# **External Consulting and Professional Activities**

Date: August 1, 2014 Number: 2.000 Status: Final

### **Contact Office:**

Assistant Dean for Research Administration University of Virginia School of Medicine PO Box 800793 Charlottesville, VA 22908-0793

Phone: 434-924-8426 Fax: 434-924-8725

## **Oversight Executive:**

Dean University of Virginia School of Medicine PO Box 800793 Charlottesville, VA 22908-0793 Phone: 434-924-5118

Fax: 434-982-0874

### Applies to:

Faculty with primary appointments in the School of Medicine

# **Reason for Policy:**

This document outlines the conditions under which faculty may conduct external consulting and professional activities, and describes the requirements for approvals and associated 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 care, 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 supports associations that do not have an adverse impact on a faculty member's primary commitment of time and intellectual energies to the SOM. This policy does not apply to legal testimony or medical services provided by health care practitioners. Those activities are covered by the policies of the Medical Center and the University Physicians Group.

#### **Procedures:**

A faculty member who wishes to engage in external consulting and other professional activities for which compensation is offered must disclose the details of the proposed 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 annually disclose their external financial interests and update the disclosure(s) as necessary throughout the year. A faculty member must disclose to his or her 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 a situation. The related documents listed at the end of this document are incorporated into this policy by reference. It is essential that faculty familiarize themselves with each item on the list in order to ensure appropriate compliance with both the documents and this policy.

### Conflict of Commitment and/or Interest

A faculty member's commitment to the SOM includes a number of responsibilities 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 Grounds, 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 under the basic science faculty remuneration plan. Likewise, the SOM expects all faculty members in the clinical departments to have a breakeven or better balance on their Clinical Faculty Remuneration Plan (CFRP) by the end of their third year of employment. It is expected that any participation in outside professional activities will be consistent with the professional development objectives of the faculty member as well as the missions of the School of Medicine and the University.

Prior to participation in outside professional activities for which compensation is offered directly to the faculty member, the faculty member will first complete the "Approval of Outside Activities" form, which his or her 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. If the payment is to be made to the University, then a Proposal Approval Form ("Goldenrod") should be submitted to the Office of Grants and Contracts; the Approval of Outside Activities form is not needed.

This policy 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, Medical Center, 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, whether compensation received represents fair market value, and departmental financial stability. The dean's office will notify the faculty member and department chair in writing if the proposed consultancy is not approved.

With the approval of the chair and the dean, the consulting activities will be handled either as contracts between the faculty member and external entity, or as sponsored awards, as described below:

Contracts between an Individual Faculty Member and an External Entity
Depending upon the nature of the activity and the amount of compensation, 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 as permitted under appropriate School of Medicine or University policy. For activities with anticipated total compensation of \$2,000 or less per transaction (i.e. initial contract, contract modification) and that do not make use of institutional resources, the associated agreements will be deemed to fall under this mechanism and will be solely between the faculty member the external entity. A department chair may request that such activities be handled as sponsored awards, but the final determination is made by the dean.

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. However, *de minimis* use of telephone and email to coordinate the activity is permitted.

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. Before entering into any such contracts, the SOM recommends that faculty members consult with their own counsel. Although assistance with negotiating the terms of the agreement,

including advice as to its content and interpretation, will not be provided, the Office of Grants and Contracts will provide <u>guidance</u> to mitigate terms that could hinder academic freedom and the faculty member's duties to the University. Examples of problematic terms include confidentiality or intellectual property terms that encroach on the faculty member's research or patient care conducted at the University. The faculty member may also be provided language that should be inserted into the agreement to ensure adequate protections of the University's interests are in place.

It is worth reiterating that the faculty member's chair assumes primary responsibility for reviewing and approving any activity associated with a faculty member's professional responsibilities. A chair has the discretion to disapprove an activity or require that the activity be treated as a sponsored award. Factors such as whether a faculty member has met the requirements of the remuneration plan, or already has substantial outside consulting, will influence the chair's decision.

# Sponsored Program Agreements between the University of Virginia and an External Entity

The faculty member is not limited to the SOM Faculty Travel Days for Professional Activities policy (policy under review, link pending) 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, 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.

A completed and signed Proposal Approval Form ("Goldenrod") will be required.

# Fair Market Value for Services Provided

For Sponsored Program agreements, the compensation for external consulting and professional activities contracts must be at fair market value for the services provided. The institution will confirm appropriate fair market value.

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 meeting. 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 asrequested basis. The faculty member must obtain specific, detailed written

statements of work from the external entity's authorized representative and must provide copies of same to the Office of Grants and Contracts.

#### Other Considerations:

# **Record Keeping**

For consulting treated as sponsored awards, 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. The SOM and the University Audit Department may conduct periodic audits of supporting documentation.

# 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 review and approve a faculty member's professional presentation is when the faculty member proposes to use the company's confidential information.

The following are generally not permitted:

- 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.

### Endorsement of a Commercial Product or Company

A faculty member's apparent or real endorsement of a commercial product or a company must not be associated with any indication of a real or implied similar endorsement by the University of Virginia and/or School of Medicine. Therefore, any endorsement must not contain reference to the faculty member's official University title(s) or the University's or School's name, logo, and/or identifiable visual images of the University (such as faculty photos in front of the Rotunda or use of University letterhead). A disclaimer stating that the views presented in a

document or during a presentation do not represent the views of or an endorsement by the University is preferred. Faculty should evaluate carefully, in consultation with their legal counsel, any proposal involving real or implied endorsement because of the potential for conflict of interest and other compliance and liability concerns. Questions on this matter may also be directed to the Assistant Dean for Research or the Assistant Dean for Research Administration.

### Professional Fees Charged to Law Firms

When a faculty member who is a health care practitioner is contacted by a law firm to provide professional services that are related to patient care activities (i.e., expert witness, etc.), it is recommended that the faculty member contact the General Counsel's office of the University Physicians Group for assistance.

# **Activities Exempt from This Policy:**

Some professional services are not considered consulting activities under this policy, and income from such activities may be paid directly to the individual faculty member. The faculty member must obtain his or her chair's approval for these activities; the chair must ensure that participation in these activities will not conflict with a faculty member's primary commitment to the SOM. Faculty members also 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 on such activities. Faculty may also be required to disclose income from these activities in accordance with School of Medicine requirements (see "Disclosure of Outside Professional Activities and Financial Interests" below). The exempt activities are:

- Lectures and addresses at 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. [Note: A faculty member traveling at the invitation of another institution or organization to deliver a lecture or similar service is not traveling on UVA business and should not be reimbursed for the trip from university funds. If such a trip can be wholly or partially justified as UVA business, however, the faculty member may submit a claim for reimbursement of travel costs in excess of any honorarium, travel allowance or other consideration paid by the host institution/organization. Justification must be provided in writing and must be approved by the department head (or by the dean, if the traveler is the department head).]
- The writing, illustration, or editing of professional articles and books.
- Services provided to the federal government or other appropriate funding agencies associated with study sections or other review groups, or other related activities.

These exempt activities do not include clinical income or consulting activity involving patient care, which are managed by the University Physicians Group in

accordance with current policy.

#### **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 SOM faculty members must report to their department chair and the dean any current or prospective situations that may raise questions of conflict of commitment or interest within 30 days. Further, on an annual basis, SOM faculty are required to disclose outside professional activities and financial interests using an electronic, online disclosure system.

### "Sunshine Provisions" of PPACA:

Under the "sunshine provisions" of the Patient Protection and Affordable Care Act, manufacturers of medical drugs and devices are required to report payments to physicians and teaching hospitals to the Centers for Medicare and Medicaid services. These reported payments will be published on a public website. Faculty should be aware that it is likely any consulting payments will be reported as direct payments to the individual, made to the faculty member or the University. More information about the "Sunshine Provisions" can be found <a href="here">here</a>.

# 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 State and Local Government Conflict of Interests Act of the Code of Virginia and federal conflicts and contracting rules carry the possibility of civil fines and in cases of intentional misconduct, criminal penalties.

### **Related Documents:**

School of Medicine Approval of Outside Activities Form

University of Virginia Provost Policy on Consulting by Faculty of the University of Virginia

Background Information for <u>Exemption Request Conflict of Interest Related to Research or Development</u>

University of Virginia Vice President for Research Objectivity in Research Policy

University of Virginia Policies on Intellectual Property

University of Virginia Financial and Administrative Policy XI.A.1, <u>Faculty Overload</u> Responsibilities for Supplemental Compensation

University of Virginia Financial and Administrative Policies Manual, Policy XV.A.1, Conflict of Interests

University of Virginia Policy PRM-011, <u>Use of Working Time and University</u> <u>Equipment for Personal or Commercial Purposes</u>

School of Medicine Policy 2.001, Policy on Conflict of Interest and Conflict of Commitment

School of Medicine Policy 2.600, <u>Endorsement of External Entities and Products</u>

Medical Center Policy No. 0013, <u>Vendors, Sales and Service Representatives</u>

University Physician's Group Policy, <u>Professional Fees Charges to Law Firms</u>

# **Policy history:**

Created March 1, 2007; revised 10/22/07; 11/21/07; 2/19/09; 4/7/09; 1/7/11, 8/1/14

Nancy E. Dunlap, MD, PhD, MBA

Nancy Enlenlopul

August 1, 2014