance with UVa Medical Center Policy 0189 (referenced below).

- Other activities. For institutional activities not listed above, the SOM COI shall review financial disclosures, identify the sources of actual and potential conflicts, and develop written plans to eliminate reduce, or manage those conflicts. The SOM COI may request additional information from the Covered Person involved and may also consult with others who might have relevant information. In making its determinations, the SOM COI will be guided by the principles discussed herein and the policies referenced below. The SOM COI shall deliver to the dean a written recommendation describing how the conflict should be managed. The dean will make a final determination on the case. SOM COI staff will communicate the dean’s decision to the Covered Person and the entire SOM COI. If the dean requires that the Conflict of Interest be managed, s/he will describe the specifics of the management plan, including oversight and reporting requirements.
Reconsideration. The UVa Policy on Conflict of Interests describes reconsiderations of UVa COI decisions concerning Conflicts of Interest in research. For conflicts that are reviewed by SOM COI, the Covered Person may request that the dean reconsider the original determination, by submitting to SOM COI staff a detailed, written description of why that determination should be modified, within two weeks of the Covered Person having been notified of the original determination. The dean may rule on the request directly or with input from SOM COI and will respond to the Covered Person ordinarily within three weeks after receiving the request. A single such request will be allowed for any case.

Management of conflicts of interest. Management plans might include, but not be restricted to, one or more of the following elements:

- creation of an oversight committee to review the integrity of data, manuscripts, and reports resulting from a project where Covered Persons have a financial Conflict of Interest;
- appointment of a faculty advocate to ensure that the career development of Trainees or junior faculty is placed ahead of their supervisor’s Financial Interests;
- requirement to disclose the Financial Interest in publications and public presentations;
- requirement that project personnel be notified of the nature of the Financial Interest.

Special considerations for research with human subjects – the “rebuttable presumption” Covered Persons who have an existing (over the past 12 months) or anticipated (over the coming year) Financial Interest in interventional research involving human subjects that exceeds $10,000 in annual income or 3% ownership may participate in its conduct only upon requesting and receiving institutional approval. The UVA COI Committee and Institutional Review Board shall consider the following in reviewing such a request:

- The nature of the research and potential risks for study participants
- Unique qualifications of the individual to perform the study
- The nature of the Financial Interest and how it is related to the research
- The extent to which the investigator may benefit financially
- The potential to reduce or effectively manage the Financial Interest

Confidentiality of Financial Disclosures

The SOM posts on a publicly accessible web site the following information on Financial Interests of Covered Persons who disclose external interests above the required thresholds: name; outside entity name; basis of Financial Interest (consulting, ownership, etc.). Financial Conflicts of Interest associated with Public Health Service funded research projects, as defined in that agency’s Objectivity in Research policy (referenced below), must be posted on a publicly accessible web site or be made available by the University in response to any request for that information. The confidentiality of other information contained within these financial disclosures shall be maintained securely. The following individuals and groups will be provided access to disclosures made by Covered Persons and also will be reminded of their responsibility to maintain confidentiality:

- The disclosing individual’s chair – to assess potential Conflicts of Commitment. For disclosing faculty who are chairs, the dean’s representative may access this information.
- SOM COI and its staff – to assess actual or potential Conflicts of Interest and compliance with this policy.
- UVa COI, its staff, and the Vice President for Research – to assess actual or potential Conflicts of Interest with respect to research.
• Medical Center Procurement – may access financial disclosures of individuals who serve on the Procurement-Related Selection Committees or the Pharmacy and Therapeutics Committee, to ensure that its procurements are not influenced by financial conflicts.
• The Director of SOM Office of Grants and Contracts or his/her designee(s) – to ensure compliance with sponsor requirements for conflicts of interest in research.
• For conflicts involving human subjects research, Institutional Review Board (IRB) staff and members may review financial disclosures.
• The disclosures may be provided to other individuals as required by law.

School of Medicine Conflict of Interest Committee
The composition and rules of order for the SOM Conflict of Interest Committee are described at http://www.medicine.virginia.edu/research/offices/research/home/som-coi-committee.html.

Penalties for non-compliance with this policy
The SOM dean may apply sanctions in the following situations:
• Non-compliance by a Covered Person with his/her responsibilities under this policy.
• Failure of a Covered Person to adhere to a decision by the SOM dean or University concerning a Conflict of Interest or Conflict of Commitment.
• Inappropriate release of financial disclosures by individuals with administrative responsibility under this policy.
Sanctions may include but not be limited to disciplinary action, suspension, salary reduction, reduction in rank, or termination.

Related Policies and Guidelines
Commonwealth of Virginia
State and Local Government Conflict of Interests Act (http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC02020000031000000000000)

Virginia website on Conflict of Interest

Virginia Department of Human Resource Management Policy on Use of Electronic Communications and Social Media
(http://www.dhrm.virginia.gov/hrpolicy/pol175UseOfInternet.pdf)

University of Virginia
UVa Policy on Conflict of Interests (http://www.virginia.edu/finance/polproc/pol/xva1.html)

UVa Policy on Consulting by Faculty of the University of Virginia
(http://www.virginia.edu/provost/docs_policies/consult.html)

UVa Policy on Resolution of Conflicts of Interest as they Relate to Research Contracts
(http://www.virginia.edu/finance/polproc/pol/viiib1.html)

UVa Policy on Faculty Overload Responsibilities for Supplemental Compensation (http://www.virginia.edu/finance/polproc/pol/xia1.html)
UVa Policy on Extracurricular Use of University Equipment
(http://www.virginia.edu/provost/facultyhandbook/policies.html#equipment)

UVa Policy on Use of University Resources
(http://www.virginia.edu/finance/polproc/pol/xvg1.html)

UVa Web page on Conflict of Interest: Frequently Asked Questions
(http://www.virginia.edu/vpr/coi/FAQs_to_coi%20members.pdf)

UVa Vice President for Research web site on objectivity in research
(http://www.virginia.edu/vprgs/objectivity.html)

UVa School of Medicine
SOM Policy on External Consulting and Professional Activities

SOM Policy on Faculty Interactions with Industry and Product Endorsement

SOM Policy on Faculty Time Away for Professional Activities
(http://wwwmedicine.virginia.edu/administration/office-of-the-dean/administration/school-policies/Faculty-Travel-Days-for-Professional-Activities.pdf)

Continuing Medical Education Planning Committee/Faculty/Author Disclosure

SOM Policy on Payments for Referring or Enrolling Patients in Clinical Trials
http://wwwmedicine.virginia.edu/administration/office-of-the-dean/administration/school-policies/PolicyonPaymentsforReferringorEnrollingPatientsinClinicalTrials.pdf

UVa Medical Center (Unless stated below, these can be referenced at http://www.healthsystem.virginia.edu/docs/manuals/policies/mc)
Policy 0008: Gifts, Gratuities, and Interactions with Vendors.

Policy 0013: Vendors, Sales and Service Representatives.

Policy 0015: Travel Reimbursement

Policy 0092: Release of Patient’s Health Information

Policy 0112: Medication

Policy 0189: Medical Center Procurement Guidelines

Policy 0202: Internet Access/Usage

Policy 0212: Closed Formulary
Policy 0233: Conflict of Interest

Medical Center Pharmacy Services Policy on Pharmaceutical Services Representatives (https://www.healthsystem.virginia.edu/opr/manuals/pharm/E33.pdf)

Federal agencies

Department of Health and Human Services, Public Health Service
Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors (http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)

Department of Health and Human Services, Office of Inspector General
OIG compliance program guidance for pharmaceutical manufacturers (http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf)

National Institutes of Health
Financial Conflict of Interest web site (http://grants.nih.gov/grants/policy/coi/index.htm)

National Science Foundation

Other organizations

Accreditation Council on Continuing Medical Education (ACCME)
ACCME Standards for Commercial Support (http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support)

Accreditation Council for Graduate Medical Education (ACGME)
Principles to Guide the Relationship between Graduate Medical Education and Industry (http://www.acgme.org/acgmeweb/Portals/0/PFAssets/PublicationsPapers/pp_GMEGuidelines.pdf)

Advanced Medical Technology Association (AdvaMed)
Code of Ethics on Interactions with Health Care Professionals (http://advamed.org/issues/1/code-of-ethics)

American Medical Association (AMA)

Association of American Medical Colleges
Financial Conflicts of Interest in Research (https://www.aamc.org/initiatives/research/coi/)

Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research (with the Association of American Universities)

Industry Funding of Medical Education: Report of an AAMC Task Force

International Committee of Medical Journal Editors
Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (http://www.icmje.org/recommendations/)

Pharmaceutical Research and Manufacturers of America (PhRMA)
(http://www.phrma.org/files/attachments/PhRMA%20Marketing%20Code%202008.pdf)

Acknowledgment

The original version of this policy was adapted, with permission, from the Yale University Policy on Conflict of Interest and Conflict of Commitment [http://www.yale.edu/provost/html/coi.html], accessed September 2007.

Policy History

Created June 26, 2008; revised 10/1/08, 5/27/09, 1/12/10, 9/28/10, 2/20/12, 5/4/15

Approved:

R. J. Canterbury, MD 5/4/15
Interim Dean
Appendix I

GUIDANCE ON FACULTY RELATIONSHIPS WITH START-UP COMPANIES

Faculty relationships with UVa Start-up Companies present opportunities for the development and commercialization of inventions but may also create Conflicts of Interest and Commitment. The following requirements govern faculty relationships with such ventures.

1. **Equity interests.** Covered Persons may hold equity interests in start-ups that license intellectual property developed at UVa. Covered Persons accepting equity in such ventures must recognize that company-sponsored research – especially research involving human subjects – may be restricted due to their ownership interest, under the “rebuttable presumption.”

2. **Membership on Boards of Directors or service as an Operating Officer.** Permitted under this policy. A Covered Person member who has assumed one of these positions should recognize that his or her ability to conduct company-sponsored research at UVa may be affected because of the financial relationship with the venture. Such individuals should also be sensitive to the need to recuse themselves from Board decisions that involve conflicting responsibilities to the start-up and to the University.

3. **Consulting relationships.** Consulting relationships between a Covered Person member and a start-up in which he or she holds equity must receive prior approval by the dean (via the Office of Grants and Contracts), under the SOM Policy on External Consulting and Professional Activities.

4. **Employment of Trainees by a start-up.** Employment by a start-up of SOM Trainees under the direction of a faculty member with a Financial Interest in that venture must be approved, as follows, before it may begin:
   - for students, by the director of his or her academic program;
   - for other Trainees, by the chair or dean.
   - For all Trainees: the SOM COI Committee must approve before employment begins.

   Exception: no approval is required for students who seek summer employment with the start-up and plan to work in a field unrelated to their academic program.

5. **Use of SOM space or equipment.** Use of SOM space or equipment by or on behalf of a start-up is not permitted, except under an institutional agreement with the company.

6. **Testing of faculty-generated intellectual property that has been licensed to that faculty member’s start-up, under company funding: research involving human subjects.** SOM faculty who have an existing or anticipated (to be paid or received in the coming year) Financial Interest in interventional research involving human subjects that exceeds $10,000 in annual income or 3% ownership may participate in its conduct only after receiving institutional approval, under the “rebuttable presumption.”

7. **Testing of faculty-generated intellectual property that has been licensed to that faculty member’s start-up, under company funding: research not involving human subjects.** Research involving products in which a Covered Person has an ownership interest in the sponsoring start-up company, or where a Covered Person holds a Board seat in the company, requires review and approval by the UVa Conflicts of Interest Committee.