

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

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Applies to:

All faculty (Board of Visitors approved appointments with rank of Lecturer or above including: Instructors, Assistant Professors, Associate Professors and Professors) with an appointment of at least 50% full time equivalent (FTE), as well as all individuals responsible for the planning, conduct, analysis and reporting of research.

Reason for this policy

In 1820, Thomas Jefferson wrote to William Roscoe, "This institution will be based upon the illimitable freedom of the human mind." To realize this lofty goal, the University of Virginia School of Medicine (SOM) encourages its employees to imagine, create, discover, and disseminate new knowledge. SOM faculty are encouraged to participate in sponsored research, consulting, entrepreneurship, *pro bono* work, development, and other endeavors that are consistent with the missions of the University and that may benefit mankind. In the pursuit of truth it is of utmost importance that SOM research, patient care, training, and community service be conducted with the greatest integrity, avoid the appearance of bias, use institutional resources appropriately, and maintain public trust.

Occasionally, the interests or the commitment of School of Medicine faculty have the potential to conflict with those of the University – situations that are regulated at the federal, state, and the 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 complete disclosure, and to create appropriate administrative procedures for the removal, reduction, or management of such conflicts.

In the interest of pursuing truth through unbiased research, disseminating accurate knowledge through impartial education, and curing and preventing disease through application of sound medical practice, it is essential that potential conflicts of interest between faculty members and their sponsoring agencies be examined and avoided or managed appropriately so as to

maximize the credibility of intellectual products coming from the institution. Conversely, it is recognized that healthy and candid interactions with non-academic sponsors can be highly beneficial to scientific, educational, and therapeutic progress. 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

All faculty and investigators will disclose all financial and commitment relationships with organizations outside of the University and these disclosures will be evaluated for possible actual or potential conflicts with the stated mission of the School of Medicine. Disclosure must be made annually and within 30 days of establishment of new relationships that occur between annual declarations. Failure to abide by the terms of this policy may lead to adjudication as stated within and lead to disciplinary action, to include possible forfeiture of employment.

All SOM faculty and medical trainees must comply with the requirements of Medical Center Policy 0008, "Gifts and Gratuities" (see https://www.healthsystem.virginia.edu/opr/usr/entiremanual.cfm?man_id=3) in connection with any services they perform within or for the benefit of the Medical Center. This Policy adopts and makes applicable to all SOM employees the requirements set out in Medical Center Policy 0008 with respect to any services they perform within or for the benefit of the School of Medicine. A summary of the new policy requirements on interactions with University/Medical Center vendors is provided in Appendix III. (Vendor activities are covered by Medical Center Policy 0013.)

Conflict of Interest (COI)

A conflict of interest occurs 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.

Potential conflicts of interest are as important to recognize and manage as are actual conflicts, since both might otherwise undermine the intellectual credibility of individual faculty and their academic activities, and the reputation of the SOM and University.

Whenever apparent or actual conflicts of interest arise, they must be disclosed to the University. All such conflicts should be reviewed and (1) reduced to or declared to be of insufficient magnitude to warrant further consideration, (2) eliminated, or (3) appropriately managed.

Conflict of Commitment (COC)

A conflict of commitment occurs when the time expended on outside activities such as consulting or entrepreneurial activities interferes with a SOM faculty member's ability to meet his or her University responsibilities.

SOM faculty may, with the approval of the department chair and the dean, "contract directly with outside entities for consulting or other external professional activities one day in seven" (School of Medicine Policy on External Consulting and Professional Activities; <http://www.healthsystem.virginia.edu/internet/about/sompolicies/externalConsultingandProfessionalActivities.pdf>). Regardless of how extensive such outside activities are, the SOM expects

faculty to fulfill their academic responsibilities in clinical medicine, research, training, and community service.

SOM faculty and investigators (as defined below) must disclose all outside activities so that their supervisor can evaluate the degree to which such activities might interfere with their University responsibilities.

Guiding Principles

The School of Medicine bases this policy on the following principles:

1. SOM faculty and investigators shall disclose all financial relationships with organizations outside of the University and these disclosures will be evaluated for possible actual or potential conflicts with the stated mission of the School of Medicine. Disclosure must be made annually and within 30 days of establishment of new relationships that occur between annual declarations.
2. Complete disclosure of financial interests to the University delegated COI committee will maximize compliance with legal requirements and assure the public that the missions and activities of the School of Medicine are not being unduly influenced by financial considerations.
3. SOM faculty and investigators shall not conduct external professional activities that interfere with their responsibilities to the University.
4. Except as approved by the SOM, remuneration for the conduct of SOM faculty's and investigators' academic responsibilities and activities shall only be received through the University or its affiliated organizations.
5. 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 (economic or otherwise) advantage.
6. The right or responsibility of faculty to freely publish or present publicly one's research findings shall not be constrained as a result of a financial conflict of interest.
7. School of Medicine resources (e.g., facilities, equipment, computer networks, and personnel) shall not be used by faculty/investigators for the financial benefit of external entities, unless authorized by the institution. Incidental use of UVA internet and phone system is governed by the Virginia Department of Human Resource Management Policy on Use of Internet and Electronic Communication Systems, referenced below.
8. SOM faculty/investigators shall not participate directly in the development or negotiation of any procurements or other arrangements between the University and an organization in which they have a financial interest unless otherwise allowed by law.
9. The University will maintain the rebuttable presumption that faculty/investigators with a financial interest in interventional research involving human subjects shall not participate in its conduct.

10. Small gifts or other items of minimal value may influence prescribing patterns. SOM faculty shall be aware of this association and avoid significant influence in clinical care or research.

Definitions

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. With respect to this policy, the dependent can either receive support from an SOM employee, or be an SOM employee who receives 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, receipt of consulting fees, speaking fees, salary, loans, gifts, lectureship fees, compensation for serving on boards of directors, scientific and other advisory boards, or other remuneration. For the purposes of this policy, financial interests do not include stock owned through mutual funds or reimbursement for reasonable travel expenses.

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.

Investigator. The Principal Investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the National Institutes of Health or the National Science Foundation, or proposed for such funding. For the purposes of this policy, this is limited to faculty whose primary appointment is in the School of Medicine.

Outside activities. These include leadership participation in professional, community, or charitable activities, any self-employment, any participation in business partnerships, or any employment or consulting arrangements with entities other than UVA. Outside activities may be either compensated or uncompensated. In general, any service on any board – for-profit, non-profit, advisory, honorary, or otherwise – will constitute an outside activity.

Research. A systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research 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). Research includes the conduct of clinical trials.

SOM faculty. For annual disclosure reporting, this includes all full and part-time (with an appointment of 50% or more) Board of Visitor-approved faculty appointments, including Lecturer, Instructor, Assistant Professor, Associate Professor and Professor. With respect to the disclosure requirements described in this policy, this definition includes the faculty member's immediate family.

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

UVA start-up companies or ventures. Relatively newly formed, privately held, for-profit companies that are based on intellectual property developed at UVA or involve faculty equity stakes.

Procedures

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

Disclosure of financial interests

The individual SOM faculty or investigator is responsible for disclosing outside financial interests or commitment. The first step in assessing actual or potential conflicts is the disclosure to the SOM and University of financial interests. Following and expanding on the AAU/AAMC publication "Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research" (reference below), the SOM requires its faculty and investigators to fully disclose all financial interests that might be associated with the missions and activities of the institution.

- *Disclosures to the School of Medicine.* All SOM faculty and investigators, as defined above, are required to submit annually a conflict of interest/conflict of commitment disclosure describing their own and their immediate family members' outside activities and all financial interests, using the UVA on-line disclosure system. These individuals must also update between annual disclosures when their own or their immediate family's financial interests or outside activities change materially from those described in the annual financial disclosure (no more than 30 days thereafter). New SOM faculty must disclose their own and their immediate family members' financial interests within 30 days of their initial appointment. Whenever an application for external research funding is submitted, the principal investigator will be required to certify that s/he and all project investigators, including subcontractors, have disclosed their financial interests.
- *Disclosure to the Institutional Review Board.* Principal investigators involved in human subjects research at UVA are required to ensure disclosure of the financial interests of all study personnel to the Institutional Review Board. These disclosures 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 statute must disclose annually their ongoing financial interests to the Commonwealth. Institutional leaders and certain administrators also are required to submit such disclosures. These annual financial disclosures are requested by and returned to UVA Human Resources and forwarded to the Office of the Secretary of the Commonwealth. Commonwealth of Virginia financial disclosures are subject to the Freedom of Information Act and can be obtained for this purpose. Also under this law (cf. §2.2-3110.5), the UVA Vice President for Management and Budget requests of all faculty/investigators whether they or their spouse or dependents have equity interest in companies that may contract with the University. Neither of these disclosures replaces the financial disclosures required by this policy, or are they described further in this document.

Together, these disclosures satisfy the requirements of this policy, the Virginia State and Local Government Conflict of Interests Act, and federal regulations.

Review of SOM disclosures

Department/center review of conflicts of commitment. Department chairs and center directors will review the financial disclosures and commitment disclosures of their respective

faculty/investigators for potential conflict of commitment. The Dean or his/her designee will review the disclosures of chairs and directors. If the initial review suggests that a conflict of commitment exists, the reviewer shall discuss the conflict with the SOM faculty/investigator and take steps to assure that any actual conflict is eliminated or appropriately managed. If the reviewer is unable to guarantee its elimination or appropriate management, s/he 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. All other financial interests will be reviewed and managed as follows:

- Research. Actual or potential financial conflicts associated with research activities will be referred to and reviewed and managed by the UVA Conflicts of Interest Committee ("UVA Committee"). The faculty/investigator should first meet with the SOM COI staff to identify the sources of the financial conflict and to develop an appropriate management plan that would be presented to the UVA Committee along with a description of the conflict and a rationale for the proposed plan. Recommendations of the UVA Committee will be forwarded to the Vice President for Research and Graduate Studies, per UVA policy (see Related Policies). The UVA Committee will coordinate with the Institutional Review Board to ensure that it is aware of existing financial interests associated with research involving human subjects. For conflicts of interest that involve federal research awards, the UVA Committee will notify the Office of Grants and Contracts that potential conflicts have been disclosed and addressed.
- Medical Center Procurement (MCP). MCP will review the disclosures of SOM faculty serving on the Procurement-Related Selection Committees or the Pharmacy and Therapeutics Committee, to ensure compliance with UVA Medical Center Procurement Guidelines (Medical Center Policy 0189).
- Other activities. For any activities (consulting, educational 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 or manage those conflicts. ("Elimination" refers to the faculty/investigator relinquishing his/her financial interest in the outside entity or the entity giving up any business relationship with the University.) If necessary, the SOM COI may request additional information from the SOM faculty/investigator involved and may also consult with others who may have relevant information. The SOM COI will determine whether an actual or potential conflict of interest exists, and, if so, by what means the conflict should be eliminated or managed. In making those 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 whether and 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 committee decisions concerning conflicts of interest in research. For conflicts reviewed entirely within the SOM, the faculty/investigator may request that the Dean reconsider his or her original

determination, by submitting to the SOM COI staff a written, detailed description of why that determination should be modified, no more than two weeks after the SOM faculty has been notified of the original determination. The Dean may rule on the request directly or with input from the 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. This process does not apply to conflicts of interest reviewed by the UVA Committee.

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

- creation of an oversight committee to review the integrity of data and manuscripts 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 any financial interests
- requirement of disclosure of the financial interest in publications and public presentations

Confidentiality of financial disclosures

The School of Medicine posts information on financial interests derived from these disclosures on a publicly-accessible web site. The web site lists the following information, for faculty who report external interests above \$10,000 in income or 3% ownership: faculty name; outside entity name; basis of financial interest (consulting, advisory board, ownership, etc.). The confidentiality of other information contained within these financial disclosures will be maintained securely. The following individuals and groups will be provided access to detailed 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 may access information on outside activities in order to assess potential conflicts of commitment. For chairs and directors, the Dean's representative will have access to this information.
- The SOM COI and its staff may access information on outside activities and financial interests in order to assess actual or potential conflicts of interest and compliance with this policy.
- The UVA Committee, its staff, and the Vice President for Research may access information on financial interests in order to assess actual or potential conflicts of interest with respect to research. (The UVA Committee reviews financial conflicts associated with research for the entire institution.)
- 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 Medical Center procurements are not influenced by financial conflicts.
- For conflicts involving human subjects research, the appropriate Institutional Review Board (IRB) staff and members may review disclosed financial interests.
- The disclosure forms may be disclosed to other individuals as required by law.

Responsibilities of the SOM Conflict of Interest Committee

- Review of conflicts of interest for all areas other than research, the latter being reviewed by the UVA Committee.
- Development of management plans for actual or potential conflicts.
- Development and periodic review of the SOM Conflict of Interest Policy.
- Development of standards for which financial conflicts of interest require committee review and potential management plans.

- Coordination with the UVA Committee and the Institutional Review Boards to ensure appropriate flow of information on actual and potential conflicts of interest, especially those affecting two or more missions of the University.
- Oversight of staff reviewing disclosure information.
- Periodic review and update of the SOM on-line financial disclosure system, in collaboration with Information Technology and Communication and the Vice President for Research and Graduate Studies.
- Education of SOM personnel on COI policy and procedures, to include the development and maintenance of a Web site.

Retention of disclosures and documentation of review and management of conflicts of interest and commitment

- Conflicts of interest associated with federal research funding must be maintained for five years beyond the filing of the final financial report for that competitive award period, per Commonwealth of Virginia records retention policy.
- For COI/COC disclosures and committee reviews that do not require further management, documentation must be retained for three years after the final decision by the Dean or Vice President for Research and Graduate Studies.
- For COI/COC reviews resulting in a management plan, documentation of must be retained for three years after the activity requiring management has been completed.

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 responsibility 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 Internet and Electronic Communication Systems

(http://www.dhrm.state.va.us/hrpolicy/policy/pol1_75.pdf)

University of Virginia

UVA Policy on Conflict of Interests

(<http://www.virginia.edu/finance/polproc/pol/xva1.html>); or to the one that currently is under construction)

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/viii1.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.itc.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/vprgs/coi/FAQs_to_coi_members.pdf)

UVA Vice President for Research and Graduate Studies Web site on objectivity in research
(<http://www.virginia.edu/vprgs/objectivity.html>)

UVA Human Resources Employment and Staffing Policies: Outside Employment
(<http://www.hrs.virginia.edu/policies/empstaff/outsideempl.html>)

UVA School of Medicine

SOM Policy on External Consulting and Professional Activities
(<http://www.healthsystem.virginia.edu/internet/about/sompolicies/externalConsultingandProfessionalActivities.pdf>)

SOM Policy on Professional Fees Charged to Law Firms
(<https://www.healthsystem.virginia.edu/internet/about/sompolicies/professional-Fees-Charged-to-Law-Firms-11-1-06.pdf>)

SOM Policy on Faculty Interactions with Industry and Product Endorsement
(<http://www.healthsystem.virginia.edu/internet/about/sompolicies/Faculty-Interactions-with-Industry-and-Product-Endorsement-REV-Sept-2006.pdf>)

Continuing Medical Education Planning Committee/Faculty/Author Disclosure (COI Policy) (CME: <http://www.healthsystem.virginia.edu/internet/cme/planning/Conflict-of-Interest-Policy-May-05.pdf>)

SOM Policy on Payments for Referring or Enrolling Patients in Clinical Trials
<http://www.healthsystem.virginia.edu/internet/about/sompolicies/PolicyonPaymentsforReferringEnrollingPatientsinClinicalTrials.pdf>

UVA Medical Center (Unless otherwise stated, the following are accessible at
https://www.healthsystem.virginia.edu/opr/usr/entiremanual.cfm?man_id=3)

Policy 0008: Gifts or 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, 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)

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-aa44-4829-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.medrad.com/pdf/advamed_code_09_03.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 Clinical Research
(<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/icjme.pdf>)

Pharmaceutical Research and Manufacturers of America (PhRMA)

Code on interactions with healthcare professionals. Washington, DC: PhRMA, revised 2004. (<http://www.phrma.org/files/PhRMA%20Code.pdf>)

Acknowledgment

Portions of this policy have been 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 October 1, 2008; revised May 27, 2009

Appendices

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

Appendix I

EXAMPLES OF CONFLICTS OF INTEREST

The following represent examples of conflicts of interest (COIs) for SOM faculty/investigators. The specific response of the UVA Conflicts of Interest Committee or SOM Conflict of Interest Committee to an individual case cannot be predicted, though the areas of concern to these committees are outlined below.

1. NIH has awarded a Small Business Innovation Research (SBIR) grant to a start-up company that is partially owned by a faculty member (>3% ownership). The award includes a subcontract to the University, for work to be performed in that faculty member's laboratory. *Areas of concern: potential use of trainees on the research project; integrity of resulting data due to the COI; assurance that the full cost of the subcontracted work is being borne by the company; disclosure of the financial conflict in resulting publications and reports.*
2. A faculty member has a consulting agreement with a device manufacturer. He wishes to participate in the selection of devices used at the Medical Center. *Area of concern: this is a 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. She also owns \$20,000 in Company B's stock. Companies A and B are vying to market the first drug against that disease. *Areas of concern: financial conflict of interest may involve both ownership in the company for whom one is testing a drug, and in any of its direct competitors; disclosure of the conflict to potential study participants; the degree to which the investigator can influence study recruitment, subject allocation, measurement of outcomes, and analysis and reporting of results.*
4. A University administrator must select a vendor to cater his faculty retreat. His wife co-owns a company that is interested in catering this event. *Areas of concern: potential violation of the Virginia State and Local Government Conflict of Interests Act.*
5. A clinician/translational investigator has developed and, via the UVA Patent Foundation, patented a novel therapeutic for a rare disease. The therapeutic has been licensed to a large pharmaceutical company. The company has provided a consulting agreement under which the investigator is helping to design clinical trials of the drug. Phase I and II studies (conducted at a different institution) have proven promising. The company has asked the inventor to lead an efficacy trial of the drug, since she has been a national leader in the clinical management of the disease and has access to the largest number of patients in the country. *Areas of concern: the investigator has a financial interest in the intellectual property, though any resulting royalties would be managed via the Patent Foundation and University patent policy; disclosure of this IP ownership to study participants; other concerns described with example 3 above.*
6. A University rheumatologist has substantial expertise on systemic lupus erythematosus (SLE). Company C has paid him to participate on their Scientific Advisory Board (SAB) and as a member of their speakers' bureau. The SAB meets twice per year, for which he

receives \$3,000 plus expenses. As a company-paid speaker, he presents current treatment options on SLE, including Company C's latest blockbuster drug, to groups of rheumatologists. He is paid \$5,000 per evening, approximately 10 times a year. The company provides him with slides for use in his presentations. Company C's drug costs three times the other drugs on the market and has not yet been recommended as first-line treatment of SLE by the American College of Rheumatology. Finally, this individual lectures on SLE to medical students and rounds with house staff on Rheumatology service. *Areas of concern: participation in a speaker's bureau; use of company slides in one's presentations; disclosure of financial interest during teaching and patient care.*

7. A senior faculty member founds a company to develop her inventions, which it has licensed from the UVA Patent Foundation. The company is still small and needs additional scientific expertise to help move its product along the development pathway. She asks a promising postdoctoral fellow in her laboratory to consult for the company. She also has asked that the company e-mail documents to her University address, where she can read and print them. *Areas of concern: potential pressure applied by senior faculty on a junior report; relative benefit to the postdoc of the consulting agreement vs. focusing on her own research and career trajectory; potential conflict of commitment; potential misuse of University resources.*

It should be apparent from this small number of examples that the ramifications of financial conflict of interest can be manifold in any given case. Similarly, a single case may impinge on several of the missions and activities of the University. It is strongly urged that SOM faculty/investigators who are concerned about conflict of interest as a result of their specific activities seek advice from SOM Conflict of Interest Committee staff.

Appendix II

CONFLICTS OF INTEREST ASSOCIATED WITH FACULTY WITH RELATIONSHIPS WITH START-UP COMPANIES

Faculty relationships with “start-up” ventures present opportunities for the development and commercialization of inventions but may also create conflicts of interest and commitment. The following guidelines govern faculty relationships with such ventures.

1. *Equity interests.* Faculty may hold equity interests in start-ups that license intellectual property developed at UVA. Such equity ownership must be promptly disclosed via the SOM on-line system. Faculty accepting equity in such ventures must recognize that company-sponsored research – especially research involving human subjects – may be restricted due to the conflict created by their ownership interest in the sponsor.
2. *Membership on Boards of Directors or service as an Operating Officer.* Faculty may serve on the Board of Directors or as an Operating Officer of a start-up. A faculty member who has assumed one of these positions should recognize that his or her ability to conduct company-sponsored research at UVA – especially research involving human subjects – will be restricted because of the conflict created by the relationship with the venture. Faculty members who assume Board seats or serve as Operating Officers on start-ups should also be sensitive to the need to recuse themselves from all Board decisions involving conflicting duties to the start-up and to the University.
3. *Consulting relationships.* Consulting agreements between a faculty member and a start-up in which he or she holds equity should receive prior approval by the Assistant Dean for Research Administration (Office of Grants and Contracts) under the SOM Policy on External Consulting and Professional Activities.
4. *Employment of trainees by a start-up.* Any employment by a start-up of trainees under the direction of a faculty member with a financial interest in that venture merits careful consideration of the potential for COI and of the career development of the trainee. Any such employment must be approved initially:
 - for students, by the director of his or her academic program;
 - for postdocs or other trainees, by the chair (or, if the faculty member is a chair, the Dean).The SOM Conflict of Interest Committee must also approve before employment can be initiated. Exception: no program or Committee approval is required for students who seek summer employment with the start-up and *plan to work in a field unrelated to his or her academic program.*
5. *Use of SOM space or equipment.* Use of SOM space or equipment by a start-up is not permitted, except under an institutionally-approved contractual agreement with the company.
6. *Testing of faculty-generated intellectual property that has been licensed to a start-up, under company funding: research involving human subjects.* The University will maintain a strong presumption against accepting funding for human subjects research from a start-up in which the faculty member overseeing or conducting the research has an equity interest, a Board seat, or other financial interest, if the project will be performed by the faculty member's

research staff, students, or postdoctoral fellows. Rigorous restrictions also apply to testing in human subjects of products in which the faculty member has a related financial interest.

The presumption may be overcome only in compelling circumstances, as judged by the UVA Conflicts of Interest Committee and the cognizant IRB, and where the Committee and IRB are satisfied that effective controls to mitigate any possible effects of the conflict can and will be implemented. Such circumstances might include, for example, that the researcher is uniquely qualified to perform the research protocol. In such situations, the Committee will consider whether the researcher should divest himself or herself of the equity interest or place the equity in a blind trust for an appropriate period of time. The presumption is less likely to be rebutted when the object of the conflicted research is testing of a device or compound for public validation or other similar purpose.

Except in extraordinary circumstances, the presumption may not be rebutted when the research in question has as its object the testing of an invention in which the faculty member has a royalty or other interest in a start-up, or a UVA invention that is licensed to a start-up in which he or she has an equity interest. For purposes of this proviso, "testing" is intended to describe doing research designed to validate to the public or perform a similar function regarding an invention created at UVA and licensed to a start-up company. (The same restrictions would generally apply to testing undertaken for a publicly held company holding a license from UVA.)

7. *Testing of faculty-generated intellectual property that has been licensed to a start-up, under company funding: research not involving human subjects.* Research not involving intervention studies in human subjects to be conducted by a faculty member who holds equity or a Board seat in the company may be permitted if a management plan is formulated and approved. Factors that increase the likelihood of approval include:
 - the faculty member's equity interests in a venture are so diluted that his or her control or influence over the firm's decisions and the possible benefit from University-based activity are negligible; and
 - the research is essential to maintain the continuity of a research effort related to the licensed intellectual property during a short interval of time (normally under six months), while the research activity is being established in the start-up.

Appendix III

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

SOM employees and medical trainees must comply with the requirements of Medical Center Policy 0008, "Gifts and Gratuities." As a result, the SOM Policy on Conflict of Interest and Conflict of Commitment requires that covered individuals not solicit or accept:

- Meals (which include bagels, donuts, coffee, etc.) offered or provided by any vendor, sales or service representative on University or Medical Center grounds. Unrestricted grants given to the University may be used to provide food or beverage at an educational event or function. Meals or beverages can still be accepted from vendors, sales or service representatives when offered to a large group of people at a trade show, exhibit or other professional meeting.
- Promotional materials (pens, calendars, notebooks, etc.). Items of nominal value having legitimate educational purpose will be permitted.
- Gifts for services performed within the scope of the SOM employee's official duties.
- Product samples for personal or family use, including but not limited to medication samples or ancillary product samples such as infant formula, lotions, etc.
- Meals, gifts or compensation, of any kind and regardless of value, for listening to a Vendor presentation, whether occurring on site or off site.

SOM employees/trainees may accept vendor paid travel, provided such travel is for purpose of product inspection, training or education.

Appendix IV

COMPOSITION AND RULES OF ORDER FOR THE SOM CONFLICT OF INTEREST COMMITTEE

The University of Virginia Conflict of Interest 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; general counsel to the SOM and Medical Center; and administrative staff as appointed by the Dean – Vice President.

The Chair and voting members normally will be appointed for three-year tenure, at the discretion of the Dean – Vice President.

Each voting member on the COI committee, including the Chair, will have an equal vote on matters of policy as well as adjudicatory recommendations. Decisions of the committee will be made by simple majority when a 70% quorum is present for voting. Decisions may also be conducted via e-mail or telephonically.

The committee will hold meetings to determine policy/direction and to review COI disclosures 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 – Vice President 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.