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Guidelines for Interactions Among UCSF Faculty, Students and Staff and Industry

Preamble

The following guidelines are being distributed to faculty, students and staff of the School of Medicine regarding the relationship with the health care industry*. The guidelines were developed to provide guidance to the School of Medicine and ensure independence of clinical decisionmaking, educational curriculum and research programs. They are meant to be an interim step in the development of more broad-based policies for all UCSF faculty, students and staff. Because of the integrated nature of our academic and clinical programs, a campus wide policy will be most beneficial and create consistent expectations across all campus sites. We recommend that the policies and procedures be developed in collaboration with the UCSF Medical Center and, to the extent possible be consistent with similar policies at San Francisco General Hospital (SFGH) and the VA Medical Center. The Medical Center policies understandably emphasize issues of importance to clinical decisionmaking and patient care, and specifically relate to selection of supplies and equipment, relationships with vendors, and sample management. These interim guidelines address these issues, but will require a coordinated approach to ensure consistency and appropriate standards for all UCSF faculty, students and staff.

General Principles

The UCSF School of Medicine policy is developed to ensure that all interactions with industry be conducted in ways that avoid actual or perceived conflicts of interest. Because of the importance of the relationship between industry and the University community, when conflicts arise, they must be addressed appropriately and all attempts must be made to minimize conflicts that affect clinical care, education or research.

All faculty, students and staff have a responsibility to ensure, to the best of their abilities that all decisions about clinical care, research activities and educational content are independent and unbiased. Decisions should be made in the best interests of patients, students and the University and should not be based on any actual or perceived personal benefit that might be derived to the individual.

The University has a long history of collaboration with industry, including pharmaceutical companies and medical technology companies. These collaborations have benefited patients, our educational programs and research activities. However, these interactions could have the potential for undue and deleterious influence by industry on the activities of the School of Medicine, its faculty, students and staff. The following guidelines have been adopted to minimize the potential for real or perceived bias in clinical care, education or

research. The goal of these guidelines is to ensure, to the extent possible that clinical decisionmaking, educational program content and research activities are as free from bias and outside influence as possible and that all real or potential conflicts are disclosed and resolved. The guidelines cannot identify every potential conflict, but provide general principles upon which faculty, students and staff should act. It is incumbent upon each of us to comply with the guidelines and, when real or potential conflicts are identified to disclose and eliminate them to the extent possible.

Guidelines Regarding School of Medicine Relationships with Industry

A. Compensation or Gifts

1. Personal gifts from an industry representative may not be accepted by any faculty, student or staff at any School of Medicine site, as part of any work-related activity or during any clinical or other educational rotation.
2. Individuals may not accept compensation, including reimbursement for expenses associated with attending a CME or other activity in which the attendee has no other role. Reasonable honoraria and payment of expenses may be provided for speakers at accredited educational meetings, consistent with guidelines developed by the Accreditation Council for Continuing Medical Education (ACCME) and University policy.
3. No gifts or compensation may be accepted in exchange for listening to a sales talk or similar presentation by a representative of a commercial interest that produces or distributes health care goods and services.
4. Faculty, students and staff are strongly discouraged from accepting gifts of any kind from industry as part of non-professional activities. Individuals should be aware of and comply with applicable policies, such as the AMA Statement on Gifts to Physicians from Industry (<http://www.ama-assn.org/ama/pub/category/8484.html>) and the Accreditation Council for Continuing Medical Education Standards for Commercial Support (<http://www.accme.org>).
5. Meals and other gifts or donations funded directly by industry may not be provided at any UCSF School of Medicine location. Vendors and other industry representatives may provide unrestricted funds to departments or divisions for educational programs. The funds will be managed according to the Standards for Commercial Support of the ACCME.
6. No gifts may be accepted in exchange for modifying patient care, such as prescribing a specific medication. Support for research and educational programs must be provided without influence on clinical decisionmaking.

7. Free samples, supplies or equipment designated for an individual are considered a gift and are prohibited. Vendors may donate products for evaluation or educational purposes to a department or division, if the University invites the donation and there is a formal evaluation process. Sample donations are restricted to the amount necessary to complete the evaluation. Items may be provided to the University or Medical Center at a discount or free as part of a formal contract and, under these conditions are not considered a gift. Other policies related to the management of samples must comply with the specific policies and procedures of each Medical Center. Faculty must abide by the policies developed at the clinical sites in which they practice.

B. Industry Support for Educational Programs

1. Commercial support for educational programs must be free of actual or perceived conflict of interest.
2. All educational programs within the School of Medicine must abide by the Standards for Commercial Support established by the ACCME. This requirement applies to all undergraduate, graduate and continuing medical education programs regardless of whether continuing medical education credit is offered.
3. All funds provided by industry or an industry representative to support educational programs must be given the University as an unrestricted grant. The funds can be provided to the Department, Program or Division, but cannot be given to an individual faculty member, student or staff. This requirement applies to all funds for meals or refreshments, speaker honoraria, or any other expense related to an educational program and includes noon conferences, grand rounds, and lectures at all UCSF sites. Funds that are provided by educational groups or other entities that act as “intermediaries” for industry must also be provided as unrestricted grants.
4. No gifts may be accepted in exchange for listening to a lecture or presentation by a representative of a commercial entity that produces health care or medical goods and services.
5. Vendors may provide educational activities on a UCSF site only if they are requested to do so by the department chair or designee. Participants in an educational program may not be required to attend any educational session in which an industry representative disseminates information about their products or services except when such services are provided as part of a contract for in-service or other training as part of an executed purchase decision.

6. The content of all educational programs will be determined by the UCSF program planning group and, when appropriate the CME office. Industry sponsors of educational programs may not determine the content or selection of speakers for educational programs.
7. These requirements do not apply to meetings governed by ASCCME Standards or meetings of professional societies and other professional organizations that may receive partial industry support. Individuals who actively participate in meetings or conferences that are supported in whole or in part by industry, including lecturing, organizing the meeting or moderating sessions should abide by the following requirements:
 - a. Financial support should be fully disclosed by the meeting sponsor
 - b. The content of the meeting or session must be determined by the speaker, not the industry sponsor
 - c. The speaker must provide a fair and balanced discussion
 - d. The speaker must make clear that the comments and content reflects the individual views of the speaker and not the University of California, the UCSF School of Medicine, or the Department
8. Faculty, students and staff should carefully evaluate whether it is appropriate to participate in off-campus meetings or conferences that are fully or partially sponsored by industry because of the high potential for real or perceived conflict of interest.

C. Provision of Scholarships or Other Educational Funds for Students and Trainees

1. Industry support for students and trainees participation in education programs must be free of any real or perceived conflict of interest. All educational grants or support of educational programs must be specifically for the purposes of education and must comply with the following requirements:
 - a. The School of Medicine Department, Program or Division must select the student(s) or trainee(s) for participation.
 - b. The funds must be provided to the Department, Program or Division and not directly to the student or trainee.
 - c. The Department, Program or Division determines that the education conference or program has educational merit.
 - d. There is no implicit or explicit expectation that the participant must provide something in return for participation in the educational program.
2. This provision does not apply to regional, national or international merit-based awards which will be considered on a case-by-case basis.

D. Disclosure of Relationships with Industry

1. Faculty and staff must disclose all financial interests with outside entities in accordance with UCSF and University of California policy. The specific disclosure obligation and method is dependent on the activity.
 - a. For research activities the relationship must be disclosed to the UCSF Conflict of Interest Advisory Committee.
(<http://www.research.ucsf.edu/coiac/coiacPolicy.asp>)
(<http://www.ucop.edu/research/disclosure.html>)
 - b. All publications should be in compliance with the guidelines of the International Committee of Medical Journal Editors (www.icmje.org).
 - c. All continuing medical education activities must be disclosed and resolved as defined by the Office of Continuing Medical Education and the ACCME (<http://www.accme.org>).
2. Faculty or staff who serve as consultants, members of a speakers' bureau, have an equity interest in or another relationship with industry for which they receive personal compensation or other support must recuse themselves from deliberations or decisionmaking regarding the selection of products or services to be provided to the Medical Center or School of Medicine (eg; selection of drugs to be added to the formulary) by the company. Faculty with such ties to industry shall not participate in decisions regarding the purchase of related items, drugs, procedures in their department unless specifically requested to do so by the purchasing unit and after full disclosure of the faculty member's industry relationship. Under all circumstances the financial relationship must be disclosed and any conflict resolved prior to participation in any decisionmaking.
3. Faculty and staff are prohibited from publishing articles that are substantially or completely "ghost" written by industry representatives. Faculty and staff who publish articles with industry representatives must participate in the preparation of the manuscript in a meaningful way to include interpretation of data and/or the writing of the manuscript and shall be listed as authors or otherwise appropriately cited for their contribution. The financial interests of all authors shall be listed in accordance with the standards of the journal.
4. Faculty with financial relationships with industry must ensure that the responsibilities to the company do not affect or appear to affect the ability to properly supervise and educate students, residents and other trainees, nor influence employment decisions for faculty and staff. All such relationships must be disclosed and resolved as defined by ACCME.

E. Access by Sales and Marketing Representatives to Faculty, Staff and Students

1. Faculty and staff at each UCSF site must abide by the policies and procedures for each institution (UCSF and UCSF Medical Center, SFGH and VA Medical Centers with regard to meeting with industry representatives. In general representatives are permitted in non-patient care areas *by appointment only*. Company representatives are not permitted in any patient care areas except to provide scheduled and approved in-service training on devices and other equipment for which there is an executed University contract for these services.

Relationship to Other University Policies

The guidelines supplement University policies on Conflict of Interest and the requirements of the Departmental Compensation Plan. Faculty and staff should familiarize themselves with the policies and reporting obligations. Questions about the policies should be discussed with the department chair and/or administrative staff.

**** For purposes of these guidelines, industry refers to proprietary entities who produce health care and medical goods or services.***