

TIPS FOR MANAGING YOUR OUTSIDE PROFESSIONAL RELATIONSHIPS IN ORDER TO AVOID CONFLICTS OF COMMITMENT AND INTEREST

Stanford faculty owe their primary professional allegiance to the University, and their primary commitment of time and intellectual energies should be to the education, research, and scholarship missions of the institution. Outside professional activities can result in allocations of time and energies which represent conflicts of commitment. In addition, these activities can result in conflicts of interest when there is a divergence between an individual's private interests and his or her University obligations, such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation, and not on the character or actions of the individual.

Faculty members should conduct their affairs so as to avoid conflicts of commitment and avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. Disclosure of such interests is required under University policy. The complete set of University and School of Medicine policies concerning conflicts of commitment and interest and related areas can be found at the following web sites:

<http://www.stanford.edu/dept/DoR/rph/Chpt4.html>

- the relevant chapter of Stanford's Research Policy Handbook

<http://www.stanford.edu/dept/DoR/rph/4-3.html>

- Stanford's policy on faculty consulting

<http://med.stanford.edu/rmg/conflict.html>

- Medical School policies and resources

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

1. If you **CONSULT for company/organization:**

- a. Your primary commitment is to the University and your individual consulting agreements should not conflict with that obligation or with any University or School policies.
- b. You need to ensure that your consulting agreements explicitly recognize that 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.
- c. You must not provide the company/organization with early or exclusive access to results of your Stanford research, unless those results come from a Stanford research project sponsored by the entity (and even in this instance, the results must be publishable - see below).

- d. 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 Stanford.
- e. Your consulting agreements (or a nondisclosure agreement) must not delay or prohibit publications resulting from your Stanford research.
- f. The scope of your consulting responsibilities needs to be very specific so that it does not grant the company/organization access to work not done under the consulting agreement or interfere with intellectual property disclosure or publications resulting from your academic work.
- g. Remember that a consulting agreement is a legal document often drawn up by the company/organization's lawyers. Who is your advocate? You may wish to have your attorney review any legal documents you sign.
- h. It might be helpful for you to provide the company/organization with a copy of the Patent and Copyright Agreement for Stanford Personnel at <http://www.stanford.edu/dept/DoR/rph/su18.html>.
- i. You must disclose your relationship with the company/organization in publications and public discussions of any of your research that is sponsored by the company/organization or related to it.

2. If you serve on a **SCIENTIFIC OR MEDICAL ADVISORY BOARD:**

- a. You are permitted to sit on a Scientific Advisory Board (SAB) or Medical Advisory Board (MAB) because such positions normally do not carry, nor are they 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 School policies.
- b. It is advisable to have a formal consulting agreement when serving on an SAB or MAB.
- c. 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.
- d. You must not provide the entity with early or exclusive access to the results of your research, unless those results come from research projects sponsored by the company/organization (and even in this instance, the results must be publishable).
- e. You must keep your financial interests arising from service on advisory boards separate from your research and University obligations in order to:
 - o protect your students, trainees, and others whom you are responsible for directing, from undue influences or the compromise of academic freedoms;
 - o preserve the integrity of your research;
 - o 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 Stanford are not "pipelined," defined as passed along at an early stage or by privileged access to the company/organization, and are disclosed in a timely fashion to the Office of Technology Licensing; and
 - avoid compromise to the free exchange of ideas or delay or prohibit publications arising from your University activities.
- f. You must disclose your relationship with the company/organization in publications and public discussions of any of your research that is sponsored by the company/organization or related to it.

3. If you serve on a BOARD OF DIRECTORS:

- a. Service on a Board of Directors carries legal fiduciary responsibility but generally not line management responsibility (which is prohibited under Stanford policy). 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 School policies.
- b. You generally are not allowed to serve in various "director" roles in a company, for example, Director of Research, Chief Scientific Officer, Director of Clinical Labs, and the like. Such titles imply management responsibilities and are perceived as such, irrespective of actual job description.
- c. 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.
- d. 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 Stanford are not "pipelined," defined as passed along at an early stage or by privileged access to the company/organization, and are disclosed in a timely fashion to the Office of Technology Licensing; and
 - avoid compromise to the free exchange of ideas or delay or prohibit publications arising from your University activities.
- e. If you also have a formal consulting agreement, see Consulting guidelines.
- f. 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.

4. If you have **STOCK OR STOCK OPTIONS in a company whose interests are related to your research, and/or you consult for the company:**

- a. Be aware of the value of your stock or stock options so that you can report this accurately on your Annual Conflict of Interest and Commitment Disclosure and on any ad hoc or transactional disclosures you make. 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.
- b. Equity can raise the issue of such incentives compromising objectivity, particularly where human subjects are involved.
- c. If you are conducting, or planning to conduct, a clinical trial, keep in mind that owning stock or stock options from the company sponsoring the trial may disqualify you from participation in all or part of the research.
- d. 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.

5. If you have a **LICENSING ARRANGEMENT with the company through the Stanford Office of Technology Licensing (OTL):**

- a. As a University employee, 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 <http://www.stanford.edu/dept/DoR/rph/Chpt5.html>)
- b. 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. Faculty may help OTL to evaluate potential licensees, but the selection of the licensee rests with OTL.
- c. 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/organization, to a company in which you have a financial or founding interest.
- d. 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.

6. If you are a **FOUNDER of a company:**

- a. 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 School policies.

- b. You cannot serve in a management capacity for the company while a Stanford employee. While you are on sabbatical leave, you are a Stanford employee. When you are on a leave of absence, you are not a Stanford employee.
- c. You must not provide the company with early or exclusive access to the results of your research, unless those results come from a research project sponsored by the company (and even in this instance, the results must be publishable).
- d. Your relationship to the company should not interfere with your primary obligations as a faculty member or University employee or conflict with any other University or School policies.
 - o You must keep your financial interests separate from your research and University obligations in order to:
 - o protect your students, trainees, and others whom you are responsible for directing, from undue influences or the compromise of academic freedoms;
 - o preserve the integrity of your research;
 - o cause no harm to human participants in your research;
 - o see that any creations or discoveries that arise during the course of your research or scholarly activities are not "pipelined" to the company, and are disclosed in a timely fashion to OTL; and
 - o not allow your relationship to compromise the free exchange of ideas or delay or prohibit publications arising from your University activities.
- e. 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.

7. If you have a **LOAN with the company:**

- a. Indebtedness from a loan might compromise or be perceived as compromising your objectivity.
- b. 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.

8. If you give **TALKS for the company:**

- a. Don't become a spokesperson for the company or its products or services.
- b. Remember that honoraria can be used as incentives, and incentives can compromise objectivity.
- c. Keep your talks fair and balanced, i.e., don't just talk about the company's product.
- d. 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.

9. If you receive **GIFTS** from a company/organization:

Gifts have been used by industry as incentives to engender loyalty or support to the company or its products, as a means to bypass paying indirect costs on sponsored research, or to get access to research results. Gifts can include such things as clinical trial enrollment incentives to investigators (which are prohibited), equipment or reagents and supplies, luxury trips, 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 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.

- a. Faculty must use University procedures to document the terms of all gifts so your freedoms are protected and the exact nature of the exchange is spelled out.
- b. 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.
- c. 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.
- d. Conflicts of interest are magnified when you receive gifts and sponsored research funds from a company with which you have a financial relationship.

HOW TO ASSESS POTENTIAL CONFLICTS OF INTEREST

One way to personally assess your own conflict of interest is to ask yourself "How would this look on the 6:00 news?", often called that the "smell test." While you might not consider your relationship with, or financial interest in, a company to pose a risk to the objectivity of the design, conduct or reporting of your research, it can create that perception. Perception of bias, or the perception that harm came to a human subject in research as a result of bias, can be just as damaging as actual bias or harm. We must, and you should, ask the following questions:

- Are basic academic values upheld?
 - an open academic environment is maintained.
 - there are no restrictions on publications or dissemination of research results.
 - fair licensing practices are ensured.
 - the use of University resources and facilities is appropriate.
 - students are not exploited for the private gain of their mentors, and they are free to choose and pursue research
 - the research is appropriate to the mission of the University.

- What is the scientific direction of the University research and what is the scientific or business direction of the company? Is it the same? Where does it overlap?
 - Could these personal financial interests have a direct and significant affect on the research?
 - how much income or equity is involved?
 - from how many sources does it derive?
 - could these financial interests be a significant incentive for the individual with the conflict?
 - could this financial interest pose a direct conflict with the research?
 - could this conflict compromise the objectivity of the research results or their evaluation and presentation?
 - Could human subjects involved in the research be harmed by the conflict?
 - Could potential incentives to show that products are effective affect future patients negatively if the products are actually not as effective as indicated in the clinical study?
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MANAGEMENT STRATEGIES FOR SIGNIFICANT CONFLICTS OF INTEREST

All financial interests or relationships related to your research must be disclosed in accordance with University policy.

Where the faculty member is participating in research involving human subjects, and has **ANY** financial interest in the sponsor (or a member of the immediate family has such an interest), that interest must be disclosed, regardless of its value. Similarly, **ANY** current or pending ownership interests (including shares, partnership stake, or derivative interests such as stock options) in a privately-held entity (e.g., in a "start up" company) must also be disclosed, regardless of value.

In addition, any income over \$10,000, or stock or stock options valued at over \$10,000 or 0.5% of the total value of a publicly-traded company are deemed to be significant financial interests.

These must be evaluated in light of the research, and any conflicts must be eliminated, mitigated or managed. Strategies for doing this include:

- require disclosure of the financial interest in publications and public discussions of the research;
- modify the research plan;
- disqualify a participant from all or a portion of the project;
- require severance of a relationship;
- require divestiture of a financial interest;
- exclude intellectual property from being licensed to a company in which there is a financial interest;
- manage the conflict through an oversight committee; and/or
- other strategies, as deemed appropriate.