General Guidelines for School of Medicine Option 1 Consulting Agreement Guidelines

Revised and approved ***

Per the <u>SOM policy on External Consulting and Professional Activities</u>, Option 1 consulting agreements are contracts between an individual faculty member and an external entity that require prior SOM approval. The University is not a party to Option 1 consulting agreements. The following are guidelines and best practices to protect the interests of the University and help you comply with its policies. They are not intended as legal advice to you. Please consult your personal attorney for advice concerning your consulting agreement.

Do:

- 1) Comply with all <u>University</u> and <u>SOM</u> and any other policies for consulting, including limiting your total days out of the office to forty-five days per year.
- 2) 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 CONSULTANT'S fulfillment of CONSULTANT'S primary obligations of teaching and/or clinical care and research for the University of Virginia."
- 3) Make sure all your consulting arrangements, including all product development arrangements, are in writing and signed by the company. Include a clearly defined scope of work in any consulting agreement.
- 4) Remember that your consulting obligations are yours and yours alone in your individual capacity and not as an employee or faculty member of UVA, and may subject you to substantial personal liability. Seek out legal advice from your personal attorney for all your consulting arrangements if you have any questions or are unsure of any obligation in such agreements.
- 5) Include the following language in all Consulting Agreements clarifying the personal, noninstitutional nature of such services:
 - "Notwithstanding anything herein to the contrary, Company agrees that CONSULTANT serves Company under this Agreement in his individual capacity, as an independent contractor, and not as an agent or representative of University of Virginia ("Institution"), that Institution exercises no authority or control over CONSULTANT while acting in such capacity, that Institution receives no benefit from such activity, that CONSULTANT and/or Company cannot and will not make use of Institution resources or Institution managed funding in acting in such capacity, that Institution is not a party to this Agreement, and that Institution makes no representations or warranties under this Agreement and assumes no liability or obligation in connection with any such work or service undertaken by CONSULTANT. Company further agrees that any breach, error, or omission by CONSULTANT acting in such capacity or otherwise under this Agreement, shall not be imputed or otherwise attributed to Institution. Moreover, nothing in this Agreement shall be read or understood to encumber, in any way, any intellectual property that Institution claims ownership of through the Institution's Intellectual Property Policy as such may be amended from time to time."
- 6) Comply with all aspects of the UVA policies on <u>patents</u> and <u>copyrights</u>, including the obligation to disclose intellectual property to the UVA Patent Foundation so it can determine whether UVA can and will assert ownership of such intellectual property.

- 7) Ensure and document (see below) that all compensation in whatever form (cash, equity, royalty, etc.) received is at no more than fair market value for the services rendered or intellectual property transferred.
- 8) Keep careful time records (activity logs) of all consulting activities.
- 9) Report/disclose all of the following consulting arrangements and other financial relationships with industry:
 - Income from the entity that is greater than \$10,000 in the past 12 months (within 30 days, using the SOM on-line reporting system)
 - An ownership stake in the entity greater than 3% (within 30 days, using the SOM online reporting system)
 - Financial relationships associated with approved or pending IRB protocols (immediately, to the cognizant IRB)
 - Financial relationships associated with federally funded research (immediately, to the Assistant Dean for Research)
 - In publications (journals, abstracts) and presentations at scientific meetings
- 10) 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.

Do not:

- 1) 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.
- 2) 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.
- 4) Accept royalty payments that are based on a flat fee, or that are a minimum guaranteed amount.
- 5) Accept advances on royalties.
- 6) Accept compensation for services, whether denominated as "consulting" or otherwise, involving the performance of your commitments to UVA, such as:
 - Teaching (including preceptorships or visiting surgeons) in the operating rooms of University-affiliated hospitals

- Patient care activities
- Research conducted under the auspices of UVA (e.g. conducted with significant University resources or pursuant to a research grant or contract administered by the University)
- Authorship of journal articles published in non peer-reviewed or peer-reviewed journals reporting research conducted under the auspices of UVA
- 7) Accept compensation for the prescription, implantation or other use of any company's drugs or devices in the course of UVA patient care activities.
- 8) Accept compensation for presentations of talks, abstracts or posters written solely by the company (<u>SOM COI policy</u>, Appendix III).

Policies related to SOM research can be accessed at http://www.medicine.virginia.edu/research/research-offices/office-for-research/home/policies/policies-1.

This document was modified, with permission, from "Consulting Agreement Guidelines - Do's and Don't's (Faculty Physicians)" (source: Washington University in St. Louis, http://provost.wustl.edu/node/108, accessed August 19, 2010).