

**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 charitable donations from Industry that support the COM mission. 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 ownership of stock of, or investments in a mutual fund that owns shares in companies constituting Industry 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 COM Legal Affairs, COM Compliance, 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 Section 8 of 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 the COM and university policies and 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. COM Personnel may not accept complimentary tickets to sporting or other events or other such benefits from Industry.

Meals or other food and hospitality funded directly by Industry may not be offered to, or accepted, by COM Personnel 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. However, meals or other 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 by COM Personnel.

3.2 Outside Relationships with Industry (e.g., any consulting arrangement, advisory board, speaking, publishing, attending meetings or Significant Financial Interest arrangements²)

Outside Arrangement means a written or verbal arrangement with Industry for COM Personnel to perform consulting services, to serve on an advisory board, to speak at or attend an Industry sponsored event, to publish in Industry funded publications, or to have a Significant Financial Interest.

COM Personnel may engage in Outside Arrangements with Industry in accordance with this policy provided such activities are not purely for commercial or marketing purposes, further the COM's mission and do not conflict with the individual's duties, responsibilities and obligations to the COM. All Outside Arrangements with Industry must be reviewed in accordance with this policy and approved in advance by the individual's Supervisor and one of the following: the individual's Chair, Director, Associate Dean or Associate Vice President, or the Dean or the Dean's designee. It is the individual's responsibility to obtain approval and to furnish a copy of such approval to COM Compliance prior to the start of the arrangement.

All written agreements for Outside Arrangements with Industry when the COM is a party must be reviewed, approved and signed in accordance with the COM and university policies and procedures. For Outside Arrangements with Industry entered into in a personal capacity, it is the responsibility of the COM Personnel to ensure that any such Outside Arrangement meets the requirements of this policy, is consistent with university regulations and policies, complies with the state and federal laws and has appropriate liability coverage. A copy of the agreement or summary of key terms shall be provided to the individual's supervisor and to COM Compliance.

¹ Exception: This provision does not prohibit acceptance of items bearing Industry logos provided as part of an off-campus 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 brought into or used in any COM facilities.

² A Significant Financial Interest is defined as \$10,000 or more based on Association of American Medical Colleges (AAMC) recommendations.

COM Personnel may not use the COM or the university's resources, including its names or logos for Industry, without the express written approval of the university.

For Outside Arrangements with Industry that exceed \$10,000 per company per year in fees received by the individual, in addition to securing the approvals described above, the individual must submit annual reports describing activities, payments, time spent, and the name of the company to COM Compliance for the duration of the relationship.

- 3.2.1 Consulting. Consulting arrangements with Industry for purely commercial or marketing purposes are prohibited. Consulting arrangements for research and scientific activities are allowed and must be fully transparent and documented, including the services/deliverables to be performed, fair market value payment terms, estimated time involved in performance of the service, and the name of the company. COM Compliance will periodically audit Industry consulting arrangements for compliance with this provision. A list of Industry consulting arrangements entered into by COM employees in their personal capacity shall be made available annually by COM Compliance to the COM Industry Relations Committee. These procedures apply whether the consulting fees are received by COM or the individual or donated to another organization. A similar process is required for any part-time employment arrangement with Industry.
- 3.2.2 Advisory board. Membership on Industry advisory boards by COM Personnel is permitted provided it is not for purely commercial or marketing purposes and the board regularly meets and provides scientific advice or other guidance that advances academic values and promotes ethical relationships between academic health sciences and Industry. Honoraria for serving on advisory boards, whether received by the individual or by the COM, must be modest and consistent with fair market value. In addition, the individual may receive reasonable travel expenses (such as airfare, mileage, lodging, meals and other transportation costs).
- 3.2.3 Industry Funded Speaking Relationships, Meetings, and Publications. COM Personnel must assure that participation in Industry-funded speaking relationships, meetings, programs and publications serves an educational or a research related purpose to advance scientific knowledge or patient care and are not Industry promotional activities.

Honoraria for speaking engagements, whether received by the individual or by the COM, must be modest and consistent with fair market value for the time spent in preparing and presenting the talk. In addition, the individual may receive reasonable travel expenses (such as airfare, mileage, lodging, meals and other transportation costs) and complimentary meeting registration.

COM Personnel are responsible for the scientific integrity of material presented in any talk or publication. COM Personnel shall not participate in educational presentations or scientific publications (a) if the content is controlled by or requires prior approval by Industry, (b) if the content is not based on the best available scientific evidence, or (c) 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. The COM shall not sponsor and/or host any Speakers' Bureau Activities.

COM Personnel are discouraged from attending Industry-sponsored educational programs that have the primary goal of increasing use of its particular drug or device, and are prohibited from accepting any food or beverage.

3.2.4 Disclosure of Outside Arrangements involving Industry

A) University Conflict of Interest Review

In addition to the COM approval process provided in this policy, COM Personnel shall report their Outside Arrangements with Industry through the regular university conflicts of interest and commitment disclosure process, using the Potential Outside Activity, Employment, and Conflict of Interest Commitment Disclosure (AA-21) available online at <http://argis.research.ucf.edu/coi/>, at least annually and more often as needed to disclose new relationships. All such reports are subject to the public records requests.

B) Disclosure to students, residents, colleagues and patients

COM Personnel shall disclose Industry, business or consulting relationships and Significant Financial Interests that are relevant to the topic discussed in scholarly publications, lectures, and presentations to students, residents or colleagues (e.g., showing a slide during each lecture/presentation). Disclosure of such relevant relationships and financial interests should also be made to patients when appropriate to enable patients to make informed decisions respecting their medical care. All such disclosures must specify when the COM Personnel is participating in an individual capacity and not on behalf of the COM or university.

C) Disclosure to purchasing unit or procurement committee

COM Personnel having a direct role in making institutional decisions on equipment, or drug or medical device procurement must disclose to the purchasing unit or procurement committee, prior to making any such decision, any Significant Financial Interest they or their immediate family have in companies that might substantially benefit from the decision. Such individuals may participate in discussions with full disclosure but shall not vote or otherwise participate in purchasing decisions where there is a conflict or potential conflict.

3.2.5 Publicly Accessible Website

The COM shall post, on a publicly accessible website, at least annually, a list of Outside Arrangements of COM Personnel, whether the fees are received by the COM or the individual or donated to another organization.

3.3 Travel Fund

The COM shall allow Industry and others 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.

3.4 Educational Program and Symposia

The 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 Department-sponsored educational programs and symposia. Contributions to such fund shall be disclosed and acknowledged.

4. Pharmaceutical, Medical Device and Medical Supply Samples

The COM prohibits acceptance of samples of pharmaceuticals, medical devices or medical supplies ("Samples") by COM practitioners or faculty members except in limited circumstances as provided in this policy and with prior approval. Samples 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 is approved by the Associate Dean for Research, and (ii) by a Nurse Manager for patient care 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, provided that the COM physician has requested, and received, a waiver from both the Medical Director and the Director of Quality and Safety of UCF Health. The request must outline a clear and convincing benefit to the patient and provide safeguards for the appropriate distribution and control of samples. The request and approval must be documented in writing. No sample may be used personally by COM Personnel. The UCF Health Director of Quality and Safety may inspect sample storage areas at any time and may revoke permission if non-compliance is identified.

5. Purchasing and Formularies

COM Personnel are not eligible to participate in product evaluation decisions if they or members of their immediate family have, or have had within the prior 5 years, a Significant Financial Interest or funded research with a related pharmaceutical or medical device company that is being considered or discussed. Every COM employee must avoid both actual conflicts of interest and the appearance of conflicts of interest and be in compliance with the university's Conflicts of Interest policy and procedures. COM Personnel who have such conflicting interests may share information regarding the drug or device, provided that the conflict is fully disclosed in advance, and the individual may participate in discussions but shall not vote or otherwise participate in selection decisions where there is conflict or potential conflict.

6. Site Access to Industry Representatives

COM does not allow use of its facilities or other resources for Industry marketing activities. Visits to COM facilities by representatives of Industry may be appropriate for exchange of scientifically valid

information and other data, improving patient care, providing essential training and instruction in use of medical and research equipment and devices or community relationship building.

6.1 Vendor Trade Displays

Industry is not permitted to participate in trade shows conducted in COM facilities except in accordance with this policy and with the prior written approval of the Dean or the Dean's designee. Permitted vendor trade displays may consist of vendor displays where several brands of medical or research devices, permitted equipment or materials are displayed simultaneously for users and key decision makers to compare them in order to recommend or make purchasing or standardization decisions.

6.2 Sales or Marketing Representatives

Sales or marketing representatives of Industry may access COM facilities only if they have registered with the COM and they have been specifically invited and have an appointment 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 wear visible identification that includes their name and current company affiliation. All Industry representatives with access to COM facilities and personnel must comply with the COM Industry Relations Policy (a copy of which must be given in advance and an acknowledgement of receipt and review obtained by the time of site visit) and procedures. Failure of the Industry representative to register or to comply with the COM Industry Relations Policy shall result in adverse actions up to and including denial of access. Meetings with sales and marketing Industry representatives shall not be held in direct patient care areas or 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. All Industry representatives seeking sales or vendor relationships must work directly with their designated COM representative and shall not solicit other COM Personnel.

6.3 Technical Assistance

Access by medical device or equipment representatives to patient care areas is permitted only when (a) a COM representative requests essential instruction in use of the equipment or device already purchased, (b) the representative is appropriately credentialed by UCF Health, (c) the representative uses personal protective equipment as requested by UCF Health and follows appropriate infection control guidelines of UCF Health, and (d) all necessary patient consents have been obtained and documented. Educational materials or product information that includes Industry marketing information may not be placed in patient care areas or waiting rooms.

7. Education

7.1 Support by Industry 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.

Industry funding is not accepted for the support of CME courses EXCEPT Industry interested in sponsoring a CME program hosted by the COM, may contribute to a central undesignated, blinded pool of funds through the University of Central Florida Foundation, for which the Dean has sole discretion on how the funds are to be used (the Dean's Discretionary Fund). Programs hosted or sponsored by the COM through such funds may include modest food and beverage.

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

Industry funding may not be accepted for social events that do not have an educational component or 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 may 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 the COM receive specific instruction regarding this policy through an online training module followed with a Q&A session by a Faculty member, and a copy of the policy and the training materials are posted online for easy reference by the medical students.

Full time employed faculty and staff and non-employed core faculty also complete a bi-annual online training module. Other COM Personnel are provided online access to this policy and training materials. Affiliate faculty, volunteer faculty and part time employed faculty will be informed of the Policy and it will be impressed upon them that COM employees and medical students are obligated to abide with the Policy while on and off COM campus and during both work and non-work hours.

8. Philanthropy

The COM welcomes and solicits donations from Industry that support the COM missions so long as the donations are given centrally to the administration of the COM, either directly or through an affiliated entity or foundation and the allocation and distribution of donation is managed by the COM. Gifts and loans to the COM of equipment, devices, supplies and similar items from Industry for use in education, research or clinical care cannot suggest the expectation of return benefit to the donor, or “quid pro quo.” The gift transaction will be documented as a gift in-kind donation.

The UCF Foundation and other tax exempt entities will assist COM in soliciting, receiving, and managing charitable donations. All charitable donations must be free of any implication or expectation of a benefit to the donor, are not tied to any purchase or business arrangement, and are openly acknowledged.

Donations from Industry are 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. The COM Industry Relations Committee may recommend to the Dean steps needed in structuring and acknowledging donations to avoid or minimize conflicts of interest or the appearance of conflicts. All offers of donations will be submitted to the COM Development Office and those at or above \$10,000 will be reviewed together with the Dean or her designee. The COM Development Office will inform the Chair(s) of the Industry Relations Committee of all offers of donations when submitted to the COM Development Office.

9. COM Partnerships and Business Arrangements with Industry

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 the 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. The COM Industry Relations 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.

COM Industry partners and vendors shall be provided copies of this policy and an acknowledgement of receipt and review must be obtained prior to commencement of a partnership or vendor relationship.

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 be approved by the Dean. Exceptions to this policy 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.

11. Ghostwriting

COM Personnel may not publish articles or materials under an individual's own name that are written in material part by Industry representatives. Specifically, COM Personnel shall not accept writing or editorial assistance; manuscript preparation, revision, production, or submission services; slide preparation or revision; or other services from Industry, either directly or indirectly, unless such materials provided by Industry are specifically attributed to the author (i.e., each slide of a presentation must be appropriately attributed). "Guest" authorship or "ghostwriting" is prohibited. All persons who make a substantial contribution to a manuscript, presentation, or other writing meeting the International Committee of Medical Journal Editors (ICMJE) standards/criteria (http://www.icmje.org/ethical_1author.html) or other accepted scientific standards for authorship should be listed as authors and their affiliations listed as either academic, Industry or other.

12. Enforcement

Suspected violations of this policy shall be referred to the individual's Supervisor, Chair, Director or Associate Dean or Associate Vice President, who shall review the matter and if warranted, refer the matter to the COM Compliance for investigation. COM Compliance may consult the COM Industry Relations Committee before advising the Dean or other senior management on proposed enforcement actions, as appropriate. 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 UCF Health clinical privileges; (h) fines; and/or (i) termination for cause.

13. 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 COM Industry Relations Committee shall include faculty members representative of COM. *Ex officio* voting COM Industry Relations Committee members shall consist of the Associate Vice President for Medical Affairs and COM Chief Legal Officer, the COM Associate Dean for Clinical Affairs, the COM Associate Vice President for Administration, Finance and Operations, and the COM Associate Dean for Research. COM Industry Relations Committee members, other than the *ex officio* members, and a chair or co-chairs shall be appointed by the Dean for three-year terms. An *ex officio* member may be appointed as a chair or co-chair for three-year terms. The COM Industry Relations Committee shall meet at least one time 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 COM Industry Relations Committee shall keep minutes and records of its reviews and recommendations. The COM Industry Relations Committee shall review the policy regularly and propose updates as appropriate.

14. 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 issues are considered further by the COM and the COM Industry Relations Committee.

Approved and Adopted

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

Revisions Approved and Adopted:

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