

General Guidelines for School of Medicine (SOM) Outside Consulting Agreements

The School of Medicine 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 University and its 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 expert witness, 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. Please make sure that you comply with all University and SOM policies for consulting, including limiting your total days out of the office to forty-five days per year.

These tips are meant to serve as a brief guide to faculty about issues that need to be considered when engaging in outside professional activities.

[Acknowledgement: These tips were taken from Stanford University and Virginia Tech]

Consulting for a company or organization

1. Your primary commitment is to the university, and your individual consulting agreements should not conflict with that obligation, VA State Ethics Law or with any university policies. Make sure that your outside activities are consistent with the performance of all your University duties, including safeguarding the ability of you and other members of the University community to conduct present and future research, education and clinical work free of conflicting commitments or obligations to third parties. Include the following language in all consulting agreements:

“Nothing in this Agreement shall be read or understood to take priority over or restrict Consultants fulfillment of CONSULTANT’s primary obligations to teaching and/or clinical care and research for University of Virginia”

2. You must ensure that your consulting agreements explicitly recognize that the title to all potentially-patentable inventions conceived, or first reduced to practice, in whole or in part, in the course of your university responsibilities, or with more than incidental use of university resources, must be assigned to the university. This means that your consulting agreements must not grant to outside entities access to ideas that did not arise as a direct result of your consulting activities or that would be deemed an extension of your university activities.
3. You must not provide the company or organization with early or exclusive access to results of your University of Virginia research, unless approved by the Office of Sponsored Programs.

4. Your consulting activities need to be as separate from your research as possible, so that these activities are not seen as an extension of your sponsored research at University of Virginia.
5. Your consulting agreements must not delay or prohibit publications resulting from your University of Virginia research.
6. The scope of your consulting responsibilities needs to be very specific so that it does not grant the company or organization access to work not done under the consulting agreement or interfere with intellectual property disclosure or publications resulting from your academic work.
7. Remember that a consulting agreement is a legal document often drawn up by the company's or organization's lawyers. You may wish to have an attorney act as your advocate and review any legal documents you sign. University legal counsel or other personnel cannot act as your advisor.

It might be helpful for you to provide the company or organization with a copy of the University of Virginia **RES-001: Ownership Rights in Copyrightable Material and RES-006 Patenting of Discoveries or Inventions at the University (Patent Policy)** You must disclose your relationship with the company or organization in publications and public discussions of any of your research that is sponsored by the company or organization or related to it.

Service on a Scientific Advisory Board

1. You are permitted to sit on a Scientific Advisory Board (SAB) because such a position normally does not carry, nor is it perceived to carry, management responsibility. However, your primary commitment is to the university, and your service on an advisory board should not conflict with that obligation or with any other university or college policies.
2. It is advisable to have a formal consulting agreement when serving on a SAB.
3. Sometimes service on an advisory board is rewarded with stock or stock options. Since such equity can compromise objectivity, it always needs to be disclosed. Concern is heightened if human participants are involved in studies of the entity's products or service. Compensation in any form must be assessed for commercial reasonableness and fair market value.
4. You must not provide the entity with early or exclusive access to the results of your research, unless approved by the Office of Sponsored Programs.
5. You must keep your financial interests arising from service on advisory boards separate from your research and university obligations in order to:

- Protect your students, trainees, and others whom you are responsible for directing, from undue influences or the compromise of academic freedoms;
- Preserve the integrity of your research;
- Cause no harm to human participants in your research;
- See that any creations or discoveries that arise during the course of your research or scholarly activities at Virginia are not "pipelined," defined as passed along at an early stage or by privileged access to the company or organization, and are disclosed in a timely fashion to Virginia Intellectual Properties; and
- Avoid compromise to the free exchange of ideas or delay or prohibit publications arising from your university activities.

6. You must disclose your relationship with the company or organization in publications and public discussions of any of your research that is sponsored by the company or organization or related to it.

Service on a Board of Directors

1. Service on a Board of Directors carries legal fiduciary responsibility but generally not line management responsibility; hence, such service is generally permissible. However, your primary commitment is to the university and your service on a board should not conflict with that obligation or conflict with any other university or college policies.
2. Your relationship to the company should not interfere with your primary obligations as a faculty member or university employee. The time devoted to service on a board should be counted as consulting time in ensuring you are in compliance with the university's limits on external consulting activity.
3. You must keep your financial interests arising from service on a Board of Directors separate from your research and university obligations in order to:
 - Protect your students, trainees, and others whom you are responsible for directing, from undue influences or the compromise of academic freedoms;
 - Preserve the integrity of your research;
 - Cause no harm to human participants in your research;
 - See that any creations or discoveries that arise during the course of your research or scholarly activities at Virginia are not "pipelined," defined as passed along at an early stage or by privileged access to the company or organization, and are disclosed in a timely fashion to University of Virginia Licensing and Ventures Group; and

- Avoid compromise to the free exchange of ideas or delay or prohibit publications arising from your university activities.
4. You must disclose this relationship in publications and public discussions of any of your research that is sponsored by the entity or related to the entity.

Compensation

1. Review the level of compensation for commercial reasonableness and fair market value. UVA General Counsel defined as “safe harbor” income that does not exceed \$500/hour. Compensation above this level may be approved if the consultation sought by the company is extremely specialized. (NOTE: Faculty receiving approval for compensation above \$500/hour probably will consider that approval as precedent for future agreements.) If unsure of whether the level of remuneration >\$500/hour is appropriate, review that faculty’s prior agreements and/or request detailed justification for the higher level of compensation. Equally important, arrangement with compensation arrangements far below commercial reasonableness call into question the nature of the relationship and may imply unfair dealing.
2. In general, do not allow compensation to be structured via a fixed retainer, as it renders impossible an evaluation of Fair Market Value. A fixed payment may be approved if the faculty member can provide a reasonable accounting for his/her time such that the hourly rate is consistent with the above UVA guidelines. *Example of such a justification:* consultant to paid 1000 € (\$1200) per month for one year. Faculty will spend 8 hours of prep work and 10 hours per quarter (total: 48 hours over the year). Approximate payment: \$300/hour.
3. Ensure that if you are promised royalties as some or all of your compensation in an agreement that:
 - Your invented or authored royalty bearing intellectual property is claimed in a patent application or issued patent, or protected by copyright, if software. Your records or the agreement itself should provide for the specific and detailed identification of the intellectual property on which you will be paid royalties by enumeration of the patent number, patent application serial number or copyright registration number; or,
 - If for royalty bearing intellectual property that is not the subject of a patent, patent application or copyright, you should not receive royalties as any part of your compensation unless the company provides: (a) a written and detailed description of the process used by the company to confirm that you have made a verifiable and valuable contribution of intellectual property to the design and/or development of the royalty-bearing product, and (b) an attestation based upon the findings of that process that the royalty rate being paid to you is consistent with the fair market value of such intellectual property.
 - You obtain and maintain records of royalty payments made to you, including the royalty rate and underlying sales figures.

4. Things not to do for compensation:

- Accept cash compensation for consulting services in excess of fair market value which may vary according to your subspecialty and ordinarily should not exceed \$500/hour.
- Accept royalties unless for products or services sold by the company that embody your intellectual property as defined in a patent, patent application or copyright; or where you have obtained a company attestation of your contribution of intellectual property and its fair market value in terms of the royalty rate, as described above.
- Accept royalty payments for your performance of defined services (e.g., consulting, advisory, product review, etc.) provided to the company; royalties should only be for verifiable intellectual property that you have contributed to specific products and services.
- Accept royalty payments that are based on a flat fee, or that are a minimum guaranteed amount.
- Accept advances on royalties.
- Accept compensation for services, whether denominated as "consulting" or otherwise, involving the performance of your commitments to UVA, such as:
 1. Teaching (including preceptorships or visiting surgeons) in the operating rooms of University-affiliated hospitals

Ownership of stock or stock options

1. Be aware of the value of your stock or stock options so that you can report this accurately on an annual basis through the **COI System**, or on any disclosure during the year. If the company is publicly traded, the market value of the equity is estimated at its highest point during the reporting period; non-publicly traded equity including stock options are reported regardless of their market value.
2. Equity can raise the issue of such incentives compromising objectivity, particularly where human subjects are involved.
3. You must disclose this relationship in publications and public discussions of any of your research that is sponsored by the company or related to the company.

Technology licensing arrangements

1. As a university employee, the title to all potentially patentable inventions conceived, or first reduced to practice, in whole or in part, by you in the course of your university responsibilities, or with more than incidental use of university resources, must be assigned to the university. See university RES001 and RES-006
2. The university must avoid conflicts of interest in licensing technology to a company in which the inventor has a financial interest; thus it is in everyone's best interest if the

inventor maintains a cordial and willing attitude in working with whatever company ends up licensing the technology or discovery.

3. New developments relating to this intellectual property must also be fairly licensed, and you must not preferentially pass or "pipeline" intellectual property or unpublished research results derived from other funding sources, such as NSF, NIH, or another company or organization, to a company in which you have a financial or founding interest.
4. You must disclose this financial interest in publications and public discussions of any of your research that is sponsored by the company or related to the company.

Founding a company

1. It is assumed that you have both an intellectual and financial commitment to the company; however, your primary commitment is to the university and your commitment to the company should not conflict with that obligation or conflict with any other university or college policies. While you are on sabbatical leave (full or part pay), you are a University of Virginia employee. When you are on a leave of absence without pay, you are not a University of Virginia employee.
2. You must not provide the company with early or exclusive access to the results of your research, unless approved by the Office of Sponsored Programs.
3. You must keep your financial interests arising from service on a Board of Directors separate from your research and university obligations in order to:
 - Protect your students, trainees, and others whom you are responsible for directing, from undue influences or the compromise of academic freedoms;
 - Preserve the integrity of your research;
 - Cause no harm to human participants in your research;
 - See that any creations or discoveries that arise during the course of your research or scholarly activities at University of Virginia are not "pipelined," defined as passed along at an early stage or by privileged access to the company or organization, and are disclosed in a timely fashion to University of Virginia Intellectual Properties; and
 - Avoid compromise to the free exchange of ideas or delay or prohibit publications arising from your university activities.
4. You must disclose this relationship in publications and public discussions of any of your research that is sponsored by the entity or related to the entity.

Establishing a loan with a company

1. Indebtedness from a loan might compromise or be perceived as compromising your objectivity.
2. You must disclose this relationship in publications and public discussions of any of your research that is sponsored by the company or related to the company.

Giving talks for a company

1. Don't become a spokesperson for the company or its products or services.
2. Remember that honoraria can be used as incentives, and incentives can compromise objectivity.
3. Keep your talks fair and balanced; i.e., don't just talk about the company's product.
4. If you are paid to give a talk, you need to disclose this to the audience during your talk, as well as disclose this in publications and public discussions of any of your research that is sponsored by the company or related to the company.
5. 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.
6. 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.

Do not accept compensation for presentations of talks, abstracts or posters written solely by the company (SOM COI Policy, Appendix III)

Accepting gifts from a company

Individuals cannot receive gifts for doing their university work. This is a violation of the Code of Virginia. Gifts to University of Virginia, or to the University of Virginia Foundation, from a company or industry can include such things as equipment or supplies, travel for trainees, or unrestricted research support. The important thing to remember is that there may well be an expectation on the part of the donor for a specific deliverable or early access to research results in response to a gift. It is important to communicate clearly that such expectations cannot be met. If you have a financial relationship with the company, gifts create a conflict of interest that must be disclosed.

1. Faculty must use university and Foundation procedures to document the terms of all gifts so your freedoms are protected and the exact nature of the exchange is spelled out. See University policies (***FIN 019 & EXT-005, EXT-008***)
2. Corporate gifts for educational activities should not create a venue for access to research results, an opportunity for promoting a company's product or products, or provide the company with preferential treatment.
3. Unrestricted gifts for research support are donations and as such, the company receives no intellectual property rights or access to research results. Such gifts should not be accepted when specific research activities are targeted for the gift money by the donor. A gift may not have a 'scope of work' or other deliverable. Situations in which you have sponsored research as well as a gift from the same company can create problems because there may be a tacit expectation that the gift will be used to support the same work as the research contract and it may be difficult to sort out intellectual property ownership.