

**University of Florida
College of Medicine
Policy on Industry Conflicts of Interest/Industry Academic Relations**

Introduction

The University of Florida has long had a document providing guidelines, policies and procedures on conflict of interest and outside activities for faculty, staff and students. All COM faculty, residents, staff and students must be familiar with this policy and its reporting requirements.

The policy can be accessed at:

http://www.research.ufl.edu/research/outside_activities.html

The faculty, staff and students of the College of Medicine (COM) must be especially sensitive to even the appearance of conflict of interest when it comes to relationships with the pharmaceutical and medical device industry. The basic principle of healthcare is that the patient's well being takes priority over that of the care giver's. Recently, several high profile instances have come to light where it appears physicians and researchers have violated this trust. The public has responded with outrage and legislation at both the state and federal levels has been proposed that would establish government regulation of the vendor-healthcare provider relationship.

The pharmaceutical and medical device industry spends more on advertising to healthcare providers and the public than it spends on research and development. There is ample evidence that such advertising efforts are effective in influencing prescribing practice, especially when advertising is accompanied by gifts. Data reflect that even small gifts create a sense of obligation in the recipient that translates as sales for the company. Besides calling into question the issue of the provider's unwavering devotion to the patient's well being, such practice also may lead to higher cost by increasing the volume of prescriptions and the tendency to prescribe name-brand rather than generic drugs.

Because there are legitimate and necessary interactions between COM faculty, residents, staff and students and the pharmaceutical and medical device industry, the COM has established a policy that defines the boundaries regarding acceptable relationships with the pharmaceutical and medical device industry, as well as establishing mechanisms to monitor these relationships.

Applicability of Policy

This policy applies to all COM faculty, residents, staff and students. This policy does not supersede the University of Florida's policy regarding the disclosure of outside activities, financial interests and conflict of interest, which is applicable to all University of Florida employees

Statement of Policy

The goal of this policy is to ensure that all clinical, educational and research decision-making is free of influence created by relationships with any outside interest and that all individuals are aware of their individual and institutional responsibilities with regard to industry relations. It is

the policy of the COM that complete transparency shall occur in all interactions and encounters between COM faculty, residents, staff and students and the pharmaceutical and medical device industry. A care giver's primary responsibility is to his/her patients. Researchers must be free of any potential for bias. When appropriate interactions occur between industry and COM faculty, residents, staff and students, the boundaries for such interaction must be consistent with this policy.

All COM faculty, residents, staff and students shall receive specific instruction tailored to their role in appropriate academic-industry interactions. Ultimately, the COM and its faculty, residents, staff and students are accountable for their respective actions. The following guidelines identify specific activities that address interactions with industry representatives and vendors. COM faculty, residents, staff and students also should consult with their respective department chairs or immediate supervisors to obtain further guidance.

Specific Activities

A. Gifts to Individuals

COM faculty, residents, staff and students may not accept gifts from industry representatives or vendors **regardless of the monetary value of the gift.**

B. Pharmaceutical Samples, Devices and Other Materials

Pharmaceutical Samples

Pharmaceutical samples shall be distributed through a voucher system administered by Shands HealthCare pharmacy service. In the event a faculty member feels doing so would jeopardize a vulnerable population of patients, the physician may request a waiver from this rule from the UFP Clinical Safety Committee. Physicians requesting a waiver must show clear benefit and provide safeguards for the appropriate distribution and control of samples. Samples shall not be accepted for personal use by faculty, staff, residents or students.

Teaching Aids/Books/Devices

COM faculty, residents, staff and students are not permitted to accept books, instruments and other teaching aids from industry representatives or vendors. Industry representatives or vendors requesting to support the educational mission of the COM may provide an unrestricted grant, which will be placed in a central fund and monitored/distributed by the COM Industry Academic Relations committee.

Patient materials

Educational materials for COM faculty, residents, staff and students or for patients supplied by industry representatives or vendors is permitted provided such materials are preapproved by the COM Industry Academic Relations committee and are not "branded" by the supplier of the materials. Such materials may not be distributed directly to COM faculty, residents, staff and students or to patients by industry representatives or vendors.

C. On-Site Access by Industry Representatives and Vendors

On-site access by industry representatives or vendors is restricted to non-patient care and public areas only. Industry representatives and vendors are permitted access to patient care areas and non-public areas only when their presence is necessary for educational purposes and then only by appointment and, when appropriate, with the prior consent of the patient. Such on-site access by industry representatives and vendors must be under the constant supervision of a COM faculty member. These activities also are subject to the policies of Shands HealthCare regarding such access.

On-site access by industry representatives and vendors at “vendor fairs” is permitted with the preapproval of the COM Industry Academic Relations committee. Participation by industry representatives and vendors in such events is subject to the provisions referenced in the “Gifts” section of this policy.

D. Continuing Medical Education (CME)

On-Site Courses

COM faculty, residents, staff and students are permitted to engage in educational activities in on-site venues. All such courses must conform to ACCME standards and must be processed through and approved by the COM’s Continuing Medical Education office.

Off-Site Courses

COM faculty, residents, staff and students are permitted to participate in off-site CME courses if these courses conform to the requirements of the ACCME. Specifically there must be full disclosure of the sources of financial support, the program must be free of bias and the planners and speakers must declare any source of possible conflict of interest. Payment for attendance is prohibited. Individuals may receive an honorarium for speaking from the sponsors of the CME event .

Required On-Site Training

Industry representatives or vendors may provide on-site training to COM faculty, residents, staff and students with preapproval from the COM’s Continuing Medical Education office. Such training shall be conducted in accordance with ACCME standards. Training to be conducted in patient care areas must conform to Shands HealthCare policy.

E. Speaker Bureaus

COM faculty, residents, staff and students participation in industry-sponsored speakers’ bureaus is discouraged. However, where such activity has an educational value and is preapproved by the employee’s department chair or immediate supervisor, COM faculty, residents, staff and students engaging in such activity must comply with the University of Florida’s regulation regarding the disclosure of outside activities, financial interests and conflict of interest. Approval for such activity will be denied if the content of the talk is in any way provided by industry or subject to industry approval or if the attendees of the event are selected by industry or provided

a gift or stipend to attend. Such activities also require the COM faculty, resident or staff to report appropriate leave usage while in engaged in such activities.

F. Food/ Entertainment

On-Site Food

COM faculty, residents, staff and students may not accept food or meals sponsored by or provided by industry representatives or vendors. Industry representatives or vendors requesting to support the educational mission of the COM may provide an unrestricted grant, which will be placed in a central fund and monitored/distributed by the COM Industry Academic Relations committee.

Food and meals supplied by industry representatives or vendors in conjunction with a CME event sponsored by the COM must comply with the guidelines established by the COM's Continuing Medical Education office.

Off-Site Food/Entertainment

COM faculty, residents, staff and students may not accept food or meals sponsored by or provided by industry representatives or vendors at off-site locations. This includes events with an educational component (e.g. journal club) unless this event has been approved by the CME office. Industry funding may not be accepted for departmental meetings, retreats or social events. Dinners or entertainment sponsored by and paid for by industry representatives or vendors for a small group of select individuals at national meetings/conferences is not permitted.

COM faculty, residents, staff and students may attend educational events during national meetings/conferences where food is provided by or sponsored by industry representatives or vendors provided such events adhere to ACCME standards.

G. Travel to Meetings/Honoraria for Attendance

COM faculty, residents, staff and students are not permitted to accept travel funds or payment from industry representatives or vendors to attend a meeting or conference. Industry representatives or vendors requesting to support the educational mission of the COM may provide an unrestricted grant, which will be placed in a central fund and monitored/distributed by the COM Industry Academic Relations committee.

H. Ghostwriting

COM faculty, residents, staff and students are not permitted to allow their professional presentations, books, articles, reports or other materials, oral or written, to be by written by another party or by an industry representative.

I. Scholarships/Fellowships

COM faculty, residents, staff and students may not accept scholarships or fellowships to support training initiatives from industry representatives or vendors. Industry representatives or

vendors requesting to support the educational mission of the COM may provide an unrestricted grant, which will be placed in a central fund and monitored/distributed by the COM Industry Academic Relations committee. There shall be no quid pro quo associated with such funding.

J. Outside Employment/Consulting

COM faculty, residents and staff may engage in outside employment, consulting, and other similar activities in addition to their COM employment provided such activities do not conflict with the employee's duties and responsibilities to the COM and to the University of Florida. Such activities also must be permitted under state law and University of Florida policies. For such activity to be approved, the COM faculty, resident and staff must provide evidence that such activities further the educational mission of the COM in exchange for any remuneration being provided.

Outside employment and consulting activities of COM faculty, residents and staff are of concern to the University of Florida and may be disallowed if they result in conflicts with the employee's duties, responsibilities, and obligations to the COM.

K. Purchasing

COM faculty, residents, staff and students engaged in the purchase of equipment, supplies, etc. are subject to the provisions of the University of Florida's regulation regarding the disclosure of outside activities, financial interests and conflict of interest.

COM department chairs and immediate supervisors are responsible for informing employees that the University of Florida requires that an approved Disclosure of Outside Activities and Financial Interests form be attached to each applicable Requisition to Purchase from an enterprise in which an employee has material financial or managerial interest. If there is a requisition prepared to purchase from an enterprise in which an employee has a material interest, the employee with the interest cannot approve the requisition. If the purchase is allowed under state law, the approval of the employee's supervisor will be required when an outside interest exists regardless of whether the proposed purchases fall under the sole source, emergency, or special purchasing categories.

L. Monitoring

The COM will establish an "Industry Academic Relations" committee to provide oversight and enforcement of the provisions of the COM's Policy on Industry Conflicts of Interest/Industry Academic Relations.

M. Disclosure and Notification

COM faculty, residents and staff wishing to engage in activities outside the COM have an obligation to disclose and receive approval prior to engaging in these activities and to assure that such activities do not infringe upon an employee's responsibilities and obligations to the COM and to the University of Florida. Each employee is responsible for complying with the rules and laws concerning outside activities and financial interests.

COM faculty, residents and staff engaging in outside activities must take reasonable precautions to ensure that the outside employer or other recipient of services understands that he or she is engaging in the activities as an individual and not on behalf of the COM or the University of Florida. An employee may not use the University's resources, including its name or addresses, without express written approval from a COM administrator designated by the University of Florida President to approve such use.

The disclosure of outside activities and financial interests are to be reported on the University of Florida's form titled Disclosure of Outside Activities and Financial Interests, which is to be reviewed by the department chair or immediate supervisor and forwarded to the dean or director as necessary for authorization. This form should be completed and filed prior to such time as the outside activity or financial interest begins and at the beginning of each contractual year of employment. If a material change in the information presented occurs during the contractual year, a new form must be submitted. All paperwork associated with continuing outside employment/activity must be renewed on a fiscal-year basis.

College of Medicine faculty who present formal lectures to students or residents of the University of Florida must disclose any and all possible conflicts, financial interests or personal relationships with industry at each presentation.

Annual Reporting

Prior to the end of each academic year, COM faculty and staff reporting the disclosure of outside activities and financial interests during the year shall report the total financial compensation received for such activities. Financial compensation shall be reported using three categories of compensation: \$0 to \$5,000, \$5,001 to \$10,000, and \$10,001 and greater.

COM faculty, residents and staff who have no outside activities or financial interests to report are required to provide an annual attestation to that effect.

N. Penalties and Enforcement

All COM faculty, residents and staff are subject to the constitution and laws of the state of Florida, and the rules, regulations and policies of the Florida Board of Governors and the University of Florida Board of Trustees.

COM faculty, residents, staff and students who fail to abide by the provisions of the COM's Policy on Industry Conflicts of Interest/Industry Academic Relations are subject to appropriate administrative or disciplinary action.

O. Education

COM directors, department chairs and immediate supervisors are responsible for informing and educating employees in their respective work units about the COM and the University of Florida's policy on disclosure of outside activities and financial interests, and for ascertaining

that an employee's COM and University of Florida responsibilities are not being abrogated by the activity after it has been disclosed.

COM directors, department chairs and immediate supervisors are responsible for providing new employees with the information regarding outside activities and conflict of interest. COM directors, department chairs and immediate supervisors also are responsible for reviewing the disclosure and notifying the employee whether or not the activity may be conducted. If not, the reasons for not allowing the activity must be provided. If the activity is allowed with conditions, the administrator shall state the conditions under which the activity may be pursued. Authorization also may be required by Research and Graduate Education if the activity involves waiving any rights to intellectual property.

P. Effective Date and Approval

This policy was approved by the College of Medicine Executive Committee and is effective June 18, 2009.

Approved:

A handwritten signature in black ink that reads "ML Good MD". The letters are cursive and somewhat stylized.

Michael L. Good, M.D.
Interim Dean, College of Medicine
Folke H. Peterson Dean's Distinguished Professor