

**University of Central Florida College of Medicine
Industry Relations Policy and Guidelines**

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1. Introduction and Scope of Policy

The UCF College of Medicine (COM) strives to be a leader in assuring the highest levels of ethics and professionalism in all dealings with the health care industry, which includes, but is not limited to, the pharmaceutical, biotechnology, medical device, and medical equipment supply industry (“Industry”), and in establishing a culture of ethical behavior and accountability for its administrators, faculty, staff, students, residents, and fellows (“COM Personnel”). The COM greatly values its Industry partners and works openly in collaboration with these partners and vendors to promote positive, productive, and ethical relationships. As leaders in science and medicine, COM experts participate in appropriate Industry advisory roles, Industry-funded scientific studies, and development of new health care discoveries and resources. As a leader in health care transformation, the COM develops collaborative partnerships and business arrangements with Industry partners. As a non-profit educational institution, the COM seeks and accepts philanthropic support from Industry. This policy will guide all COM Personnel in structuring and participating in Industry relationships to assure integrity of professional judgment, the highest ethical behaviors, and the objectivity of medical education.

This policy applies to all individual and institutional financial relationships, business arrangements, and interactions with Industry vendors and developers of products and services that are marketed and sold to medical schools, academic health science centers, researchers, educators, and clinicians. This policy applies to all COM Personnel and covers relationships and activities that occur during both work and non-work hours.

Indirect minority investment interests, such as investments in a mutual fund that owns shares in a pharmaceutical company, are not considered conflicting interests for purposes of this policy.

2. Statement of Policy

It is the intent of the COM to work collaboratively with Industry partners that share a heightened commitment to maintaining the highest ethical standards. All COM relationships and interactions with Industry will be structured, managed, and monitored to assure adherence to such ethical standards. Individual and institutional decisions, actions, and relationships must be free from even the appearance of bias relating to vendor/Industry relationships. Clinical judgments, business agreements, education, and research activities must not be impacted by undue influence resulting from financial relationships with, or gifts provided by, Industry. All collaborations and financial relationships with Industry must be based on the goals of advancing science, education, and clinical care consistent with the COM mission and values.

For questions or further guidance, COM Personnel should consult with a member of the COM Industry Relations Committee (the “Committee”) or with the Dean. It is the responsibility of each individual to seek necessary guidance and approvals in advance of participating in an Industry relationship. Philanthropic gifts provided by Industry are subject to this Policy and may be subject to additional policies of the COM or affiliated entities or foundations fundraising on its behalf. In addition to review for ethical issues, all financial and business relationships with Industry must be carefully reviewed for compliance with all applicable legal, regulatory, reimbursement, and accreditation requirements. Associated contracts must be reviewed, approved and signed in accordance with COM and University procedures.

3. Gifts and Individual Financial Relationships with Industry

3.1 Gifts and Meals

COM Personnel shall not accept or use personal gifts (including food) from representatives of Industry, regardless of the nature or dollar value of the gift.

Gifts from Industry that incorporate a product or company logo on the gift (e.g., pens, notepads, or office items such as clocks) introduce a commercial, marketing presence that is not appropriate to a non-profit educational and healthcare system¹. However, food provided in connection with an educational program accredited by the Accreditation Council for Continuing Medical Education (ACCME) or a professional society-sponsored meeting with paid registration may be accepted.

Meals or other food and hospitality funded directly by Industry may not be offered in any COM facility. COM Personnel may not accept free meals or other food or hospitality funded by Industry, whether on-campus or off-campus, and may not accept complimentary tickets to sporting or other events or other such benefits from Industry, unless otherwise provided in this policy.

3.2 Consulting Relationships

COM Personnel may engage in consulting arrangements provided such activities further COM's mission and do not conflict with the individual's duties, responsibilities and obligations to COM. Consulting arrangements with Industry must be reviewed in accordance with this policy and approved in advance by the individual's Chair, Director, or Associate Dean or the Dean or the Dean's Designee.

Consulting arrangements must be set forth in written agreements, or narrative description if agreement is not available, clearly specifying expert services to be paid for at fair market value. Participation on Industry advisory boards is permitted so long as the board regularly meets and provides scientific advice and other guidance that advances academic values and promotes ethical relationships between academic health sciences and Industry. Agreements must be reviewed, approved and signed through usual COM procedures. COM Compliance will periodically audit consulting agreements for compliance with this provision. A list of Industry consulting agreements of COM employees shall be made available annually to the Committee. These procedures apply whether the consulting fees are received by COM or the individual or donated to another organization.

For individual consulting relationships with fees that exceed \$10,000 per company per year, annual reports describing activities, payments, and time spent must be submitted to COM Compliance as long as the relationship lasts.

¹ Exception: This provision does not prohibit acceptance of items bearing Industry logos provided as part of an off-site educational program (such as a meeting of a professional society), including name tag lanyards and totes where the items are provided and used incidental to attendance, the items are of nominal value, and the items are not used in any COM facilities.

3.3 Industry Funded Speaking Relationships, Meetings, and Publications

COM Personnel must assure that participation in Industry-funded speaking relationships, meetings, and publications serves to advance scientific knowledge and patient care and are not primarily Industry marketing activities. Industry funded speaking arrangements must be approved in advance by the individual's Chair, Director, or Associate Dean or the Dean or the Dean's Designee. Honoraria for speaking engagements, whether received by the individual or by the COM, must be modest and consistent with fair market value of the time spent in preparing and presenting the talk and reasonable travel expenses.

COM Personnel are responsible for the scientific integrity of material presented in any talk or publication and shall decline to participate in educational presentations or scientific publications if the content is controlled by or requires prior approval by Industry, if the content is not based on the best available scientific evidence, or if significant portions are written by someone who is not an author or otherwise properly acknowledged.

Participation by COM Personnel in "Speakers' Bureau Activity" is prohibited. "Speakers' Bureau Activity" means any speaking engagement in which COM Personnel would be speaking on behalf of Industry where the content of the talk is not original to the COM Personnel or is subject to Industry approval, or the attendees to the event are selected by Industry or are provided a gift or stipend. COM shall not sponsor and/or host any Speakers' Bureau Activities.

COM Personnel may participate in Industry-sponsored meetings where investigators are presenting results of their Industry-sponsored studies to peers and there is opportunity for critical exchange. If an individual is speaking at such an Industry-sponsored meeting, acceptance of a modest honorarium and travel expenses is permitted as described above. Otherwise, COM personnel may not accept payment, gifts, or financial support from Industry to attend lectures and meetings other than through an approved consulting or business arrangement.

3.4 Travel Fund

COM shall allow Industry and others that wish to do so to contribute, through the University of Central Florida Foundation, to (i) a central COM fund to be used at the Dean's discretion to provide travel assistance to COM personnel, including students, for professional development; or (ii) other approved Department account for use at the particular Department Chair's discretion to provide travel assistance to Department personnel, including students, for professional development. Contributions to such fund shall be disclosed and acknowledged.

3.5 Educational Symposia Fund

COM shall allow Industry and others to contribute, through the University of Central Florida Foundation, to (i) a central COM fund to be used in the Dean's discretion to provide COM-sponsored educational programs and symposia; or (ii) other approved Department account for use at the particular Department Chair's discretion for the Department-sponsored educational programs and symposia. Contributions to such fund shall be disclosed and acknowledged.

3.6 Disclosure of Financial Interests and Outside Activities regarding Industry

COM Personnel wishing to engage in outside activities or hold financial interests relating to Industry that are required to be reported to the University must receive prior approval from their supervisor for such interests or activities and assure that such activities do not conflict with their duties, responsibilities and obligations to COM or University. COM Personnel may not use COM or the University's resources, including its names or logos for Industry or outside activities, without the express written approval of the Dean or the Dean's designee. COM Personnel shall report their outside relationships with Industry through the regular University conflicts of interest disclosure process, using the Request for an Exemption/Disclosure Under Section 112.313(12)(h), Florida Statutes, online at <http://www.coi.ucf.edu/forms.html>, at least annually and more often as needed to disclose new relationships. All such reports are open to the public. The general conflicts of interest review process will identify personal financial relationships with health care vendors, including pharmaceutical, medical device, and biotechnology companies, equipment companies, and other health care vendors.

COM Personnel shall disclose all relevant Industry, business or consulting relationships and financial interests, including financial interests of immediate family, in speaking engagements and scholarly publications and when presenting to students, residents or colleagues (e.g., showing a slide during each lecture/presentation). Disclosure of such relationships and financial interests should also be made to patients to enable patients to make informed decisions respecting their medical care; such disclosures should specify that the COM Personnel is participating in an individual capacity and not on behalf of the COM or University.

Individuals having a direct role in making institutional decisions on equipment, drug or medical device procurement must disclose to the purchasing unit or selection committee, prior to making any such decision, any financial interest they or their immediate family have in companies that might substantially benefit from the decision and shall be recused from involvement in purchasing decisions relevant to the conflicting interests.

4. **Pharmaceutical and Medical Device Samples**

The COM prohibits acceptance of samples of pharmaceuticals or medical devices by COM practitioners or faculty members except in limited circumstances as provided in this policy. Samples of pharmaceuticals or medical devices may be accepted (i) for use in research, provided such use is in a manner that assures full clinical evaluation of its use and adheres to applicable protocols, and (ii) under circumstances involving a vulnerable patient population when a COM physician believes lack of provision of samples to their patient would jeopardize their patient's health, only after the COM physician has requested, and received, a waiver from the medical director. The request must outline a clear and convincing benefit to the patient and provide safeguards for the appropriate distribution and control of samples. No sample may be used personally by COM Personnel or their families.

5. **Purchasing and Formularies**

COM Personnel are not eligible to participate in Pharmacy and Therapeutics or product evaluation decisions if they or members of their immediate family have, or have had within the prior 5 years, a personal financial relationship or funded research with a related pharmaceutical or medical device

company that is being considered or discussed. Committee members who have conflicting interests may share informed opinions regarding the drug or device, provided that the conflict is fully disclosed in advance and the member is recused from participating in the decision.

6. Site Access to Industry Sales Representatives

Visits to COM facilities by representatives of Industry may be appropriate for exchange of scientifically valid information and other data, improving patient care, and providing essential training and instruction in use of medical equipment and devices. COM does not allow use of its facilities or other resources for Industry marketing activities.

Sales or marketing representatives of Industry may access COM facilities only if their company has registered with the COM and they have been specifically invited to meet with a COM representative for a particular purpose. Individual physicians or other COM Personnel may request a presentation by or other information from a particular company. While in the COM facilities, all Industry representatives must sign in and out and must be identified by name and current company affiliation. All Industry representatives with access to COM, Pegasus Health clinical facilities, and COM Personnel must comply with COM policies and procedures. Failure to register or to follow COM policies or procedures shall result in penalties up to and including denial of access. Meetings with sales and marketing Industry representatives shall not be held in direct patient care areas and education areas. Involvement of students or trainees in meetings with Industry Representatives should occur only for educational or training purposes and only under the supervision of a faculty member.

Access by medical device or equipment representatives to patient care areas is permitted when (1) a COM representative requests essential instruction in use of the equipment or device, (2) the representative is appropriately credentialed by Pegasus Health, and (3) all necessary patient consents have been obtained and documented. Educational materials or product information may not be placed in patient care areas or waiting rooms but clinical staff may accept materials or information for sharing with patients, as appropriate.

All Industry personnel seeking sales or vendor relationships must work directly with their designated COM representative and shall not solicit other COM Personnel.

7. Education

7.1 Support of Continuing Medical Education and On-site Educational Activities

All continuing medical education (CME) events hosted or sponsored by the COM must comply with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of Educational Programs (or other similarly rigorous, applicable standards required by other health professions), whether or not CME credit is awarded for attendance at the event. The COM will maintain a central CME office through which all requests for Industry support and receipt of funds for CME activity are coordinated and overseen and programs are periodically audited for compliance with ACCME requirements and standards.

If Industry is interested in sponsoring a CME program hosted by COM, the strongly preferred structure is through a contribution to the COM Educational Symposia Fund, enabling a COM-

sponsored program. Presentations structured and presented by COM through this Fund may include modest food and beverage.

All CME programs hosted by COM must be academically oriented. Industry may not restrict program content or specify who is selected as presenters. Industry funding sources should be directly acknowledged in all announcements and literature about particular CME offering.

Industry funding may not be accepted for social events that do not have an educational component. Industry funding may not be accepted to sponsor COM meetings or retreats (either on or off-campus). Such meetings and events may be supported through a general Dean's discretionary fund, and Industry is encouraged to contribute to the Dean's Discretionary Fund.

COM facilities (clinical and non-clinical) may not be rented by or used for Industry funded and/or directed programs, except for programs structured in accordance with this policy.

7.2 Industry Support for Scholarships, Fellowships, and Other Support for Trainees

The COM solicits and welcomes Industry contributions for scholarships, fellowships, and other support for trainees, so long as the funds are given centrally to the administration of the COM, either directly or through an affiliated entity or foundation; there is no expectation of benefit to the donor; the evaluation and selection of recipients is in the sole discretion of the COM; and the allocation and distribution of funds is managed by the COM.

7.3 Training of COM Personnel

The COM medical school curriculum includes instruction for medical students in understanding and addressing individual and institutional conflicts of interest in interactions with Industry and how the potential for conflicts of interest impacts/influences education, research and patient care/clinical judgment. Medical students at COM receive specific instruction regarding this policy through attending a live session, and a copy of the policy and the training materials are posted online for easy reference by the students.

Other COM Personnel are provided online access to the policy on vendor interactions and how to manage Industry relationships, as well as training materials.

7.4 Education of COM Industry Partners and Vendors

COM Industry Partners and vendors shall be provided copies of this policy and instructions regarding appropriate COM contracts and registrations procedures.

7.5 Industry Educational 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 Module Director or Clerkship Director, 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. Any questions regarding the appropriateness of such materials may be directed to the individual's Director.

8. Philanthropy

The COM welcomes and solicits charitable donations from Industry that support the COM missions. The UCF Foundation and other tax exempt entities will assist COM in soliciting, receiving, and managing funds. Such donations must be free of any implication or expectation of a benefit to the donor, not tied to any purchase or business arrangement, and openly acknowledged. Each donation from Industry will be reviewed in accordance with this policy and any additional standards that may be developed by the COM Industry Relations Committee and approved by the Dean, and the Committee may recommend to the Dean steps needed in structuring and acknowledging such gifts to avoid or minimize conflicts of interest or the appearance of conflicts. Information regarding donations and gifts from Industry shall be provided to COM Compliance. In addition, information regarding all donations and gifts over \$10,000 shall be submitted to the COM Development office, which will review it with the Dean's Office.

9. Partnerships and Business Arrangements

The COM may enter into a variety of business arrangements and partnerships with Industry when such arrangements advance the COM missions. These are relationships that extend beyond purchasing the standard Industry product or service and may include, for example, shared research, development, and/or ownership of a health care product or service. As in purchasing, any individuals with a conflicting personal financial relationship or interest must disclose such interests and may not vote on adopting by COM of a proposed Industry partnership or business arrangement. Each proposed partnership or business arrangement will be reviewed in accordance with this policy and any additional standards that may be developed by the COM Industry Relations Committee and approved by the Dean, and the Committee may recommend to the Dean any steps needed in structuring the partnership or business arrangement to avoid or minimize conflicts of interest or the appearance of conflicts.

10. Research with Human Subjects

COM Personnel may not conduct research with human participants if such personnel have a significant financial interest in an existing or potential product or a company that could be affected by the outcome of the research. Any exceptions to this policy must be reviewed by the COM Industry Relations Committee and the responsible Institutional Review Board (IRB) and approved by the Dean, and may be permitted only if (a) the individual's participation is essential for the conduct of the research and (b) an effective mechanism is established for managing the conflict and protecting the integrity of the research. A significant financial interest is defined as \$10,000 or more based on Association of American Medical Colleges (AAMC) recommendations, or such lesser amount that may be determined in a specific study by the University of Central Florida IRB or other IRB that approves the study.

11. Enforcement

Suspected violations of this policy shall be referred to the individual's Dean, Associate Dean, and immediate supervisor, who shall review the matter and determine what actions, if any, shall be taken. Alleged violations of this policy within the COM shall be investigated by COM Compliance, which shall advise the Dean on proposed enforcement actions. Violations of this policy by COM Personnel may result in the following actions (or in any combination), depending upon the

seriousness of the violation, whether the violation is a first or repeat offense, whether the violator knowingly violated the policy or attempted to hide the violation and other appropriate considerations: (a) counseling of the individual involved; (b) written reprimand, entered into the violator's employment or faculty record; (c) banning the violator from any further outside engagements for a period of time; (d) requiring that the violator return any monies received from the improper outside relationship; (e) requiring the violator to complete additional training on conflicts of interest; (f) removing the violator from supervision of trainees or students; (g) revoking the individual's Pegasus Health clinical privileges; (h) fines; and/or (i) termination for cause.

12. COM Industry Relations Committee

The Dean shall appoint an advisory COM Industry Relations Committee to assist in implementation of this policy and management of COM Industry relations. The Committee shall include faculty members representative of COM. *Ex officio* voting Committee members shall consist of the Associate Vice President for Medical Affairs, the COM Associate Dean for Clinical Affairs, the COM Associate Dean for Finance and Administration and the COM Associate Dean for Research. Committee members, other than the *ex officio* Committee members, and a chair or co-chairs shall be appointed by the Dean for three-year terms. An *ex officio* Committee member may be appointed as a chair or co-chair for three-year terms. The Committee shall meet at least two times per year, or more often as needed, to review, monitor, and advise the Dean regarding implementation and enforcement of this policy and the financial and business arrangements that require review. The Committee shall keep minutes and records of its reviews and recommendations. The Committee shall review the policy regularly and propose updates as appropriate.

13. Continuing Evolution of COM Industry Relations Policy

The COM recognizes that oversight, guidance and debate around Industry relationships and conflicts of interest must continue to evolve at local and national levels. This policy will continue to evolve as it is implemented and issues are considered further by the College and the Committee. At the time that the proposed financial conflict of interest regulations of the National Institutes of Health (NIH) are finalized, this policy will be updated to incorporate any relevant provisions.

Approved and Adopted

Deborah C. German, M.D.
Vice President for Medical Affairs
Dean, College of Medicine
August 16, 2010

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