

June 13, 2008

Memorandum

To: School of Medicine Faculty

From: Arthur Rubenstein, Dean of the School of Medicine
Glen Gaulton, Executive Vice-Dean and Chief Scientific Officer

Re: Consulting Arrangements

The University has long recognized the value to the institution and to the faculty of permitting faculty members to engage in extramural consulting activities, as long as these activities do not adversely affect the faculty member's responsibilities to PENN Medicine. Avoiding conflicts of interest in the conduct of these activities is an obligation of all faculty. Over time, we have seen a significant increase in the number and complexity of consulting arrangements – arrangements that may strengthen the expertise of the faculty and lead to important inventions and/or to making scientific and medical breakthroughs. In the rapidly evolving environment in which we work, both from a scientific perspective as well as an institutional one, these arrangements often raise unique issues and challenges, which must be carefully considered in light of our foremost responsibility to ensure the integrity of our research effort and to avoid even the appearance of a conflict of interest. Given this responsibility, and our obligations to the University and to our School, we need to make certain that the University of Pennsylvania's policies and procedures with respect to consulting arrangements are followed appropriately. We need to also ensure, in a parallel manner, that the conduct and supervision of these items is equitable and timely. To remind and better educate everyone about our policies, a summary of the most significant considerations appears below.

1. **Conflict of Interest.** All consulting agreements need to be reviewed to make sure that (1) the financial terms do not give rise to a conflict of interest, and (2) all appropriate disclosure to patients and others is made in a timely fashion. Because of the obvious potential for a conflict, it is particularly critical to establish full transparency of this information, including the amount of consulting income, in those instances where a faculty member is engaged in clinical research. These items must be reported both to the department Chair and to the IRB for any relevant protocol when requesting approval, and reported in the annual extramural reporting review form from the School.
2. **Review of Agreements.** All faculty extramural consulting agreements must be submitted to the appropriate department chair for approval prior to entering into any agreement. The purpose of this review is to make sure that the agreement is consistent with University policies – in particular: conflict of interest, conflict of commitment, intellectual property, confidentiality, and the use of the University's name and property. To support the chairs and make the process as expeditious as possible, the Office of Corporate Alliances has a dedicated staff (Kelly Curran) who will review the agreements to make sure that they are consistent with University policies. It is important to remember, however, that neither Kelly nor anyone else at the University can provide personal business or legal advice to the faculty member in the course of the review. Faculty members should understand that whatever personal risks or liability that might result from the consulting arrangement– these risks and liabilities are their responsibility to consider and address.

3. **Acknowledgement of Faculty Member Obligations.** In order to make clear that the company or other outside entity understands that the consultant has pre-existing obligations as a faculty member, all agreements must include a provision which specifically acknowledges that the consultant is a faculty member subject to University policies.
4. **Confidentiality.** Typically, a company will want to disclose proprietary information to the consultant and will want assurances that this information will be kept confidential. In order to ensure that you understand precisely what information is confidential, the agreement needs to define “confidential information” to include only that information that is identified in writing as confidential. It also should include exceptions to permit disclosure of information that is publicly available, known by the faculty member before disclosure, independently developed by the faculty member, or as required by law.
5. **Publication.** Nothing in the consulting agreement may prevent or restrict the faculty member from publishing research conducted in his /her capacity as a faculty member of the University.
6. **Intellectual Property.** Increasingly, outside consulting agreements include a provision that requires assignment of inventions and other intellectual property rights to the company. Under the University patent policy, however, the general rule is that all intellectual property developed under a consulting agreement or otherwise is owned by the University and subject to our patent policy. There are limited exceptions in cases where all of the following are met: (1) the engagement is consistent with the University conflict of interest policy; (2) no student or trainee is involved in the engagement; (3) compensation does not include royalties or equity and the faculty member does not have a significant equity interest in the company; (4) performance of the consulting engagement must not involve the substantial use of University resources; and (5) the engagement may not conflict with any other sponsored research commitments of the faculty. If applicable, all such requests must be disclosed and approved in advance by the Dean, as well as the Department Chair. In no case, however, may faculty members give away any intellectual property or data generated in any of their Penn research programs.
7. **Use of University Name.** While it is appropriate for faculty members to refer to their affiliation with the University, it is important that no agreement suggest in any way that the University endorses the activity. For example, the agreements should provide that the company will not use the faculty member’s name for any marketing effort or in any way that implies University endorsement of a product. Any use of the University’s name, other than the above noted affiliation, requires a formal request to the Office of the University Secretary.
8. **General Comments on Liability.** Some contracts require that consultants demonstrate that they are adequately insured to cover any liability that may result from performance of the consulting services. Please be aware that consulting work for a company is a private matter between the consultant and company. As a result, the University’s general liability and professional malpractice insurance, which is available to the faculty in the role of an employee of the University, does NOT apply to cover consulting work.
9. **Exclusivity or Non-Compete Provisions.** Exclusivity provisions should be carefully reviewed so that they do not in any way restrict the academic freedom of the faculty. Some provisions may limit what the faculty member can do within the University, such as non-compete clauses. An example is language that prohibits a faculty member from conducting any work for a

competitor. Such a provision could prevent the faculty member from working on University research or other scholarly activities: this violates a primary tenant of academic freedom, and may conflict with the performance of University duties.

10. **Use of University Resources.** University resources may not be used to fulfill duties under a consulting agreement. Incidental use of computers, email, and phones is generally considered permissible provided this use does not interfere with University obligations or activities.

The very conduct of our work, in patient care, biomedical research and education necessitates that the School of Medicine and its faculty take a leadership role in the disclosure and conduct of private consulting arrangements. As noted above, to expedite these processes we recruited Kelly Curran in the Office of Corporate Alliances to work on behalf of the Chairs in reviewing these arrangements, and to respond to your questions. Vicki Mulhern in the Office of Faculty Affairs, and Wendy White and Lee Dobkin in the Office of General Counsel are also ready and willing to help with any questions you have. Nevertheless, we recognize that the complexity of these arrangements often adds time to the approval process. We hope that we have better positioned you to both better manage consulting agreements and to preempt delays in their approval by clarifying the University's expectations for consulting arrangements. We are also reviewing our current means for approval of consulting arrangements with the Chairs and staff to further refine and expedite these processes.

Lastly, we should not lose sight of our obligations as faculty of the University. We must recognize that consulting activities carry certain intrinsic risks, which have the potential for diverting the University and its faculty from their primary educational, research, and service missions. Our policies were established to ensure that faculty have a means to conduct these activities in accordance with the University conditions and regulations of appointment. Accordingly, failure to follow these policies will be addressed in the most serious manner.