

TITLE: Guidelines, Policies and Procedures Regulating Industry Relationship with Academic Faculty and Trainees at UF-COM-Jacksonville

INTRODUCTION:

The relationship between academic institutions and the pharmaceutical, device or service industry (Industry) occurs at multiple levels. The interactions can occur with clinicians, researchers and trainees, through continuing medical education (CME), professional societies and medical journals.

The interaction of Industry and academia promotes innovation and enhancement of health care but is fraught with situations where a conflict of interest (COI) may arise. Dealing with COI can be achieved with a variety of actions including prohibition, divestiture, abstention, mediation and disclosure.

The faculty and staff at UF-COM JAX recognize that their primary professional responsibility is to support the Institution in achieving its goals of teaching, patient care and research. The basic principles of COI with regard to outside activities and financial interests as well as the reporting requirements and review procedures are addressed in a previous UF policy available at <http://www.generalcounsel.ufl.edu/downloads/COI.pdf>. The present document is an extension of that policy with the narrower focus on industry-academia relationship with emphasis on ensuring and preserving physician professionalism.

PURPOSE:

Recognizing that there are legitimate and necessary interactions between faculty, residents, staff and students and the Industry, it is the purpose of this policy to define the boundaries of this relationship and establish mechanisms to monitor the relationships.

POLICY:

The activities of all representatives of Industry within UF-COM-JAX and affiliated facilities shall NOT compromise the fiduciary relationship between clinicians and patients and shall include only those activities that are beneficial to the goals of the University in teaching, patient care and research.

PROCEDURE:

I. Presence of pharmaceutical or device or service company representatives (pharma reps) on campus:

Pharma reps (e.g. sales representatives, medical or scientific liaisons, or any third party contracted or paid by the Industry) are not allowed on campus defined as all the areas where UF physicians carry out their official duties. The exceptions to this policy are:

- 1) Pharma reps are allowed on campus during a designated “pharma rep day” organized by GME office or by a group or individual designated by the Dean.
- 2) Pharma reps are allowed on campus only for pre-approved on-site courses for training, processed by CME office and outside of patient care areas. When CME credit is not offered and residents are involved, the activity must be approved by the GME office. If training requires presence in patient care areas, or the presence of the rep is requested for his/her technical expertise, the rep must comply with hospital policy (Policy N0. Rx 11-063) for such activity and his/her presence on campus should be limited to a pre-specified time that is enough to accomplish the task.
- 3) Pharma reps are allowed in non-clinical areas designated by each Department if they have a prior appointment with a faculty member.

II. Foods and beverages for faculty, trainees and staff provided by the Industry on campus and off campus:

Foods and beverages “off campus” and “on campus” are allowed if organized by a UF office through a grant from the Industry provided to an education fund in Dean’s office or CME office. Industry support is acknowledged by course director but reps are not allowed to attend or to make any marketing presentations. Meals purchased directly by Industry for “on campus” activities are not allowed.

Participation in “off campus” non-UF activity is left at the discretion of the faculty member or resident.

III. Gifts for faculty, trainees and staff provided by pharmaceutical companies:

All gifts for faculty, trainees and clinical or administrative staff provided by the Industry are completely banned

IV. Faculty and resident travel paid for by Industry.

Faculty and house staff travel expenses can be paid through an unrestricted educational account deposited in a central account maintained in the Department or in the GME office. It is prohibited to accept travel payments from the Industry except as a reimbursement of costs incurred during the individual's involvement in speakers' bureau or consulting activities specified in section V.

V. Participation in industry sponsored speakers' bureaus and in consulting activities for pharmaceutical companies:

Consulting activities for pharmaceutical companies and participation in industry sponsored speakers' bureaus should be conducted in accordance with the UF Guidelines, Policies and Procedures on conflict of interest and outside activities including financial interests as described at: <http://www.generalcounsel.ufl.edu/downloads/COI.pdf>. Faculty members are discouraged from participating in industry sponsored speakers' bureau when they are personally compensated.

VI. Participation in research funded by pharmaceutical industry:

Faculty is encouraged to participate in both investigator and industry initiated research activities so long as they are compliant with current policies governing research activities on campus. The participating research subjects should be informed of any potential conflicts of interest of the investigators. All requests for grants to support research should be initiated through the Research Office.

VII. Acceptance of grants from pharmaceutical industry to fund post doctoral positions or "summer" students:

All grants from pharmaceutical industry to fund post doctoral positions or "summer" students should be pre- approved by the GME office prior to submission of the application. These grants should be free of any restrictions imposed by the funding company including any role in selection of recipients of the awards. The funds received should be deposited in a GME account.

Only the GME office will acknowledge the support of the sponsoring entity in an official communication.

VIII. Guest speakers sponsored by pharmaceutical companies:

Guest speakers sponsored by the Industry are not allowed. The Industry can support CME through a grant to the CME office or to a Departmental GME account if the standards of the Accreditation Council for Continuing Medical Education (ACCME) are met. The candidate speaker should be chosen by the host without any input of the sponsoring company. The presentation should be reviewed by the course director to ensure compliance with the principles of fair presentation and lack of marketing slant.

IX. Acceptance and dispensing of pharmaceutical or device samples:

Pharmaceutical or device sampling is allowed when it is accepted at a centralized unit (e.g. pharmacy or materials management for devices) that will monitor the distribution and dispensing of the samples. Alternatively, the samples can be shipped or delivered by a courier to the Chief of Service or his/her designee in the clinics who will be responsible for stocking and monitoring of its use. This should not be used as a mechanism for pharma reps to have access to clinic staff or trainees. Pharma reps are not permitted in patient care areas and should not have access to clinic staff or trainees except by prior appointment.

X. Acceptance of educational materials from pharmaceutical or device companies:

Teaching aids and support for scholarships or fellowships may be provided if a vendor wishes to support the educational mission of the institution. These may be provided only through unrestricted educational grants placed in a central fund or departmental GME account, and monitored by the Dean or his/her designated compliance officer. "Branded" educational materials provided by the Industry are not allowed on campus. Exceptions to the latter are the devices and supplies that have manufacturer's standard information or brand name. Scholarship is encouraged but gifts are not allowed. The Center for Simulation Education and Safety Research will arrange to utilize branded equipment, devices and supplies for medical education through appropriately negotiated contractual agreements with vendors, and with review and approval by the Dean. In addition, textbooks may be donated by Industry and can carry a sticker inside the cover to acknowledge the donor.

XI. Philanthropic gifts from the Industry:

True philanthropic gifts from the Industry can be accepted through the UF Foundation.

XII. Authorship of manuscripts drafted by pharmaceutical industry or their sub-contractors.

Authorship of manuscripts that are written by Industry or their subcontractors without any significant contribution of the author, sometimes referred to as “ghost writing” is prohibited.

XIII. Monitoring and enforcement of the policy:

Alleged violations of this policy will be investigated by the Office of the Assistant Dean of Administration. Suspected violations of the policy will be referred to the individual’s immediate supervisor, departmental Chair and/or the Dean who will determine what action if any should be taken. The Assistant Dean of Administration will develop the procedures for monitoring and investigating the alleged violations. The current policy of approval of outside activities will remain in effect and can be used as the mechanism to enforce the COI policy as described at <http://www.generalcounsel.ufl.edu/downloads/COI.pdf>. In accordance with Public Record Laws all faculty COI declarations will be available for public inspection.

Violations of this policy by University employees may result in the following actions (singly or in any combination), depending upon the seriousness of the violation, whether the violation is a first or repeat offense, and whether the violator knowingly violated the policy or attempted to hide the violation:

1. Counseling of the individual involved;
2. Written reprimand, entered into the violator’s employment or faculty record;
3. Banning the violator from any further outside engagements for a period of time;
4. Requiring that the violator return any monies or gifts received from the improper outside relationship;
5. Removing the violator from supervision of trainees or students;
6. Suspension without pay;
7. Termination for cause.

Any disciplinary action taken hereunder shall follow the established procedures of the University of Florida.

Violation of any of the above procedures by pharma representatives shall result in responsive action which may include, but shall not be limited, to the following:

1. First violation: Verbal and written warning to representative; written notification to district manager or representative's supervisor.
2. Second violation: Suspension of representative and all other company sales/marketing representatives from the UF Campus for six months.
3. Third violation: Suspension of representative and all other sales/marketing representatives of the company from the UF Campus for one year or more. A review of products obtained from the company will be conducted.

Suspended representatives found on UF Campus promoting their products will be escorted from the premises and their companies notified as appropriate.