Charles E. Schmidt College of Medicine Administrative Policies

**Subject:** Industry Relations

**Effective Date:** July 10, 2014


**Responsible Authority:** Senior Associate Dean for Research

**Policy Statement:**

The Charles E. Schmidt College of Medicine (COM) at Florida Atlantic University (FAU) recognizes the possibility of conflict of interest or apparent conflict of interest in interactions with corporations, representatives of corporations and other individuals supported by medically-related industries. At the same time COM recognizes that several medically-related industries provide appropriate and legitimate support for educational and patient care activities. This policy serves to describe an acceptable learning environment where faculty, students and residents are shielded from industry bias. This policy incorporates standards of practice comparable to those adopted by medical schools nationwide.

The COM assures the public that it is aware of the risks involving conflict of interest, and takes conflict of interest seriously. Medical students and residents should not be exposed to interactions that may create a conflict or the appearance of a conflict of interest. Faculty interacting with students and residents are expected to model appropriate interactions and to prevent inappropriate exposure of students and residents to representatives of medically-related industries.

Accordingly the COM at FAU follows the following policy concerning interactions with industry, and adheres to the guidelines below. Additionally two university wide policies pertaining to conflict of interest must also be followed, in addition to other applicable university regulations and policies:

- General Conflict of Interest Policy
- Research Conflict of Interest Policy

Full-time COM faculty are subject to this policy at all times. This policy applies to affiliate and part-time faculty when they are acting on behalf of the University within the scope of their appointment (teaching, supervising trainees, etc.). When not acting in their role as an FAU faculty member, affiliate and part-time faculty are not subject to this policy. The COM recognizes that its affiliated hospitals and clinical sites have their own specific policies regarding corporations and vendors, and will actively support and enforce these policies as well, to the extent they are consistent with University policy.

The Senior Associate Dean for Medical Education is responsible for student education on acceptable interactions with industry, so that students can make appropriate choices should a potential conflict arise. The Senior Associate Dean for Graduate Medical Education is responsible for resident education on acceptable interactions with industry, so that residents can make similar appropriate choices. The appropriate Department Chair is responsible for assuring compliance with this policy.
Definitions:
- Industry - Includes, but is not limited to, pharmaceutical, device, equipment, biotechnology, service, software, supplies, biomedical investment, and for-profit educational companies, and foundations sponsored by companies such as drug and device companies.
- Faculty - Includes the full-time, part-time and affiliate faculty of the COM.
- PHI - Protected Health Information as defined by the HIPAA Privacy Rule: any health related information that can be used to identify an individual.
- Consulting - Any relationship where a University employee is retained by an industry business entity to provide professional advice or services outside of his/her University employment.

Gifts and Materials from Industry

Students and residents of the COM may not accept gifts or meals provided by Industry under any circumstances. Students and residents will be educated regarding the potential for gifts and meals to bias objective professional judgment and clinical decision-making, and will be expected to refuse any offers for such items.

Items from Industry that may be perceived as marketing materials, such as pens, notepads and other items, with company or product logos may not be accepted under any circumstances. Gifts in the form of entertainment or recreational activities/items, cash, or cash equivalents (such as gift certificates), and items for personal benefit may not be accepted at any time, regardless of value.

Faculty in a direct supervisory role of residents or students should assure that the learning environment is free from industry influence, including free of meals and gifts as noted above. Part-time and affiliate faculty should make every attempt to schedule industry-sponsored activities or meals during a time when students and residents are scheduled in other locations. If meals are scheduled at a time when students and residents are in the office, they should not be offered the opportunity to participate or offered any gifts. For the privacy of patients, all on-site meals must be scheduled in advance and held in non-patient care areas where PHI is not seen or overheard.

Pharmaceutical Samples

Pharmaceutical samples can benefit patient care by allowing patients to try a new medication for effectiveness and tolerance prior to incurring a cost, and by expediting access. With these benefits comes the responsibility for managing the medications to ensure security of medication inventory, prevent dispensing of expired medications, and recording of all dispensed medications in the respective patient records. Students and residents may not be involved in the receipt, storage or dispensing of pharmaceutical samples.

COM faculty, residents, and medical students may not accept remuneration of any kind for either receiving or dispensing sample medications.
Industry Representative Visits

Industry representatives are required to schedule an appointment to meet with any COM faculty and must limit their interaction to that physician. Students and residents may participate in discussions with industry representatives where questions are asked; however the Attending Physician must be present and use this as an opportunity to discuss the potential for bias and to look at additional information sources as well. On their initial visit to any COM affiliated site, Industry representatives are to be notified of Industry Relations and Conflict of Interest policies. Industry representatives are not allowed access to patients or PHI unless authorized by the treating physician and patient for involvement in patient care in accordance with appropriate patient consent or in accordance with an IRB/Privacy Board approved research authorization or waiver.

Educational materials, products or product information that may be useful to patients may be directly accepted by the physician and designated clinic staff, but not by students or residents. Industry representatives are not permitted to place educational materials in patient care areas or waiting areas. Any educational sessions presented by Industry representatives are to be held away from patient care areas so that PHI is not viewed or heard.

Professional Meetings and Presentations

Attendance by COM faculty, residents and students at conferences or meetings where objective scientific and/or educational activities are the primary focus of the conference or meeting ("Professional Meetings") is encouraged. Direct payment or reimbursement by Industry of travel, or other expenses associated with attendance at Professional Meetings, to faculty, residents or students is not permitted.

Participation by faculty as speakers at Professional Meetings is encouraged. Such participation enhances the national reputation of the COM, Florida Atlantic University, and of the individual faculty member. The COM recognizes that faculty spend time and effort apart from their regular University duties in preparing for such engagements, and that compensation based on the faculty member's expertise, experience, regional/national/international reputation, and specialty by the sponsor or organizers of the Professional Meeting for the faculty member's time, expertise and the expenses of attendance may be offered, according to ACCME policies.

Faculty participation as speakers or content experts at Professional Meetings where Compensation/honoraria is offered shall normally be conducted as an outside activity. Affiliate faculty may do this on their own time and on their own behalf, and should not utilize or refer to their COM faculty title during the presentation. Part-time and full-time faculty members may also participate in the Professional Meeting as an outside activity on their own time without the use of their COM title; however they must disclose the activity via the outside activity reporting guidelines (Reporting Outside Activities Database), discuss the forum with their Department Chair and obtain approval from their Chair. Approval will not be unreasonably withheld, but will be dependent upon whether the faculty member is meeting his or her departmental assignments/expectations. The faculty member may also need to submit a request for annual leave if the participation will take place during University business hours.
(Monday-Friday 8am-5pm) or during periods when scheduled for on-call duties, as discussed with the Department Chair.

Any honorarium or other payments may be made directly to the faculty member and should be fair and reasonable compensation. The actual costs of travel, lodging and other reasonable expenses of attending the event may also be paid or reimbursed by the sponsor or organizer of the meeting but should not be paid directly to the faculty member by Industry.

Faculty participating as speakers at Professional Meetings for which continuing professional education (CPE) credit is offered will be subject to the CPE policies and procedures of the ACCME accredited CME provider. Honorarium and payment or reimbursement of expenses for lecturing at CPE events should be paid by the ACCME accredited CME provider to the faculty member but should not be paid directly to the faculty member by Industry.

Occasionally, faculty members will be invited to lecture at conferences sponsored by nationally recognized professional organizations (e.g. AAMC). In these situations, the professional organization will be the credentialing body for the event and will also require faculty to follow its CPE policies and procedures.

The COM recognizes that its faculty may be sought after as speakers to present information relevant to a company’s products to the medical and health care provider community. Affiliate or part-time faculty may spend time and effort apart from their regular assigned University duties in preparing for such presentations, and compensation by the company for the faculty member's time may be offered.

Faculty participation as speakers on behalf of industry products must be conducted as an outside activity. Any paid faculty member must disclose the activity via the outside activity reporting guidelines (Reporting Outside Activities Database) and obtain approval from their Department Chair. Approval will not be unreasonably withheld, but will be dependent upon whether the faculty member is meeting his or her departmental assignments and obligations. The faculty member must also submit a request for annual leave if the participation will take place during University business hours (8am-5pm, Monday-Friday) or during periods when scheduled for on call duties. Faculty members are prohibited from using or referring to their COM titles when giving such presentations, and may not involve students or residents in these activities.

Payment to faculty members must be reasonable and fair compensation for the work performed based on the faculty member's expertise, experience, regional/national/international reputation, and specialty. The gathering where the information is presented must be primarily dedicated to informing healthcare professionals about a product or treatment, providing scientific information, and promoting educational discourse on the topic presented. The venue must be conducive to informational communication and meals (a) are modest as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication. In addition, inclusion of a healthcare professional’s spouse or other guest in a meal accompanying an informational presentation made by or on behalf of Industry is not appropriate.
Presentation materials on drug products must follow pharmaceutical guidelines and present information on the FDA-approved use of the drug product and may not promote the "off-label" use of a drug product. Faculty members may not participate in product promotional activities when acting on behalf of FAU or using their FAU affiliation.

**Consulting Relationships with Industry**

The COM expects that its faculty will be sought after as consultants to Industry and agrees that such relationships can lead to medical innovation, better medical and surgical products, and can ultimately promote better patient care. Affiliate faculty and part-time paid faculty may enter into these arrangements. However, such consulting relationships must not:

- compromise professional ethics;
- utilize an individual’s title as a member of the COM faculty;
- have elements that may be construed by the government as an illegal kickback, resulting in criminal charges;
- be used as a vehicle for direct payment to faculty aimed at convincing them to use a company's products; or
- interfere with university duties, including supervision of medical students and residents.

Accordingly, consulting relationships with Industry are permitted for affiliate faculty and part-time paid faculty under the following conditions:

- for paid part-time faculty the relationship must be disclosed via the outside activity reporting guidelines (Reporting Outside Activities Database); and approved by the Department Chair; and
- paid part-time faculty must submit a request for annual leave if the participation will take place during University business hours (Monday – Friday 8am-5pm) or during periods when scheduled for on-call duties;
- the relationship must be based on a written agreement which documents the specific, legitimate tasks and deliverables; and
- payment amount must reflect reasonable and fair compensation and be commensurate with the tasks performed, considering the faculty member's specialty, expertise and regional/national/international reputation.

A copy of the final, fully executed contract must be submitted to the Department Chair for the department file.

On occasion, a company will ask for a release letter from Florida Atlantic University indicating that the University has authorized the faculty member to engage in the outside activity in question. The faculty member may provide the approved outside activity form in response to this request at the discretion of the Department Chair.