

**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 School of Medicine (SOM) Trainees and non-faculty employees, with respect to interactions with vendors and other corporate representatives, as described in the Policy Statement and Appendix III.

Definitions

Conflict of Commitment (COC). A conflict arising when time expended on Outside Activities such as consulting or entrepreneurial activities interferes with a SOM faculty member's ability to meet his or her Institutional Responsibilities. (Currently, SOM faculty may, with approval of their chair and the dean, contract with outside entities for consulting or other external professional activities no more than 45 days per year, per SOM Policy on External Consulting and Professional Activities, referenced herein. For part-time faculty, these 45 days are pro-rated with their FTE.)

Conflict of Interest (COI). A situation occurring when the professional, commercial, or Financial Interests or activities of a SOM faculty member 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.

Dependent. Any person, whether or not related by blood or marriage 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, dependent children, and any other person residing in the same household as the SOM employee who is a Dependent of that employee or of whom the employee is a Dependent.

Institutional Responsibilities. An Investigator's professional responsibilities on behalf of the Institution, which may include activities such as 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 research funded by the U.S. Public Health Service or the National Science Foundation, or for a proposal seeking such funding. For the purposes of this policy, this is limited to individuals who have a primary appointment in the School of Medicine.

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 faculty member's Institutional Responsibilities. Outside Activities may be either compensated or uncompensated.

Research. A systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research, clinical trials, and product development. The term includes, but is not limited to, any such activity for which research funding is available from an outside entity (federal or non-federal).

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 or Ventures. Privately held, for-profit companies that are based on intellectual property developed at UVa or involve faculty equity stakes.

Reason for this policy

The University of Virginia School of Medicine (SOM) encourages its faculty to imagine, create, discover, and disseminate new knowledge via sponsored research, consulting, entrepreneurship, *pro bono* work, development, 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 the greatest integrity, avoid the appearance of bias, use institutional resources appropriately, and maintain public trust.

Occasionally, the interests or commitments of School of Medicine faculty 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 elimination, reduction, or management of such conflicts.

Although it is essential that potential Conflicts of Interest be avoided or managed appropriately so as to maximize the credibility of intellectual products coming from the institution, it is recognized that constructive engagements with non-academic sponsors can be highly beneficial to scientific, educational, and therapeutic advancement. There are many existing federal, state, University, and SOM policies that address potential Conflicts of Interest and/or Commitment. This document is intended to identify, summarize, and supplement these existing policies and to define the process for disclosing, evaluating, and adjudicating potential conflicts.

Policy Statement

SOM Faculty and Investigators shall not conduct Outside Activities that interfere with their Institutional Responsibilities.

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

SOM Faculty and Investigators shall not conduct University business, training, patient care, or research under circumstances in which a reasonable person would infer that the integrity of their performance of these activities was compromised by the desire for or expectation of external personal advantage.

The right or responsibility of SOM Faculty 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 SOM Faculty or Investigators 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).

All SOM Faculty and Investigators shall disclose financial and commitment relationships with organizations outside of the University that relate to their Institutional Responsibilities, as described herein.

SOM Faculty and Investigators who have an existing 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*.

All SOM faculty, staff, and trainees must comply with the requirements of Medical Center Policy 0008, "Gifts and Gratuities," in connection with any services they perform within or for the benefit of the Medical Center or the School of Medicine (summarized in Appendix III).

Procedures

What Financial Interests should be disclosed to the SOM

SOM Faculty and Investigators 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 plus 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 being appointed to the SOM faculty.

What Financial Interests should not be disclosed to the SOM

SOM Faculty and Investigators 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 the University of Virginia is a party (including grants and contracts and Option 2 consulting);
- income from financial instruments that are not controlled by the faculty member (e.g., mutual funds); or
- income from the University of Virginia Licensing & Ventures Group or University Physicians Group (formerly UVa Patent Foundation and Health Services Foundation, respectively).

How Financial Interests must be disclosed to the SOM and other University offices

The individual SOM Faculty or Investigator shall disclose his or her Financial Interests as described below:

- *Disclosure to the School of Medicine.* All SOM Faculty and Investigators 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/uvacoj>). New Financial Interests must be disclosed within 30 days. New SOM Faculty 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 SOM Faculty/Investigators of their Financial Interests in companies that may contract with the University. Neither of these reports 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 and center directors will review the financial disclosures of their faculty for potential Conflict of Commitment. The dean or designee will review the disclosures of chairs and directors. 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 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 SOM Faculty/Investigator 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 to develop an appropriate management plan to be presented to the UVa COI. 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 SOM Faculty/Investigator 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 faculty/investigator 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 SOM Faculty/Investigator 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 SOM Faculty 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 SOM Faculty/Investigator 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 SOM Faculty/Investigators 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 SOM “rebuttable presumption” Faculty investigators who have an existing 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 cognizant 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 SOM Faculty who disclose external interests above the required thresholds: faculty 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 SOM faculty/investigators and also will be reminded of their responsibility to maintain confidentiality:

- The disclosing individual's chair or center director – to assess potential Conflicts of Commitment. For disclosing faculty who are chairs or directors, 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.

Retention of financial disclosures and documentation on conflicts of interest and commitment

- Documentation of COIs associated with Public Health Service funding shall be retained for five years after filing of the final financial report for that competitive award period.
- Documentation for COI/COC reviews that result in a management plan (non-Public Health Service) shall be retained for three years after completion of the activity requiring management.
- Documentation for COI/COC reviews that do not result in further management shall be retained for three years after the final decision by the dean or Vice President for Research.

School of Medicine Conflict of Interest Committee

The composition and rules of order for the SOM Conflict of Interest Committee are described in Appendix IV.

Penalties for non-compliance with this policy

The SOM dean may apply sanctions in the following situations:

- Non-compliance by a SOM Faculty/Investigator with his/her responsibilities under this policy.

- Failure of a SOM Faculty/Investigator to adhere to a decision by the SOM dean or University concerning a Conflict of Interest or Conflict of Commitment.
- Inappropriate release of confidential information on 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+TOC0202000003100000000000>)

Virginia web site on Conflict of Interest
(<http://www.commonwealth.virginia.gov/StateGovernment/Conflict/conflict.cfm>)

Virginia Department of Human Resource Management Policy on Use of Electronic and Social Media
(<http://www.dhrm.state.va.us/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 Use of University Equipment
(<https://etg07.its.virginia.edu/policy/policydisplay?id=PRM-011>)

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
(<http://www.medicine.virginia.edu/administration/office-of-the-dean/administration/school-policies/External-Consulting-and-Professional-Activities.pdf>)

SOM Policy on Faculty Interactions with Industry and Product Endorsement
(<http://www.medicine.virginia.edu/administration/office-of-the-dean/administration/school-policies/Faculty-Interactions-with-Industry-and-Product-Endorsement-REV-Sept-2006.pdf>)

Continuing Medical Education Planning Committee/Faculty/Author Disclosure
<http://www.medicine.virginia.edu/education/more/cme/resource-download-folder-documents/conflict-of-interest-policy-may-05.pdf>

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

UVa Medical Center (Unless stated below, these can be referenced at
https://www.healthsystem.virginia.edu/documentation/manual.cfm?manual_id=A70A3A2A-110A-2E68-14DBB50667C4BA10)

Policy 0008: Gifts and Gratuities.

Policy 0013: Vendors/Sales Representatives.

Policy 0015: Travel Reimbursement

Policy 0092: Release of Patient's Health Information

Policy 0112: Drug samples

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

Grants Policy Statement on COI

(http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part4.htm#_Toc54600065)

Financial Conflict of Interest web site (<http://grants.nih.gov/grants/policy/coi/index.htm>)

National Science Foundation

Grant Policy Manual - COI Policies

(http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510)

Other organizations

Accreditation Council on Continuing Medical Education (ACCME)

ACCME Standards for Commercial Support

(www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf)

Current definitions and interpretations related to the ACCME Standards for Commercial Support (http://www.accme.org/dir_docs/doc_upload/60cd3131-ea44-4829-a87a-9b23ee97f25f_uploaddocument.pdf)

Accreditation Council for Graduate Medical Education (ACGME)

Principles to Guide the Relationship between Graduate Medical Education and Industry

(http://www.acgme.org/acWebsite/positionPapers/pp_GMEGuide.pdf)

Advanced Medical Technology Association (AdvaMed)

Code of Ethics on Interactions with Health Care Professionals

(<http://www.advamed.org/NR/ronlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>)

American Medical Association (AMA)

Opinion E-8.061: Gifts to physicians from industry (<http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.shtml>)

Association of American Medical Colleges

Financial Conflicts of Interest in Academic Medicine

(<http://www.aamc.org/research/coi/start.htm>)

The Scientific Basis of Influence and Reciprocity: a Symposium (available at https://services.aamc.org/Publications/index.cfm?fuseaction=Product.displayForm&prd_id=215&cfid=1&cftoken=B4B7BBF1-B5C8-4ACD-925AE46B3D83544A)

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

(https://services.aamc.org/Publications/index.cfm?fuseaction=Product.displayForm&prd_id=220&prv_id=268)

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

(https://services.aamc.org/Publications/index.cfm?fuseaction=Product.displayForm&prd_id=232&prv_id=281&cfid=1&cftoken=875EED1E-3C66-42FA-A900CC9EC21DABB7)

International Committee of Medical Journal Editors

Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (http://www.icmje.org/urm_full.pdf)

Pharmaceutical Research and Manufacturers of America (PhRMA)

Code on interactions with healthcare professionals. Washington, DC: PhRMA, revised 2004.

(<http://www.phrma.org/files/attachments/PhRMA%20Marketing%20Code%202008.pdf>)

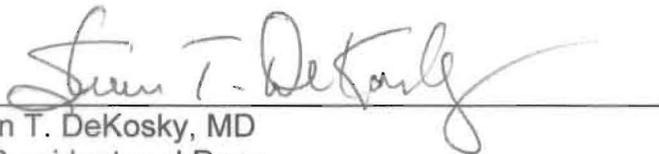
Acknowledgment

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

Approved:



Steven T. DeKosky, MD
Vice President and Dean

18 FEB 2012
Date

Appendices

The following appendices serve as educational tools and additional requirements for faculty members and as implementation guidelines to the SOM Conflict of Interest Committee.

Appendix I

EXAMPLES OF CONFLICTS OF INTEREST

The following scenarios represent COIs and associated areas of concern . It should be apparent that the ramifications of specific financial COI can cross several University missions and activities.

1. NIH has awarded a Phase I Small Business Innovation Research (SBIR) grant to a faculty-owned UVa Start-up Company. The project includes a subcontract to the University for work to be performed in that faculty member's laboratory. *Areas of concern: potential use of SOM Trainees on the project; loss of data integrity due to the COI; possible financial subsidy of the company; disclosure of the financial conflict in resulting publications and reports.*
2. A faculty member has a consulting agreement with a device manufacturer and wishes to participate in the selection of devices to be purchased by the Medical Center. *Area of concern: potential violation of Medical Center Policy No. 0189 – Medical Center Procurement Guidelines.*
3. A clinical investigator has received a clinical trials agreement from Company A, to test the efficacy of its candidate drug against a neurodegenerative disease. S/he also owns Company B stock worth \$25,000. Companies A and B are vying to market the first drug against that disease. *Areas of concern: financial COI due to ownership in a direct competitor of the company for whom one is testing a drug triggers the SOM "rebuttable presumption."*
4. A University administrator must select a vendor to cater a faculty retreat. The administrator's spouse co-owns a company that wishes to cater this event. *Areas of concern: potential violation of the Virginia State and Local Government Conflict of Interests Act.*
5. A clinician scientist has invented a novel therapeutic for ALS that has been licensed to a pharmaceutical company. She consults with the company to design clinical trials for the drug. The company asks her to lead an efficacy trial of the drug, since she is a leader in the clinical management of ALS and has access to a very large patient population. *Areas of concern: restriction from leading or participating on the study due to the consulting agreement under the SOM "rebuttable presumption."*
6. Company C pays a UVa clinician to present treatment options for lupus to regional rheumatologists (10 talks/year @\$5,000). The company's new drug for lupus costs much more than its competitors and is not recommended as a first-line treatment by the American College of Rheumatology. He lectures on lupus to medical students and rounds with house staff on Rheumatology service. *Areas of concern: participation in a speaker's bureau (cf. SOM consulting policy); disclosure of Financial Interest during teaching and patient care; potential prohibition on serving as investigator on any of Company C's clinical studies.*
7. A faculty member founds a start-up to develop her invention, which it licenses from the UVa Licensing & Ventures Group. She asks her postdoc to consult with the company to help develop its product. She asks that the company send documents to her UVa e-mail, where they will be easier to read and print. *Areas of concern: pressure applied on a junior report; relative benefits to the postdoc of consulting vs. focusing on his own research and career goals; potential misuse of University resources.*

Appendix II

FACULTY RELATIONSHIPS WITH START-UP COMPANIES

Faculty relationships with UVa Start-up Ventures 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.* SOM Faculty may hold equity interests in start-ups that license intellectual property developed at UVa. Faculty 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 SOM “rebuttable presumption.”
2. *Membership on Boards of Directors or service as an Operating Officer.* Permitted under this policy. A faculty 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 faculty 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 SOM “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 SOM faculty have an ownership interest in the sponsoring start-up company, or where SOM faculty hold a Board seat in the company, requires review and approval by the UVa Conflicts of Interest Committee.

Appendix III

INTERACTIONS BETWEEN SCHOOL OF MEDICINE EMPLOYEES/TRAINEES AND COMMERCIAL SPONSORS/VENDORS/REPRESENTATIVES

All School of Medicine employees and Trainees (“covered individuals”) are required to comply with the following:

- Food, beverage, gifts or compensation, of any kind and regardless of value, may not be accepted for attending a vendor or promotional presentation, whether occurring on site or off site.
- Food or beverage of any kind and regardless of value shall not be solicited or accepted from any vendor of the University, except as follows:
 - Funds given to the University without restrictions on their use (“unrestricted gifts”) may be applied to provide food or beverage at an educational event or function. Organizers should not announce the source of those funds at sponsored events; an initial thank you note to the vendor/donor should suffice.
 - Meals or beverages may be accepted from vendors or sales or service representatives when offered to a large group of people at a trade show, exhibit or other professional meeting.
- Food or beverage, gifts or compensation, of any kind and regardless of value, shall not be solicited or accepted for simply attending a CME or other educational event or activity.
- Promotional materials (pens, notebooks, tote bags, etc.) may not be solicited or accepted on or off grounds. Items of nominal value having legitimate educational purpose may be accepted.
- Gifts may not be solicited or accepted for services performed within the scope of the covered individual’s official duties.
- Product samples may not be solicited or accepted for personal or family use, including but not limited to medication samples or ancillary product samples such as infant formula, lotions, etc.
- Covered individuals may accept vendor paid travel, provided such travel is for the purpose of product inspection, training or education.
- Covered individuals may not publish as their own any articles or reports that were written wholly or partially by commercial entities without describing those contributions (“ghost authorship”).

Appendix IV

COMPOSITION, RULES OF ORDER, AND RESPONSIBILITIES OF THE SOM CONFLICT OF INTEREST COMMITTEE

Responsibilities of the SOM Conflict of Interest Committee

- Development of the basis and extent of conflicts of interest.
- Review of conflicts of interest associated with education, non-Medical Center procurement, and consulting.
- Development of management plans for actual or potential conflicts.
- Assist with development and periodic review of this policy.
- Development of standards for which financial conflicts of interest require committee review and potential management plans.
- Coordination with the UVA COI and the Institutional Review Boards to ensure appropriate flow of information on actual and potential financial COIs, especially those affecting multiple missions of the University.
- Periodic review and update of the SOM on-line financial disclosure system, in collaboration with Information Technology Services and the Vice President for Research.
- Education of SOM personnel on COI policy and procedures, to include the maintenance and periodic review of a web site.

The committee shall consist of a chair and an even number of voting members appointed by the dean of the SOM. Additional non-voting, advisory members will include: one or more associate/assistant deans of the SOM; SOM and Medical Center general counsel; and administrative staff as appointed by the dean.

The chair and voting members normally will be appointed for three-year tenure, at the discretion of the dean.

Rules of order

The chair and each voting member on the COI committee will have an equal vote on matters of policy and adjudicatory recommendations. Committee decisions will be made by simple majority and require a 70% quorum. Decisions may also be conducted via e-mail or telephonically.

The dean may request that the chair of the COI Committee appoint a subcommittee to conduct a preliminary investigation to determine whether or not an issue should be brought before the entire committee for formal review. At the discretion of the committee chair, subject matter consultants may be asked to provide expertise to the subcommittee or the entire committee. The subcommittee must report its findings and recommendations to the full Committee.

The committee will hold meetings to determine policy/direction and to review COI reports at least semi-annually. Meetings for adjudication will be held on an *ad hoc* basis.

Recommendations of the COI Committee for adjudication of issues regarding COI will be forwarded to the dean for decision and implementation.

Strict privacy regarding faculty disclosures as well as COI Committee discussions and decisions will be enforced by the Dean's Office.