

Policy on External Consulting and Professional Activities

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Applies to:

School of Medicine faculty

Reason for Policy:

This document outlines the conditions under which faculty may conduct external consulting and professional activities, and establishes the requirements for certifications and financial disclosures. It will assist faculty and administrators in identifying, evaluating, and correcting any real, perceived, or potential conflicts of interest and commitment in a consulting or other external professional relationship.

Policy Statement:

The School of Medicine (SOM) recognizes that the quality of teaching, research, patient care¹, and program administration can be enhanced when faculty members participate in external activities such as consulting, professional affiliations, service to the field, or community service. The SOM also recognizes that such activities are valuable to the individuals and the institution alike, and

¹ Note: this policy does not apply to the creation of new or expanded clinical services. Review and approval for these activities must be in accordance with the established process through the Health System's Market Strategy Committee (September 2005)

supports associations that do not have an adverse impact on a faculty member's primary commitment of time and intellectual energies to the SOM.

Procedures:

A faculty member who wishes to engage in external consulting or professional activities for which compensation is offered must disclose the details of the relationship and obtain written approval from the department chair and the dean. The faculty member must obtain this written approval before engaging in consulting or other external professional activities.

All faculty members must certify annually their compliance with policies related to conflict of interest and commitment. A faculty member must disclose to his or her chair and the dean current or prospective situations that may raise questions of conflict of commitment or interest as soon as the faculty member is aware of such a situation.

Failure to comply with this policy may result in sanctions including, but not limited to, compensation adjustment, withdrawal of research privileges, suspension, or termination.

At the end of this policy document is a list of related documents. They are incorporated into this policy by reference here and it is essential for faculty to familiarize themselves with each item on the list in order to ensure appropriate compliance with them and with this policy.

Conflict of Commitment and/or Interest

A faculty member's commitment to the SOM includes a number of areas such as conducting patient care, teaching, performing research, publishing scholarly work, writing and submitting grants, serving on departmental, School, and University committees, and being available to students and colleagues outside of the classroom, laboratory, or clinic. When an individual's outside professional activities require excessive periods of time away from campus, or whenever a full-time faculty member's professional loyalty is not to the University's Academic or Medical Center divisions, a conflict of commitment and/or interest exists. Outside professional activities usually do not jeopardize the ability of the individual to fulfill the obligations that he or she has assumed by accepting an appointment to the faculty.

Income Derived from Outside Professional Activities

The SOM expects all tenured and tenure track faculty in the basic science departments to reach the minimum standard of extramural salary support (currently 50%) by the end of the third year of employment. Likewise, the SOM expects all faculty members in the clinical departments to have a breakeven or

better balance on their Clinical Faculty Remuneration Plan by the end of their third year of employment. Any participation in outside professional activities should assist a faculty member in meeting these expectations through the establishment of relationships that lead to acquisition of extramural funding.

Prior to approval of or participation in outside professional activities for which compensation is offered, a faculty member must disclose the details of the relationship and obtain written approval of both the department chair and dean in order to either establish or renew a contractual relationship. The faculty member will first complete the “Approval of Outside Activities” form, which their department chair must review and sign, if approved. The faculty member will submit the approved form with the scope of work contemplated and the draft contract to the Assistant Dean for Research Administration for review and approval. The dean’s office will review and respond to the “Approval of Outside Activities Form” within five business days under normal circumstances.²

The faculty member will also be asked to complete and submit the “University of Virginia Principal Investigator Certification on Investigator Conflict of Interest Form” and, if necessary, update the “University of Virginia Annual Disclosure of Financial Interest Related to Research Form” to ensure compliance with University conflict-of-interest policies.

The SOM’s policy on external consulting and professional activities determines how payment is made and received for the professional services rendered. In general, the dean’s review of the proposed activity will take into account the interests and obligations of the SOM, MC, and University, including conflicts of interest and/or commitment, protection of intellectual and other property rights, liability exposure, compliance with Medicare and other regulatory requirements, and departmental financial stability. The dean’s office will notify the PI and department chair in writing if the proposed consultancy is not approved. If the dean’s office approves the proposed activity, the dean’s office will approve payment and administration of the contract via one of the following three options:

Option 1 – Contracts between an Individual Faculty Member and an External Entity

Depending upon the nature of the agreement and with the approval of the department chair and the dean, SOM faculty members may contract directly with outside entities for consulting or other external professional activities one day in seven.

² Note: Consulting Agreements for SOM faculty will be reviewed in accordance with **SOM Consulting Agreement Review Policy and procedure.**

When the faculty member contracts directly with the external entity, he or she will receive 100% of the payment for services rendered. The faculty member may not use any University resources in the performance of the work outlined in the agreement. This includes, but is not limited to, the use of University proprietary information such as trade secrets and patient information, University computers, office space, laboratory equipment, e-mail, internet service, telephone, fax, secretarial support, mail services, and the University name except for professional identification.

The faculty member also assumes full liability for the activity outlined in the agreement, is not protected by the University's insurance coverage, and may not use the services of the University's General Counsel. The SOM recommends that faculty members consult with their own counsel.

Option 2 – Sales and Service Contracts between the University of Virginia and an External Entity

When contracting through the University, the faculty member is not limited to the one day in seven rule outlined above under Option 1. Consulting engagements contracted through the University will be considered either sponsored program activities or sales and service activity. In accordance with federal sponsored research requirements, faculty effort shall be recorded and tracked based on the anticipated amount of effort to be committed to completing the scope of work as articulated in the agreement. Faculty must adhere to SOM policies regarding days away (a maximum of 22 vacation time and 23 for professional days away) when carrying out the work involved in sales and service agreements.

Contracts for external consulting or professional activities will be executed between the University and the party requesting services. The SOM's Office of Grants and Contracts must review and approve any contract to provide outside consulting or professional services³ prior to its execution and an authorized signatory of the University must execute the contract. The faculty member may use University resources such as computer, telephone, fax, email, supplies, and secretarial support in carrying out the contract. As authorized by Va. Code § 2.2-1837, the faculty member will be covered by the State risk management plan while engaged in approved outside activities on behalf of the University.

For Sales and Service Agreements which make minimal use of University resources, a fee equivalent to 20% of the full F&A rate will be assessed. (The current on-Grounds research rate is 51.5% and the sales and service rate for FY08 is 10.3%.) This fee will be reviewed annually and adjustments to it will be incorporated into current policy.

When the University contracts with an external agency for a faculty member to provide professional services, 100% payment for these services will be made to the University. At the chair's discretion, up to 50% of the payment for direct costs

on sales and service agreements may be distributed to the faculty member as an immediate incentive payment if the faculty member has met the minimum standards for extramural salary support or has a breakeven balance or better on the clinical faculty remuneration plan.

Any undistributed income from sales and service consulting agreements will first be used to cover expenses incurred by the department for the use of University resources in carrying out the external work. Any remaining undistributed income may then be used to meet minimum support requirement for basic science faculty or the remuneration plan balance for clinical faculty, or to support research, academic, or other SOM-related professional expenses.

Option 3 – Sponsored Program Agreements between the University of Virginia and an External Entity

The faculty member is not limited to the one-day-in-seven limit on consulting if a contract is executed through the University and it is determined that the proposed activity falls within the definition of a “sponsored program.” Faculty effort will be recorded and tracked based on the anticipated effort committed to complete the scope of work delineated in the agreement. The appropriate facilities and administrative rate will be applied to these agreements.

When the University contracts with an external agency for a faculty member to provide professional services, 100% payment for these services will be made to the University. Compensation related to agreements that fall into the sponsored program category is handled in the standard manner currently in place for all other sponsored program activity.

For both Sales and Service agreements and Sponsored Program agreements, the compensation for external consulting and professional activities contracts must be at fair market value for the services provided. The Office of Grants and Contracts will determine the appropriate fair market value, which must be approved by the Assistant Vice President for Finance and University Comptroller. The services must be reasonable and necessary for a legitimate business purpose of the external entity, and must not involve endorsement or promotion of the entity’s products or services. The term of the contract must be for at least one year, unless the services are limited in duration and not ongoing, such as a single presentation. The faculty member must avoid repeated renewals of short-term contracts (less than a year in length). The contract must describe the particular services to be provided and whether or not the services are to be provided on an ongoing or on an as-requested basis. The faculty member must obtain specific, detailed written requests from the external entity’s authorized representative and must provide copies of such to the Office of Grants and Contracts. Compensation must be calculated based on time increments and associated rates (e.g., \$___ per hour). The faculty member must prepare and maintain documentation of the services provided, on forms that describe the

services and the time spent performing them, in the increments required in the contract, and also document out-of-pocket expenses if covered by the contract. The department must maintain this documentation and submit a copy of it with any consulting incentive payment requests. The SOM and the University Audit Department will conduct periodic audits of supporting documentation.

Activities Exempt from This Policy

The following professional services are not considered consulting activities, and income from such activities may be paid directly to the individual faculty member. The faculty member must report these activities prospectively to his or her chair, who must ensure that participation in these activities will not conflict with a faculty member's primary commitment to the SOM. Faculty members should report these activities to their department chairs annually or on a more frequent basis as determined by each chair. The chair may request that the SOM dean's office review and comment upon such activities. The exempt activities are:

- Per diem allowances and honoraria for lectures and addresses paid for by universities and other educational or not for profit institutions. It is a stipulation that the content for such presentations be independently produced by the individual faculty member making the presentation.
- Royalties received in connection with the writing, illustration, or editing of professional articles and books.
- Royalties received from the University of Virginia Patents Foundation and paid directly to the individual under the University's approved patent royalty distribution formula.
- Per diem allowances and consultation fees received from the federal government or other appropriate funding agencies for service on study sections or other review groups, or other related activities.

The chair and dean must approve in advance all other exceptions to this policy.

Please see the School of Medicine policy 1.220, "Professional Fees Charged to Law Firms," for additional guidelines relating to professional fees charged to law firms.

This policy on exempt activities does not apply to clinical income or consulting activity involving patient care. All clinical income or revenue from patient care related revenue must continue to flow through the Health Services Foundation in accordance with current policy.

Professional Speaking Engagements

School of Medicine faculty are permitted and encouraged to speak at activities approved by an accredited Continuing Medical Education (CME) provider. These activities typically are based on evidence-based content, independently developed and free of commercial bias or influence.

For non-CME eligible presentations, School of Medicine faculty must retain control and authority over professional material they present and must not allow such material to be subject to prior approval by any commercial entity. Faculty should not participate in speaking engagements that would violate these stipulations. The only exception in which a company may exercise control over a faculty member's professional presentation is when the faculty member proposes to use the company's confidential information.

The following are inappropriate:

- Presentations for which the industry sponsor has the contractual right to dictate what the faculty member says or to provide final approval of any content and edits.
- Provision of the presentation materials by the sponsor to the speaker.
- Presentations in which the faculty member will serve as a company spokesperson or otherwise be perceived as one.
- Presentations that include promoting a company's product.
- Presentations that are "packaged" with other promotional activities, such that there is an implied endorsement.

Exceptions to the policy may be granted by the dean of the School of Medicine through the Office of Grants and Contracts.

Disclosure of Outside Professional Activities and Financial Interests

Consistent with the University of Virginia School of Medicine Policy on Conflict of Interest and Conflict of Commitment

<http://www.healthsystem.virginia.edu/internet/about/sompolicies/ConflictsofInterest.pdf> SOM faculty members must disclose to their department chair and the

dean any current or prospective situations that may raise questions of conflict of commitment or interest, as soon as the faculty member is aware of such situations. Further, on an annual basis, SOM faculty with a 50% or greater appointment are required to disclose outside professional activities and financial interests using an electronic, online disclosure system. Details about the system may be found at the SOM Office for Research website:

<http://www.healthsystem.virginia.edu/internet/research/coi.cfm>

Failure to Comply:

Depending upon the circumstances and consistent with University policy, failure to comply with the conditions outlined in this policy may result in actions such as: compensation adjustment, the withdrawal of research privileges, suspension or termination of employment. Procedures are available by which faculty may grieve a disciplinary action. Violations of the Virginia Conflict of Interests Act and federal conflicts and contracting rules carry the possibility of civil fines and in cases of intentional misconduct, criminal penalties.

Forms

These are in the on-line repository, <http://www.healthsystem.virginia.edu/ofr/>.

- University of Virginia School of Medicine Approval of Outside Activities Form
- University of Virginia Principal Investigator Certification on Investigator Conflict of Interest
- University of Virginia Disclosure of Financial Interest Related to Research Form

Related Documents:

- University of Virginia Provost's "Policy on Consulting by Faculty of the University of Virginia," http://www.virginia.edu/provost/docs_policies/consult.html
- University of Virginia Provost's "Conflict of Interests Policy," http://www.virginia.edu/provost/docs_policies/conflict.html
- University of Virginia Vice President for Research's "Objectivity in Research Policy," <http://www.virginia.edu/vprgs/objectivity.html>
- University of Virginia's Policies on Intellectual Property, <http://www.virginia.edu/vprgs/polproc.html#intellectual>
- University of Virginia Financial and Administrative Policies Manual, Policy XI.A.1, "Faculty Overload Responsibilities for Supplemental Compensation," <http://www.virginia.edu/finance/polproc/pol/xia1.html>
- University of Virginia Financial and Administrative Policies Manual, Policy XV.A.1, "Conflict of Interests," <http://www.virginia.edu/finance/polproc/pol/xva1.html>
- University of Virginia Financial and Administrative Policies Manual, Policy XV.G.2, "Use of University Equipment," <http://www.virginia.edu/finance/polproc/pol/xvg2.html>
- SOM policy 2.600, "Conflict of Interest Regarding Faculty Endorsement of Industry," <https://www.healthsystem.virginia.edu/opr/manuals/som/Faculty-Interactions-with-Industry-and-Product-Endorsement-REV-Sept-2006.pdf>
- SOM policy 1.220, "Professional Fees Charged to Law Firms," <https://www.healthsystem.virginia.edu/opr/manuals/som/Professional-Fees-Charged-to-Law-Firms-11-1-06.pdf>

- Medical Center Policy No. 0013, "Vendors/Sales Representatives," <https://www.healthsystem.virginia.edu/opr/manuals/mc/0013-Vendors-Sales-Representatives.pdf>

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