GENERAL OVERVIEW GUIDANCE AND ADVICE FOR FACULTY WHO ENGAGE IN OUTSIDE CONSULTING

Introduction

The University of Rochester supports and encourages outside consulting relationships, as such relationships often provide both valuable experience to the faculty in their research and teaching activities, and public benefit to the community. However, it is important to navigate the activities and terms of consulting agreements to conform with University policies that are intended to protect the rights of the University and its faculty.

This General Overview is offered to provide advice and guidelines for faculty regarding some of the key aspects of their consulting arrangements, including how they relate to the faculty's obligations to the University regarding intellectual property, conflicts of interest, and the legal and practical implications of the terms and conditions often contained within consulting agreements.

Relevant Policies

Faculty members are responsible for complying with University of Rochester policies in the course of their consulting activities. Policies implicated in outside consulting include:

<u>Faculty Handbook – Policies on External Activities Related to Research and Scholarship</u>: This policy sets general limitations and provides parameters on outside consulting arrangements. Under this policy, full-time faculty are generally permitted to consult for up to one day per week on average, provided these activities enhance, and do not reduce, their ability to meet their responsibilities to the University.

<u>SMD Regulations of the Faculty</u>: This policy sets similar limitations and parameters specific to faculty in the School of Medicine & Dentistry, and further provides that outside consulting by SMD faculty is limited to non-clinical consulting. Any clinical effort by full time SMD faculty for a third party would be under a University contract as required by the SMD Clinical Faculty Compensation Plan.

<u>Conflict of Interest Policy</u>: This policy establishes the procedures to be followed when a faculty member has or may appear to have a potential conflict of interest between a consulting role and a University role. The policy outlines the requirements that each faculty member report their outside financial interests to the University annually, and update such disclosures within 30 days of receiving certain outside compensation, in the University's online reporting portals or forms, and disclosure in RSRB applications. In addition, management strategies may be required if the faculty member conducts sponsored research at the University, which may include limitations on the faculty member's role in the study. Certain financial interests must be reported to federal research sponsors.

Intellectual Property Policy: Pursuant to this policy, and consistent with federal law, all faculty are required to assign intellectual property rights created using significant use of University Resources and Institutional Works to the University. In accordance with these University and federal requirements, faculty are required to sign the University's Intellectual Property Agreement upon hire. Consulting agreements should not purport to convey to the company any rights to any intellectual property developed using University facilities, developed under grants or contracts awarded to the University, or conceived or first reduced to practice while working for the University.

Interactions between the University of Rochester Medical Center (URMC) and the Pharmaceutical, Biotech, Medical Device, and Hospital Equipment and Supplies Industries ("Industry"): This policy establishes guidelines for interactions with Industry representatives for all Personnel of the University of Rochester Medical Center and requires a written contract with a defined scope of work and confirmation that payments are fair market value. It also defines acceptable criteria for speaking engagements, prohibiting certain types of speaking engagements that are or may appear to be promotional.

<u>Simultaneous Appointments Policy</u>: This policy defines when outside and simultaneous appointments are acceptable, and establishes a process for their review and approval. Simultaneous appointments are not considered "Outside Consulting" and faculty considering these should consult that policy.

International Research and Global Collaboration - Guidance for the University of Rochester Community: This document provides guidance on issues to be considered and actions required when collaborating with international entities.

Guidance on Faculty Member Consulting

- <u>Discussion with Chair</u>. The general scope and time requirements of outside consulting arrangements should be discussed with the faculty member's department chair prior to the engagement and periodically throughout the engagement, especially if the consulting role changes. See the Consulting Policy contained in the UR <u>Faculty Handbook</u> and the SMD <u>Regulations of the Faculty</u>.
- 2. Use of University Resources. Faculty members may not use facilities, equipment, materials, funds, specialized technical resources and core facilities, personnel or similar resources of the University in the consulting activities. They may use University telephones, email accounts, desktop and laptop computers and software programs that are generally available to the University community, and library resources (but not library personnel), so long as the use is reasonable in duration and frequency, does not compromise the security or integrity of University property, information or software, and does not violate any other University policy. Note that while use of University email accounts is not prohibited as a matter of policy, faculty are encouraged to avoid using University-owned or controlled email accounts, cloud accounts and other electronic resources for outside consulting activities because information communicated through or stored in such accounts cannot be considered private or confidential, which may violate the terms of the consulting agreement. Access to information communicated through or stored in University electronic resources may be limited or unavailable in the event the faculty member leaves the University or their appointment ends. See also the Guidance for UR Research Community on Significant Use of University Resources and Intellectual Property Ownership.
- 3. <u>Engagement of Students and Trainees</u>. The faculty member may not engage or employ students, post-doctoral fellows or similar researchers to provide services under the consulting arrangement without the prior consent of the department chair and/or school's dean/director for graduate studies. Refer to the <u>Guidelines on Research Integrity and Conflict of Interest: Graduate Students and Postdoctoral Appointees.</u>

- 4. <u>Private Agreement</u>. The consulting agreement is a private agreement between the faculty member and the company. It should not be in the University's name, use the University's address or other contact information, or direct payments to the University. Note that the University has no responsibility for the faculty member's compliance with the terms of the agreement or the performance by the faculty member of the consulting services. Faculty should seek review of any proposed arrangement by personal legal and tax advisors.
- 5. <u>Use of University Name</u>. Neither the faculty member nor the company for which they consult may use the University's name or logo in connection with the consulting services, except in describing the faculty member's credentials or title. Faculty should avoid using the University's letterhead in communications related to their consulting. If they do so, they must include an express written disclaimer stating that "This communication, the underlying work, and all opinions contained herein, are solely performed and made in my individual capacity as a consultant, and are not formal or informal statements or opinions made by or on behalf of the University of Rochester."
- 6. <u>Confidentiality of University's Proprietary Information</u>. The faculty member may not disclose to the company information that is proprietary to the University and not generally available to the public, such as inventions and other intellectual property that is not subject to patent protection, unpublished research results, and other similar data. Consulting activities must be consistent with the <u>Intellectual Property Agreement</u> signed by all faculty members.
- 7. <u>Research Activities</u>. Consulting relationships that faculty generally enter into are for services to the outside entity, and are generally not permitted for the conduct of research. Note that consulting that involves research may entail additional considerations and concerns, such as overlap with the faculty members' University research portfolio. Research conducted under consulting time must be reported to federal funding agencies in the other support statements. Consult with the applicable Dean's office or ORPA prior to taking on outside research obligations.
- 8. <u>Office of Counsel Review</u>. Consulting agreements received from outside entities often include provisions that may result in violations of University policies, but can typically be negotiated to conform to such policies. Faculty are encouraged to submit proposed consulting agreements to the Office of Counsel for advice on any changes necessary to ensure consistency with University policies. The review provided will not otherwise constitute legal or other advice on the terms of the consulting agreement, and University personnel will not be responsible for negotiating the terms of consulting agreements on behalf of faculty members. However, the Office of Counsel does often identify terms that may affect intellectual property rights, limit the faculty member's activities, or otherwise conflict with the faculty member's other obligations.

Consulting Agreement Terms of Potential Concern

This section highlights some issues that could arise in the course of a specific consulting arrangement that might be of concern or interest to the consultant.

1. <u>Scope of Work</u>. The agreement should always include a defined scope of work. The scope of work should be closely tailored to the work the consultant expects to perform. A definition of services

to be performed stating "the consultant shall provide such services as may be requested by the company from time to time" or "the consultant shall provide services to the company in the area of cancer research" is too broad.

- 2. <u>Compensation</u>. Faculty are responsible for ensuring that the compensation under consulting arrangements is fair market value. This is a particular concern for physicians and other clinicians who consult for companies that manufacture drugs or devices they may prescribe or provide to their patients, to avoid violating anti-fraud and abuse laws and regulations. Retainer agreements, while often an efficient mechanism for compensating certain arrangements, should be evaluated carefully. Companies may contract to pay for consulting or other services under a retainer, but then do not require any services, or only minimal services. This can be construed as payment intended to promote patient referrals, resulting in fines and sanctions against the companies and the clinicians. It is also important to avoid retainer arrangements that are intended only as a mechanism for obtaining an endorsement, for example, payment for serving on a scientific advisory board where no or minimal services are required. Faculty are encouraged to ensure that retainer arrangements include a defined scope of work, and to terminate them if a meaningful degree of work is not required within a reasonable period of time (e.g., up to one year).
- 3. Intellectual Property Ownership. Often outside consulting agreements require assignment of inventions and other intellectual property to the company. It is important to note that such terms, if drawn too broadly, may impede the University's ability to demonstrate its ownership of IP, its ability to license its IP rights to other companies, and its compliance with the requirements of the Bayh-Dole Act. This is especially of concern when there is overlap between the subject of the consulting arrangement and their University responsibilities or research programs. Faculty should thus use caution when presented with agreements that assign rights to inventions related to the consulting activity to the company. In particular, faculty should ensure that the scope of work is sufficiently narrow in describing the consulting activities, to avoid any appearance of overlap with their University responsibilities or research programs. Faculty should also avoid assigning rights to inventions that may result from activities outside of the scope of work, or that will or may be created with significant use of University resources. Faculty should also ensure that the agreement does not potentially jeopardize current or future University research programs by ensuring that the definition of inventions and IP assigned to the outside entity are limited to those created in the course of performing the consulting activities. Faculty are encouraged to seek advice from the Office of Counsel or UR Ventures if the consulting activities are or may appear to be related to University IP or to their University research or other activities, because

Also, faculty may wish to avoid or limit the application of any provision that assigns the company as the faculty member's "attorney in fact" for purposes of signing patent applications or other documents. Further, faculty may wish to ensure that any assistance they are required to provide in support of patent applications or other protection of the company's IP rights are at the company's expense.

Faculty members should note that the University's Intellectual Property policy requires that they disclose all inventions conceived or reduced to practice in the course of their responsibilities or using any University resources to the University, even if the faculty member believes they should be owned by the company.

- 4. <u>Confidentiality</u>. Consulting agreements often require that consultants keep the company's proprietary information confidential. Faculty should ensure that the definition of confidential information is narrowly defined to the information shared by the company for the purposes of the consulting arrangement. The definition should exclude publicly available information, information known to the faculty member through other means, and information the faculty member is required to disclose as part of legal proceedings. Faculty should understand precisely what information is to be kept confidential, and the obligations required to protect the information from disclosure. It would be prudent to require any information the company wants to be kept confidential to be clearly marked to indicate that it is confidential.
- 5. Indemnification ("Hold Harmless") and Limitation of Liability.

<u>General Comments on Liability</u>. Consulting for a company is a private matter between the consultant and the company. The University's general insurance coverage, including workers' compensation, general liability insurance, and the professional liability coverage provided to Medical Center faculty, does not cover outside consulting work. Faculty who sign agreements imposing potential liability on them should consider obtaining professional liability insurance to cover such liability.

<u>Indemnification</u>. Agreements may impose an obligation on the faculty member to indemnify the company in the instance of a lawsuit or claim related to the consulting activity. Faculty are encouraged to remove such provisions from the contract. In situations where the consulting activity could lead to liability for the consultant (e.g. consulting on the design of a medical device or greater than minimal clinical trial), the faculty member may wish to request that the company indemnify (or "hold harmless") the faculty member for any third party action or similar claim related to the consulting services. In other words, if a third party believes it was injured by the company's product/service and sues the company, the consultant could also be sued. An indemnification obligation by the company would require the company pay the consultant's defense costs and, in some circumstances, any resulting liability.

<u>Limitation of Liability</u>. The consultant will likely have little or no control over how the advice or services provided are incorporated into the company's business or products. Faculty are advised to include a provision in the consulting agreement that the consultant's liability is limited to his/her [gross] negligence or willful misconduct. The agreement should also expressly disclaim any liability of the consultant for any product produced by the company.

- 6. <u>Exclusivity or Non-Compete Provisions</u>. Faculty should remove any provision that attempts to restrict their provision of advice or services to other companies or organizations, or that would restrict any work within the University. There should be no restriction on the consultant's research activities.
- 7. <u>Tax Issues.</u> The consultant is an independent contractor for the company, therefore will NOT be paid as an employee. Specifically, there will be no income tax or social security tax (FICA) withheld from the consulting fee. The consultant will receive an IRS Form 1099, which is used by the company to report the consultant's income to the government. The consultant is responsible for

ensuring payment of taxes on that income. Faculty may wish to consult with their tax advisor to ensure proper reporting of the income and payment of applicable taxes.

If there are still questions after reviewing this Guidance, faculty are advised to consult with their Department Chair or supervisor, or their school's dean or associate dean for research. Further questions may be referred to the appropriate University office (e.g., <u>UR Ventures</u>, <u>ORPA</u>, Office of Counsel).

Please note that this document provides advice about ensuring compliance with University policies, and does not constitute personal legal advice. Faculty are also encouraged to consult their personal attorney for legal advice.