Purpose

UCSF has a long history of collaboration with the health sciences industry, including, but not limited to, pharmaceutical, biotechnology and medical technology companies. These interactions have benefited the institution’s patients, educational programs, and research activities. The University must continue to collaborate with industry and other outside organizations to fulfill its academic, clinical and educational responsibilities. At the same time, these collaborations have the potential to create conflicts of interest or conflicts of commitment that must be both understood and addressed. UCSF wishes to minimize such conflicts and to ensure to the best of its ability that all decisions regarding clinical care, research activities and educational content are unbiased and independent of outside influence. Any circumstance that may give rise to a conflict of interest or commitment must be acknowledged and managed appropriately.

UCSF Policy on Health Care Industry Relations (Policy) defines the responsibilities of faculty, students and staff with respect to interactions between the University community and industry as they relate to educational, clinical and research activities. The Policy is intended to define the nature of the relationship between the academic community and industry; it takes into account the current standards, as defined by the University and accrediting and educational organizations. The Policy is consistent with the University of California Health Care Vendor Relations Policy implemented by the Office of the President on March 21, 2008. Because of the ongoing dialogue regarding these issues and the evolution of standards and best practices related to the industry-academic relationships, the Policy will continue to be reviewed and revised, as necessary.

Definitions

Gift

Includes outright gifts, pledges, and bequests, but excludes grants from private sources as defined in the guidelines for review of gifts/grants for research dated July 8, 1980 (http://www.ucop.edu/ucophome/coordrev/policy/7-08-80.html)

Industry
For purposes of this policy ?industry? refers to any proprietary entity that produces health care and medical goods or services, scientific products used for research or educational purposes and the representatives of such entities. ?Industry? includes all health care vendors producing and marketing drugs, devices, nutritional products and other medical products or services.

UCSF-Owned or Operated Location

All UCSF locations, including UCSF Medical Center, UCSF Benioff Children?s Hospital, UCSF Mount Zion Medical Center, other UCSF campus sites and other locations in which clinical care is provided or research activities are performed by UCSF faculty and staff.

UCSF Educational Program

Includes all undergraduate, graduate and continuing education programs and all activities such as conferences, lectures and grand rounds, regardless of whether educational credit is offered.

Policy

A. Prohibition on Accepting Gifts, Free Pharmaceutical or Device Samples, and Compensation Provided by Industry.

- UCSF faculty, staff, students, and trainees may not accept gifts from industry. Industry may not provide gifts to UCSF faculty, staff, students, trainees, volunteers, contractors, and agents at any UCSF-owned or operated location.

  Volunteers, including volunteer clinical faculty, contractors, and individuals acting as agents of UCSF at any location may not accept gifts from industry when acting in the course and scope of their UCSF responsibilities.

  UCSF faculty, staff, students and trainee may not accept payment or reimbursement for the following:

  a. payment to the individual from industry for attending a continuing education course, or other educational or professional activity.
  b. payment to the individual from industry for attending a sales or marketing presentation or a lecture or presentation that discusses proprietary products and services. This restriction does not preclude a university official from inviting industry representatives to discuss research or other collaborative opportunities, career opportunities or participate in educational programs such as lectures on entrepreneurship or similar topics.

- UCSF faculty and staff providing clinical care may not accept any payment or gift as
compensation for modifying patient management, medications or other therapies (see 2.a. below for policy regarding free supplies, equipment or samples)

When supplies or equipment are provided to the University or individual investigators at no cost to support research or educational activities, the purpose for the gifting of the supplies or equipment will be reviewed by the Executive Vice Chancellor and Provost or designee to review the proposed donation, determine whether a conflict exists and, if so, to eliminate or manage the conflict; for gifts related to clinical services, the review will be performed by an appropriate medical center or departmental official or committee.

All UCSF faculty, staff, and students must also comply with the policies and procedures for acceptance of donations from industry for each medical center or clinical site at which they practice or have clinical rotations.

- Industry may not provide free samples, supplies, devices, equipment or donations of supplies or equipment to UCSF faculty, staff, students, trainees, volunteers, contractors or agents, unless:
  (i) The agreement to accept free supplies, devices and equipment will be reviewed by the appropriate agent of UCSF, in most cases either Medical Center purchasing or a clinical department,
  (ii) an evaluation process will be articulated as part of the agreement
  (iii) the agreement will be executed by an authorized agent of UCSF
  (iv) for donations of supplies or equipment, the donation is restricted to the time necessary to complete the evaluation and determine whether a purchase decision is appropriate or, for samples, the donation is restricted to the quantity required to complete the evaluation; and
  (v) the donation is either: (i) restricted to use in a free clinic, or to a UCSF clinic for specific use in the management of a low income and indigent patient; or

(b) For educational and research purposes, the following conditions have been met
   (i) The proposed donation is in support of an educational or research program and donation is not restricted to donation by a specific company, and
   (ii) The proposed donation and its purpose are reviewed by a process established by the UCSF Compliance Office to ensure its appropriate acceptance of the donation in light of any real or perceived conflicts of interest.

- Industry may provide unrestricted funds to UCSF departments, divisions or programs for educational purposes, under certain conditions. For more information, please see Section C, Industry Support for Educational Programs.

B. Interaction Between Industry and University Personnel

- Industry representatives must have a scheduled appointment to meet with University
faculty and staff and must fulfill the following requirements:

a. Industry representatives are permitted in UCSF-owned or operated locations to provide scheduled and approved in-service training or other approved educational programs.

b. For clinical activities, industry representatives may provide support and servicing of devices, equipment, and other instruments only pursuant to an executed University contract.

c. Industry representatives may provide such training, support and services by appointment only with appropriate UCSF personnel.

d. Industry representatives may meet with faculty and staff for purposes of research collaborations and other activities consistent with this policy and only with a prior scheduled appointment (see B.3. below).

e. Industry representatives may attend UCSF educational programs when open to the public and paying the established registration fees.

Students and trainees may participate in such meetings for educational purposes only, and may do so only under the supervision of a UCSF faculty member.

Industry representatives may participate in other programs that foster educational or research collaborations, such as discussions about collaborative research initiatives. Such programs must not include sales or marketing presentations or other commercially oriented lectures or discussions. They may only take place on the invitation of a designated University official.

UCSF faculty, staff, students and trainees may not participate in any company speakers’ bureaus in which the sponsor determines the content of presentations or in any way controls or limits what may be presented by the speaker.

UCSF faculty, staff, students and trainees who work at clinical sites other than a UCSF owned or operated site must comply with the requirements of the policies and procedures for interactions with industry set forth in this policy. When working at a non-UCSF owned or operated site that has a policy that is in conflict with this policy, faculty, staff, students and trainees, upon learning of the inconsistency, should report this conflict to the UCSF Compliance Office for clarification about how to respond and recommendations for its resolution.

C. Industry Support for Educational Programs

Industry support for educational programs must be provided free of industry influence on the content of the educational session, clinical care, education or research. All UCSF educational programs must abide by the conflict of interest standards for commercial support established by the relevant national governing body, such as the:

Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support (http://www.accme.org/)

Accreditation Council for Pharmacy Education (ACPE) Standards for Continuing Pharmacy Education
If the relevant national governing body has not established conflict-of-interest standards for commercial support, the ACCME Standards for Commercial Support should be used as a guide (ACCME Standards). Any questions about the interpretation of the requirements for educational programs should be directed to the Executive Vice Chancellor and Provost or designee.

D. Restrictions on Industry Funding for UCSF Educational Programs

This policy and the restrictions outlined apply to all funds provided by industry for UCSF educational programs, including meals or refreshments, speaker honoraria and other expenses. These restrictions also apply to funds provided by educational groups or other entities that act as “intermediaries” for industry. Specifically:

Industry may provide funds to support UCSF educational programs, contingent upon satisfaction of the following requirements:

a. the funds are in the form of an unrestricted grant or gift, and

b. the funds are provided to the relevant department, program or division, and not to an individual UCSF faculty, staff, student, or trainee.

Faculty, staff, students, and trainees planning each educational program and, when applicable, the continuing education office, rather than industry sponsors, shall determine the content or selection of speakers for all UCSF educational programs.

Industry may provide educational activities at a UCSF-owned or operated location, subject to the above-stated restrictions only:

a. upon the request of a department chair or designee; or

b. in accordance with the terms of a final, executed purchase contract with UCSF that provides for in-service or other training.

UCSF faculty or staff members may not require UCSF students or trainees to attend any educational session in which industry representatives disseminate information about proffered products or services.

UCSF faculty, staff, students and trainees making presentations at meetings or conferences not governed by ACCME, ACPE, ANCC, CERP or similar standards for commercial support, and which are supported in whole or in part by industry, must:

a. be allowed to provide a fair and balanced presentation; and

b. not have the content dictated by industry; and
c. be assured financial support provided by industry is publicly disclosed

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

Industry support to UCSF for participation in educational programs must be free of any real or perceived conflict of interest. All educational grants or support for educational programs provided to UCSF faculty, staff, students, and trainees by industry must be specifically intended for the purposes of education and must comply with the following:

The applicable department, program, or division must determine that the proposed conference or program has educational merit.

The applicable UCSF department, program or division must select the faculty, staff, student, or trainee (participants) who will participate in the educational program.

Industry must provide the funds to the participant's department, program, or division rather than directly to the participant.

The industry support is not associated with any implicit or explicit expectation that UCSF, the department, program, division, or participant will provide any tangible or remuneration to industry in return for the support.

Section E does not apply to regional, national, or international merit-based awards or to scholarships, which will be considered on a case-by-case basis.

F. Disclosure of Relationships with Industry

UCSF faculty, staff, students and trainees must disclose their financial interests with outside entities in accordance with University of California and UCSF policy, as well as with the requirements of these guidelines. The specific disclosure obligation and methodology is dependent on the activity:

General Disclosure Requirements

Faculty and staff must comply with UCSF and University of California disclosure requirements, including submission of the annual attestation for members of the Health Sciences Compensation Plan or other disclosure requirements that may be implemented by the University.

Research. UCSF faculty, staff, students and trainees should disclose industry relationships that are related to research activities to the UCSF Conflict of Interest Advisory Committee in accordance with existing UCSF, University and other public disclosure requirements.

(Please refer to the links: [http://or.ucsf.edu/osr/coi.html][13] and [http://www.ucop.edu/research/policies/documents/coipolicy.pdf][14])

Publishing. UCSF faculty, staff, students and trainees should disclose industry relationships, in accordance with the guidelines of the International Committee of Medical Journal Editors [15] for each submitted manuscript.

Education and Management Decisions. UCSF faculty and staff with financial relationships with industry must ensure that the responsibilities to the company do not affect, or appear to affect,
their ability to properly supervise and educate students, residents, and other trainees, nor influence employment decisions.

All financial interests that are relevant to educational activities, including but not limited to, continuing educational activities, must be disclosed and resolved in accordance with ACCME Standards or similar standards for Dentistry, Nursing, and Pharmacy educational activities. In addition, faculty and staff must comply with other UCSF and University of California disclosure requirements, including the annual attestation required for members of the Health Sciences Compensation Plan.

Purchasing. UCSF faculty and staff who receive gifts from or have financial relationships with industry may be disqualified from deliberations or decisions regarding the selection of products or services for UCSF or the UCSF Medical Center (e.g.; selection of drugs to be added to the formulary). They must disclose all relevant gifts or compensation received from industry and recuse themselves from deliberations or decisions, in accordance with the University of California Conflict of Interest Code [16], as well as other related University of California and UCSF policies. The designated committee chair or University official responsible for making the purchasing decision will determine whether the individual faculty or staff member relationship with industry requires that the individual be recused from discussions about selection of products or services or purchasing decisions (ie; votes). Recent Draft FDA Guidance on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees may serve as a guide.

Ghostwriting. UCSF faculty, staff, students and trainees are prohibited from publishing articles that are substantially or completely "ghost" written by industry representatives.

UCSF faculty, staff, students and trainees 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 should be listed as authors or otherwise appropriately cited for their contributions.

The financial interests of UCSF faculty, staff, students and trainees should be listed in accordance with the standards of the journal in which the article is published.

G. Education

All faculty, staff and students to whom this policy applies shall receive training regarding the policy and its implications. The specific format for the educational programs shall be determined by the Executive Vice Chancellor and Provost and be implemented as part of the overall educational effort regarding all policies of the University.

Responsibilities
The office of the Executive Vice Chancellor and Provost is charged with the responsibility of administration of this policy.

Procedures
This Policy should be read in conjunction with the University of California Health Care Vendor Relations Policy [13], because it does not cover all subjects and circumstances addressed by the broader University of California policy.
This Policy also supplements other University and UCSF policies on conflicts of interest, as well as the requirements of the Health Sciences Compensation Plan, as applicable. UCSF faculty, staff, students and trainees should familiarize themselves with these policies and their reporting obligations.

In cases in which this Policy and either a University or UCSF policy conflict, the more restrictive policy shall apply. Questions about this Policy and related UCSF policies should be discussed with one’s department chair and/or administrative staff.

References

- Letter From UCOP President Dynes: [17]
- UCOP Health Care Vendor Relations Policy (HCVRP) [3]
- UCOP HCVRP Frequently Asked Questions: [18]
- Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation on FDA Advisory Committees, US Department of Health and Human Services, Food and Drug Administration, March, 2007