



Faculty Disclosure of Conflicts of Interest

School of Medicine Policy Overview

Conflicts of interest are common and practically unavoidable in a modern research university. At Stanford, conflicts of interest can arise out of the fact that a mission of the University is to promote public good by fostering the transfer of knowledge gained through University research and scholarship to the private sector.

Two important means of accomplishing this mission include consulting and the commercialization of technologies derived from faculty research. The opportunity for researchers to receive financial rewards from these endeavors is not intrinsically unacceptable. However the potential for financial gain creates risks for the individual investigator and for the institution. Financial interests in human subjects research are of special concern. Financial conflicts are distinct from other interests that might impart bias because financial interests are discretionary. Such conflicts are not usually necessary for the conduct of the research. Finally, conflicts of interest can call into question the professional objectivity and ethics of the individual, and also reflects negatively on the University.

Opportunities to profit from research may affect - or appear to affect the direction of the research, objectivity of the data, or interpretation of research results. Moreover, in human research, these opportunities to profit may affect, or appear to affect, a researcher's judgments about which human subjects to enroll, the clinical care provided to subjects, the proper use of subjects' confidential health information, and create biases in study design, data collection and analysis, adverse event reporting, or the presentation and publication of research findings. On the other hand, while human subject research is the highest risk, there may be special and rare circumstances which require an individual to engage in research on human subjects despite having a financial conflict of interest

We seek to assist Stanford personnel in translating their discoveries and developments so that we can fulfill our mission to benefit the public.

We also seek to minimize the adverse affects of conflicts of interest, and to advise faculty and staff on how to avoid, mitigate, or, if necessary, how to manage those conflicts.

The purposes of this policy are to educate faculty about disclosure requirements, and to provide information about how conflicts of interest are assessed.

Disclosure of Financial Interests

The large amount of research, particularly that which involves human subjects, requires that the School of Medicine exercise special care to ensure that we have identified any financial interests or relationships related to research conducted here. Thus our policy varies slightly from that of the university, which is focused primarily on non-human research. We require that:

- A. All faculty disclose **any** personal financial interest (defined as income, honoraria or other payment for services [such as payment for consulting], equity such as stock, stock options or other ownership interests, and royalties) for the faculty member (or his/her spouse or domestic partner and dependent children) or relationship with a for-profit company that either directly supports research being conducted by that individual or is related to research being conducted by that individual, such as financial interests that are related to federally funded studies. This means that any transactions such as grants, contracts, gifts, licensing agreements, human research protocols, collaboration agreements, material transfer agreements, or procurements require this disclosure. **All personal financial interests related to Stanford activities must be reported, regardless of dollar amount.** All reported financial interests will be reviewed by the Conflict of Interest Review Program (COIRP) to determine if a significant conflict of interest exists.
- B. All faculty must disclose any personal financial interest related to human research to the subject in the consent form.
- C. All faculty with personal financial interests as defined in Section III must disclose those interests in public discussions and public presentations of research results if those financial interests are directly or indirectly related to that research or the COIRP has identified a conflict of interest.

Financial Interests or Relationships That Pose Conflicts of Interest

While most disclosures of financial interests will probably be deemed *de minimus* or not significant conflicts of interest, financial interests above certain thresholds will automatically be deemed significant conflicts of interest and will require closer scrutiny and possible elimination, mitigation, and/or management. The thresholds are as follows:

- A. These interests are over \$10,000 in monetary value.
- B. (1) These interests involve the ownership or promise of stock or stock options over \$10,000 or 0.5% of the total value of the company, in a **publicly traded** company.

(2). These interests involve the ownership or promise of stock or stock options of any amount in a **privately-held** or start-up company.
- C. An individual serves in a consulting or other fiduciary role for a financially interested company, whether or not remuneration is received.

Research involving human subjects will require that all conflicted investigators provide compelling reasons justifying their involvement in the research despite their conflict, if their financial interests are above the thresholds described in this document. A simple statement of an investigator's importance or expertise will not suffice. An investigator with a significant financial stake in the outcome of the research would need to provide a sufficient reason detailing his/her unique contribution to the study, and a reasonable plan that will protect the human subjects, the data, and the university. Without compelling reasons and a plan that isolates the investigator from direct interaction with the human subjects or identified specimens, the COIC may require that the investigator either divest his/her financial interest or not perform the work at Stanford.

Assessing Conflicts of Interest

Disclosures of financial interests above these thresholds will be reviewed by the COIRP to determine if the financial interests or relationships are significant enough to create the perception of, or actual potential for bias or compromise the objectivity of the research, potentially harm a subject in the study, provide the company early or exclusive access to research results, constitute an inappropriate use of university resources and facilities, restrict the freedom to publish or publicly disseminate research results, compromise academic freedom--particularly of students or other trainees, create the opportunity to exploit or coerce students, trainees, faculty who work within their divisions, or others supervised by the conflicted investigator, or inhibit

the fair licensing of intellectual property. Financial interests or relationships that could potentially have any of these negative impacts would be deemed to have a direct and significant affect on the research. Such conflicts of interest would be referred to the Conflict of Interest Committee in order to determine what steps might be needed to eliminate, mitigate or manage the conflict.

Eliminating, Mitigating, or Managing Conflicts of Interest

Conflicts that are deemed to have the potential or are likely to be perceived as having the potential to have a direct and significant affect on the research must be eliminated, mitigated, or managed. Such strategies for eliminating, mitigating, or managing conflicts can include:

- public disclosure of significant financial interests;
- training on conflicts of interest and commitment for all personnel involved in the research;
- monitoring of research by independent reviewers;
- modification of the research plan;
- disqualification from participation in all or a portion of the research;
- divestiture of significant financial interests; and/or
- severance of relationships that create actual or potential conflicts.

The Conflict of Interest Committee will make this determination and decide which steps are necessary for managing the conflict or conflicts.

Below find additional information and web links pertaining to university conflict of interest and commitment policies, as well as other academic policies.

University Conflict of Interest and Commitment Policies

Faculty

Stanford's Faculty Policy on Conflict of Commitment and Interest <http://www.stanford.edu/dept/DoR/rph/Chpt4.html> stipulates that all faculty members 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 programs of the institution.

It also requires:

Appropriate presence on campus

- Limiting outside professional activities
- The free and open exchange of research results
- The appropriate use of University resources, including facilities, personnel, equipment, and information
- Annual disclosure of conflicts of commitment and interests (See Annual & Ad-hoc Disclosure Procedures for more info)

Outside professional activities should not exceed 13 days/quarter or conflict with a faculty member's primary professional obligations. Principles and standards of outside professional activities are defined in *Outside Consulting Activities by Members of the Academic Council Faculty Consulting Policy* (RPH 4.3) <http://www.stanford.edu/dept/DoR/rph/4-4.html> .

Academic Staff

In accordance with the *Conflict of Interest and Commitment for Academic Staff* policy academic staff employed on a full time basis at Stanford, owe their primary professional allegiance to the University, and their primary commitment of time and intellectual energies should be to the programs on which they are working. Academic Staff Conflict of Interest Policy (RPH 4.4) <http://www.stanford.edu/dept/DoR/rph/4-4.html> Academic staff may consult only with permission, in writing, by the Principal Investigator. Such approved consulting must not exceed 13 days/quarter. Specific requirements are consistent with the *Faculty Policy on Conflict of Commitment and Interest* .

Staff

The *Staff Policy on Conflict of Commitment and Interest* http://adminguide.stanford.edu/15_2.pdf stipulates that when University staff members or their immediate families have significant financial interests (over \$100,000 or 0.5% equity) in, or consulting or employment arrangements with, other business concerns they must avoid actual or apparent conflicts of interest or conflicts of commitment between their University obligations and their outside interests. Staff are prohibited from consulting unless a written exception has been approved.

Other Related University Policies

- Principles Concerning Research (RPH 2.1) <http://www.stanford.edu/dept/DoR/rph/2-1.html>
- Rights and Responsibilities in the Conduct of Research (RPH 2.2) <http://www.stanford.edu/dept/DoR/rph/2-2.html>
- Academic Freedom Academic Freedom (RPH 2.3) <http://www.stanford.edu/dept/DoR/rph/2-3.html>
- Principal Investigator Eligibility and Criteria for Exceptions PI

Waivers (RPH 2.4)

<http://www.stanford.edu/dept/DoR/rph/2-4.html>

- Scientific Misconduct: Policy on Allegations, Investigations, and Reporting Scientific Misconduct (RPH 2.5)
<http://www.stanford.edu/dept/DoR/rph/2-5.html>
- Openness in Research Openness in Research (RPH 2.6)
<http://www.stanford.edu/dept/DoR/rph/2-6.html>
- Multi-Authored Research Papers Multi-Authored Research Papers(RPH 2.7)
<http://www.stanford.edu/dept/DoR/rph/2-7.html>
- On Academic Authorship On Academic Authorship(RPH 2.8)
<http://www.stanford.edu/dept/DoR/rph/2-8.html>
- Retention of and Access to Research Data Retention of/Access to Research Data (RPH 2.10)
<http://www.stanford.edu/dept/DoR/rph/2-10.html>
- Relationships between Students (including Postdoctoral Scholars) and Outside Entities Student Relationships with Outside Entities (RPH 2.11)
<http://www.stanford.edu/dept/DoR/rph/2-11.html>
- Inventions, Patents and Licensing Inventions, Patents and Licensing (RPH 5.1)
<http://www.stanford.edu/dept/DoR/rph/5-1.html>

School of Medicine Procedures

Contact Information

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Annual Disclosure (New process)

The Annual Disclosure process is now completed **online** at:

<https://coi.stanford.edu/> (SUNET ID access required. Only faculty will be able to view the submit form functionality on that webpage.)

School of Medicine Ad Hoc Faculty Disclosures

Ad Hoc Faculty Disclosure Form (Word Document)

http://med.stanford.edu/conflict/documents/ad_hoc_disclosure_form.doc

Complete and submit to Barbara Flynn, Manager Conflict of Interest Program.

Tips for Avoiding Conflicts of Commitment and Interest

Stanford faculty members 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 programs of the institution. Outside professional relationships, can result in conflicts regarding 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, as well as School of Medicine policy. The complete set of University policies concerning conflicts of interest and commitment and related areas can be found at the following web sites:

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

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

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

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.

If you **CONSULT** for company

- Your primary commitment is to the University and your consulting agreement should not conflict with that obligation or conflict with any other university rules or regulations.

- You need to ensure that your consulting agreement recognizes 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 agreement does not grant the company access to any ideas that do not arise as a result of your consulting activities or would be deemed an extension of your University activities.
- You must not provide the company with early or exclusive access to results of your Stanford research, unless those results come from a sponsored research project with the company.
- 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.
- Your consulting agreement must not delay or prohibit publications resulting from your Stanford research.
- The scope of your consulting responsibilities needs to be very specific so that it does not grant the company access to work not done under the consulting agreement or interfere with intellectual property disclosure, or publications resulting from your academic work.
- Remember that your consulting agreement is a legal agreement drawn up by the company's lawyers. Who is your advocate? You may wish to have your attorney review any legal agreements you sign.
- It might be helpful for you to provide the company with a copy of the *Patent and Copyright Agreement for Stanford Personnel* <http://www.stanford.edu/dept/DoR/rph/su18.html>
- You must disclose this relationship with the company in publications and public discussions of any of your research that is sponsored by the company or related to the company.

If you **serve on a SCIENTIFIC OR MEDICAL ADVISORY BOARD**

- You are permitted to sit on scientific or medical advisory boards because such positions do not carry, nor are they perceived to carry, management responsibility. However, your primary commitment is to the University and your service on a Scientific or Medical Advisory Board should not conflict with that obligation or conflict with any other university rules or regulations.
- You can serve on a Scientific Advisory Board (SAB) or Medical Advisory Board (MAB), however it is advisable to have a formal consulting agreement in those situations. (see **CONSULT**)

- Often service on an advisory board is rewarded with stock or stock options—such equity can raise the issue of such incentives compromising objectivity, particularly where human subjects are involved in studies of the company’s products.
- You must not provide the company with early or exclusive access to the results of your research, unless those results come from a sponsored research project with the company.
- 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 the research;
 - * cause no harm to human subjects used in your research; and
 - * see that any creations or discoveries that arise during the course of your research or scholarly activities at Stanford are not pipelined to the company, and are disclosed in a timely fashion to the Office of Technology Licensing; and
 - * not allow your relationship to compromise the free exchange of ideas or delay or prohibit publications arising from your University activities.
- You must disclose this relationship in publications and public discussion of any of your research that is sponsored by the company or related to the company.

If you **serve on a BOARD OF DIRECTORS**

- Service on a board of directors carries with it legal fiduciary responsibility but generally not line management responsibility (which is prohibited under Stanford policy) and hence, is generally permissible. However, your primary commitment is to the University and your service on a Board of Directors should not conflict with that obligation or conflict with any other university rules or regulations.
- You 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.
- If you are also the principal investigator of a research project you have fiduciary responsibility for the grant or contract. If you have fiduciary

responsibility as the Principal Investigator (PI) on Stanford research and have fiduciary responsibility as a Member of the Board—how do you plan to separate these two obligations?

- Your relationship to the company should not interfere with your primary obligations as a faculty member or University employee.
- You must avoid any conflict of commitment between your University responsibilities and your relationship with a company.
- You must keep your financial interests as 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 the research;
 - * cause no harm to human subjects used in your research; and
 - * 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 the Office of Technology Licensing.
- If you also have a formal consulting agreement, see **CONSULT**.
- 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.

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

- Pay attention to what the value of the stock or stock options are so that you report this accurately on your *Annual Conflict of Interest and Commitment Disclosure* and on any *ad hoc* or transactional disclosures you make.
- Equity can raise the issue of such incentives compromising objectivity, particularly where human subjects are involved.
 - * if you are conducting, or planning to conduct, a clinical trial, do you really want to accept stock or stock options from the company sponsoring the trial, as you will likely be prohibited from participation in all or part of the research?
- The more significant the equity is financially, or the more likely the research may benefit the company (and thus your equity—particularly in the case of stock options), the greater the risk of biasing the research or research results.

- 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.

If you **have a LICENSING ARRANGEMENT** with the company through the Stanford Office of Technology Licensing

- 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.
<http://www.stanford.edu/dept/DoR/rph/Chpt5.html>
- 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 the Office of Technology Licensing (OTL) to evaluate potential licensees, but the selection of the licensee rests with OTL.
- New developments relating to this intellectual property must also be fairly licensed and you must not pipeline or funnel intellectual property to a company in which you have a financial or founding interest.
- Is the company licensing your technology sponsoring further research in the area of the intellectual property?
- Do you have PHS or NSF funds for research related to this intellectual property? The results of this research or creations or discoveries arising from this research must not be pipelined or funneled to the company that has a license.
- 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.

If you are a **FOUNDER** of a company

- 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 rules or regulations.

- You cannot serve in a management capacity for the company while a Stanford employee.
- You must not provide the company with early or exclusive access to the results of your research, unless those results come from a sponsored research project with the company.
- 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 rules or regulations.
- You must keep your financial interests 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 the research;
 - * cause no harm to human subjects used in your research; and
 - * 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 the Office of Technology Licensing; and
 - * not allow your relationship to compromise the free exchange of ideas or delay or prohibit publications arising from your University activities.
- 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.

If you **have a LOAN** with the company

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

If you **give TALKS** for the company

- Don't become a spokesperson for the company or its product.
- Honoraria can be used as incentives and incentives can compromise objectivity.

If you **receive GIFTS** from a company

- 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.
- 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.
- 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.
- 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.
- Conflicts of interest are magnified when you receive gifts and sponsored research funds from a company with which you have a financial relationship.

The Stanford Industry Interactions Policy addresses many of these issues in detail (see below).

HOW DO WE ASSESS 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'. We often call 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. Thus, 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?

HOW DO WE MANAGE SIGNIFICANT CONFLICTS OF INTEREST?

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

PLEASE NOTE THAT THE SCHOOL OF MEDICINE REQUIRES DISCLOSURE OF ANY FINANCIAL INTEREST OR RELATIONSHIP, REGARDLESS OF THE DOLLAR AMOUNT, WHICH IS DIFFERENT THAN THE UNIVERSITY POLICY FOLLOWED BY OTHER SCHOOLS.

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, or stock options or promises of stock in any amount in a private company, are deemed significant financial interests. These must be evaluated in light of the research, the financial relationships and 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

Policy and Guidelines for Interactions between the Stanford University School of Medicine, the Stanford Hospital and Clinics, and Lucile Packard Children's Hospital with the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries (“Industry”)

Purpose of Policy:

The purpose of this policy is to establish guidelines for interactions with industry representatives for medical staff, faculty, staff, students, and trainees of the Stanford School of Medicine, Stanford Hospital and Clinics and the Lucile Packard Children's Hospital. Interactions with industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices, and research equipment and supplies on-site, on-site training of newly purchased devices, the development of new devices, educational support of medical students and trainees, and continuing medical education. Faculty and trainees also participate in interactions with industry off campus and in scholarly publications. Many aspects of these interactions are positive and important for promoting the educational, clinical and research missions of the Medical Center. However, these interactions must be ethical and cannot create conflicts of interest that could endanger patient safety, data integrity, the integrity of our education and training programs, or the reputation of either the faculty member or the institution.

Statement of Policy:

It is the policy of the Stanford School of Medicine, Stanford Hospital and Clinics and the Lucile Packard Children's Hospital that interactions with industry should be conducted so as to avoid or minimize conflicts of interest. When conflicts of interest do arise they must be addressed appropriately, as described herein.

Scope of Policy:

This policy incorporates the following types of interactions with industry. It does not include faculty research and related activities, which are included in the Stanford University Faculty Policy on Conflict of Commitment and Interest (<http://www.stanford.edu/dept/DoR/rph/4-1.html>).

- I. Gifts and compensation
- II. Site access by sales and marketing representatives
- I. III. Provision of scholarships and other educational funds to students and trainees
- III. Support for educational and other professional activities
- IV. Disclosure of relationships with industry
- V. Training of students, trainees, and staff regarding potential conflict of interest in industry interactions

I. Gifts and Compensation

A. Personal gifts from industry may not be accepted anywhere at the Stanford School of Medicine, Stanford Hospital and Clinics, the Lucile Packard Children's Hospital, the Menlo Clinic or at any other clinical facility operated by either hospital, such as the LPCH Pediatric Unit at El Camino Hospital. In addition, Stanford faculty, staff and trainees may also not accept gifts at any non-Stanford-operated clinical facility such as other hospitals, outreach clinics and the like. Non-faculty medical staff are strongly discouraged from accepting gifts at non-Stanford-operated clinical facilities but are not proscribed by this policy from doing so.

1. It is strongly advised that no form of personal gift from industry be accepted under any circumstances. Individuals should be aware of other applicable policies, such as the AMA Statement on Gifts to Physicians from Industry (<http://www.ama-assn.org/ama/pub/category/4001.html>) and the Accrediting Council for Continuing Medical Education Standards for Commercial Support (www.accme.org).

B. Individuals may not accept gifts or compensation for listening to a sales talk by an industry representative.

- C. Individuals may not accept gifts or compensation for prescribing or changing a patient's prescription.
- D. Individuals must consciously and actively divorce clinical care decisions from any perceived or actual benefits expected from any company. It is unacceptable for patient care decisions to be influenced by the possibility of personal financial gain.
- E. Individuals may not accept compensation, including the defraying of costs, for simply attending a CME or other activity or conference (that is, if the individual is not speaking or otherwise actively participating or presenting at the event).

II. Site Access by Sales and Marketing Representatives

- A. Sales and marketing representatives are not permitted in any patient care areas except to provide in-service training on devices and other equipment and then only by appointment.
- B. Sales and marketing representatives are permitted in non-patient care areas by appointment only. Appointments will normally be made for such purposes as:
 - 1. In-service training of Stanford Hospital and Clinic or Lucile Packard Children's Hospital personnel for research or clinical equipment or devices already purchased.
 - 2. Evaluation of new purchases of equipment, devices, or related items.
- C. Appointments to obtain information about new drugs in the formulary will normally be issued by the hospital pharmacy or by Pharmaceutical and Therapeutics Committees.
- D. Appointments may be made on a per visit basis or as a standing appointment for a specified period of time, at the discretion of the faculty member, his or her division or department, or designated hospital personnel issuing the invitation and with the approval of appropriate hospital management.

III. Provision of Scholarships and Other Educational Funds to Students and Trainees

- A. Industry support of students and trainees should be free of any actual or perceived conflict of interest, must be specifically for the purpose of education and must comply with all of the following provisions:
1. The School of Medicine department, program or division selects the student or trainee.
 2. The funds are provided to the department, program, or division and not directly to student or trainee.
 3. The department, program or division has determined that the funded conference or program has educational merit.
 4. The recipient is not subject to any implicit or explicit expectation of providing something in return for the support, i.e., a “quid pro quo.”
- B. This provision may not apply to national or regional merit-based awards, which are considered on a case-by-case basis.

IV. Support for Educational and Other Professional Activities

- A. Individuals should be aware of the ACCME Standards for Commercial Support. They provide useful guidelines for evaluating all forms of industry interaction, both on and off campus and including both Stanford- sponsored and other events. The Standards are appended to this policy and may be found at www.accme.org.
- B. All education events sponsored by the Stanford School of Medicine, Stanford Hospital and Clinics or the Lucile Packard Children’s Hospital must be compliant with ACCME Standards for Commercial Support whether or not CME credit is awarded.
1. Educational grants that are compliant with the ACCME Standards may be received from industry but must be administered by departments or divisions and not by individual faculty.
 2. Divisions and departments must maintain records of compliance with the ACCME Standards.

- C. Meals or other types of food directly funded by industry may not be provided at Stanford School of Medicine, Stanford Hospital and Clinics, the Lucile Packard Children's Hospital, or the Menlo Clinic.
- D. Faculty and medical staff should evaluate very carefully their own participation in meetings and conferences that are fully or partially sponsored or run by industry because of the high potential for perceived or real conflict of interest.
- E. This provision does not apply to meetings of professional societies that may receive partial industry support, meetings governed by ACCME Standards, and the like. Individuals who actively participate in meetings and conferences supported in part or in whole by industry (e.g., by giving a lecture, organizing the meeting) should follow these guidelines:
 1. Financial support by industry is fully disclosed by the meeting sponsor.
 2. The meeting or lecture content is determined by the speaker and not the industrial sponsor.
 3. The lecturer is expected to provide a fair and balanced assessment of therapeutic options and to promote objective scientific and educational activities and discourse.
 4. The Stanford participant is not required by an industry sponsor to accept advice or services concerning speakers, content, etc., as a condition of the sponsor's contribution of funds or services.
 5. The lecturer makes clear that content reflects individual views and not the views of Stanford School of Medicine, Stanford Hospital and Clinics or the Lucile Packard Children's Hospital
 6. The use of the Stanford name in non-Stanford event is limited to the identification of the individual by his or her title and affiliation.

V. Disclosure of Relationships with Industry

- A. Individuals are prohibited from publishing articles under their own names that are written in whole or material part by industry employees.

- B. In scholarly publications, individuals must disclose their related financial interests in accordance with the International Committee of Medical Journal Editors (www.icmje.org).
- C. Faculty with supervisory responsibilities for students, residents, trainees or staff should ensure that the faculty's conflict or potential conflict of interest does not affect or appear to affect his or her supervision of the student, resident, trainee, or staff member.
- D. Individuals having a direct role making institutional decisions on equipment or drug procurement must disclose to the purchasing unit, prior to making any such decision, any financial interest they or their immediate family have in companies that might substantially benefit from the decision. Such financial interests could include equity ownership, compensated positions on advisory boards, a paid consultancy, or other forms of compensated relationship. They must also disclose any research or educational interest they or their department have that might substantially benefit from the decision. The purchasing unit will decide whether the individual must recuse him/herself from the purchasing decision.
 - 1. This provision excludes indirect ownership such as stock held through mutual funds.
 - 2. The term "immediate family" includes the individual's spouse or domestic partner or dependent children.
- E. For disclosure requirements related to educational activities, see the ACCME Standards for Commercial Support (www.accme.org).

VI. Training of Students, Trainees, and Staff Regarding Potential Conflict of Interest in Interactions with Industry

- A. All students, residents, trainees, and staff shall receive training regarding potential conflicts of interest in interactions with industry.