

USF System USF USFSP USFSM USFP

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Subject: **Limiting Conflicts of Interest in Interactions with the
Pharmaceutical, Medical Device, and Biotechnology Industries**

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(1) Definitions. The following definitions apply to this Regulation:

(a) “**COM**” means the University of South Florida, College of Medicine.

(b) “**COM personnel**” means any employee or appointee of the University of South Florida (whether full-time, part-time or courtesy, compensated or uncompensated) including, but not limited to, any Faculty, Administration, Staff and Temporary employee who has a COM appointment and/or assignment; the term also includes COM medical students, graduate students, and postgraduate physicians-in-training.

(c) “**Industry**” means the pharmaceutical, medical device, and biotechnology industries and their representatives.

(2) Introduction. COM personnel must devote particular attention to potential conflicts of interest in any interactions with Industry in order to protect the integrity of professional judgments and to preserve public trust in physicians, researchers, and academic medical institutions. At the same time, there are many legitimate, important and necessary interactions between COM personnel and Industry. Therefore, the COM has established this Regulation to define the boundaries regarding acceptable interactions with Industry and to provide mechanisms to monitor these interactions.

(3) Applicability of Regulation. This Regulation applies to all COM personnel. This Regulation is supplemental to and does not supersede any other applicable University of South Florida (USF) regulations and policies, including without limitation USF Regulations 10.206 and 10.107 regarding Ethical Obligations, Conflicts of Interest and Outside Activities.

(4) General Statement of Regulation.

(a) The goal of this Regulation is to increase transparency with regard to Industry interactions and to eliminate or mitigate conflicts of interest created by these interactions. All interactions between COM personnel and Industry must be consistent with this Regulation.

(b) All COM personnel are expected to become familiar with and adhere to this Regulation. COM personnel should consult with the COM's Associate Dean for Faculty & Academic Affairs with any questions or to obtain further guidance. COM personnel ultimately are individually accountable for their actions.

(5) Gifts and Individual Financial Relationships with Industry.

(a) **Gifts.** The COM recognizes that the acceptance of gifts, even in modest amounts, can exert influence on the recipients' behavior, which may affect patients. Accordingly, COM personnel may not accept gifts from Industry regardless of the monetary value of the gift unless such a gift is specifically allowed under certain narrow circumstances as provided by this Regulation. A "gift" is anything accepted by COM personnel, or by another person on behalf of the COM personnel, when equal or greater payment is not given within 90 days of receipt. Gifts include, transportation, lodging, parking, membership dues, admission fees, flowers, personal services, preferential rates or terms on a debt, loan, goods or services, forgiveness of a debt, and the use of real property.

(b) Meals.

1. COM personnel may not accept on-site meals or any other gifts of food for themselves or others if sponsored, catered, or provided by Industry unless such meals are specifically allowed under certain narrow circumstances as provided by this Regulation. Industry funding for meals or in-kind contributions of food or beverages may not be accepted for COM Departmental meetings, retreats or social events. In general, acceptance of meals provided by Industry at off-site locations is discouraged except for certain prior approved meetings conducted by sponsors of clinical research at investigator meetings when launching a new study or reviewing an existing sponsored study. Such meetings related to research or the development and/or initiation of clinical trials, or a new study when conducted by sponsors of clinical research provide education, discussion and training directly related to the specific protocol requirements; and the attendance at these investigator meetings by the principal investigator and his/her study staff is an important mechanism to document that the site at USF Health has the appropriate training and experience to conduct the study. In this narrow instance with prior approval by the Dean of the College of Medicine/Designee the industry sponsor may provide transportation, lodging and meals for attendees at the investigator meetings.

2. As a limited exception to the foregoing, food supplied by Industry in conjunction with a Continuing Medical Education (CME) event is allowed if such provision of food complies with Accreditation Council for Continuing Medical Education (ACCME) standards and guidelines.

3. Industry may support the educational mission of the COM by providing unrestricted educational grants or gifts which will be placed in an appropriate USF or USF Foundation account as controlled by or accessible to the Senior Vice President, USF Health, the COM or its Departments and monitored/distributed pursuant to USF and/or USF Foundation regulations, policies and procedures.

(c) **Consulting Relationships.**

1. The COM recognizes that COM personnel may be sought after as consultants to Industry and that such relationships can lead to innovation and improvements in medical and surgical products, and can ultimately promote advances in patient care. At a Department's option, such consulting duties may be assigned (in lieu of outside activity) by the Department Chair with all revenue accruing to be paid directly to the Department for the support of Departmental programs and the COM personnel in accordance with USF Regulation. However, such consulting relationships must not: (a) interfere with University duties; (b) compromise professional ethics; (c) have elements that may be construed by the government as an illegal kickback; or (d) be used as a vehicle for direct payment to faculty aimed at convincing them to use an Industry company's products.

2. Accordingly, outside consulting relationships with Industry are permitted (except for COM Departments providing such consultation services as a part of Departmental assigned activity) under the following conditions:

a. The relationships must be disclosed via the outside activity reporting process (Reporting Outside Activities Database - ROAD) prior to engaging in the outside activity; and approved by the Department Chair, unless other arrangements are made with the Department Chair to conduct the activity as part of the COM personnel's Departmental assignment; and

b. The COM personnel 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; and

c. The relationship must be described in a formal written contract which documents the specific, legitimate tasks and deliverables, and payment for services must be commensurate with the tasks performed considering the faculty member's specialty, expertise, experience, and regional/nation/international reputation.

d. A copy of the final, fully-executed contract must be submitted to (i) the Department Chair for the Department file, and (ii) the COM's Office of Faculty Affairs.

3. On occasion, an Industry company will ask for a release letter from the University indicating that the University has approved the consulting activity in question. The COM personnel may provide the approved outside activity report form in response to such requests.

4. In accordance with USF System Policy 0-309, COM personnel who participate in a USF System Research Project involving the Industry company with whom the consulting relationship is proposed must disclose whether the individual or the individual's Immediate Family has a Reportable Financial Interest or Relationship in the USF System Research Project through the eCOI Disclosure system: <https://arc.research.usf.edu/Prod>.

5. Outside employment, consulting activities, and financial interests of COM personnel may be disallowed if they result in conflicts with the employee's duties, responsibilities, and obligations to the COM as set forth in University of South Florida regulations and policies. It is the responsibility of the COM personnel to ensure that no consulting or employment agreement that he or she enters into violates any University of South Florida regulations and policies as well as state and federal laws.

(d) **Industry-Funded Speaking Relationships.**

1. The COM recognizes that COM personnel may be sought after as speakers to present information relevant to an Industry company's products, and recognizes that such speaking opportunities may serve to provide necessary scientific and educational information to the medical and health care provider community. The COM recognizes that COM personnel spend time and effort apart from their assigned COM duties in preparing for such presentations, and that compensation by the Industry company for the COM personnel's time may be offered. The COM also recognizes that speaking relationships must not function as de facto gifts from Industry or marketing of Industry products.

2. COM personnel participation as speakers on behalf of an Industry company relative to its products must be conducted as an approved outside activity. The COM personnel must disclose the activity via the outside activity reporting process (Reporting Outside Activities Database - ROAD) prior to engaging in the outside activity. Approval will not be unreasonably withheld, but will be dependent upon whether the COM personnel are meeting his or her Departmental assignments/expectations. Speaking engagements will only be allowed for one year (12 months) but may be renewed using the procedure as described above. The COM personnel 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.

3. Payment to the COM personnel must be commensurate with the tasks performed considering the COM personnel's specialty, expertise, experience, and regional/national/international reputation. 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 any meals (a) are reasonable 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 the COM personnel's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of an Industry company is not appropriate.

4. The COM personnel shall be responsible to retain full control of the educational content and ensure the ethical and scientific integrity of the information he/she presents. The content of the presentation/speech should be produced by and/or fully vetted for scientific accuracy by the faculty member. The Departmental Chair or Center Director reserves the right to review all content for appropriateness.

5. If an industry engagement requires that a faculty member must as a condition of the engagement use industry prepared presentation materials on drug products, then the presentation and audiovisual materials 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. Speakers and their materials should clearly identify the company that is sponsoring the presentation, the fact that the speaker is presenting on behalf of the company, and that the speaker is presenting information that is consistent with FDA guidelines.¹

6. Participation in an Industry-sponsored speaker's bureau may create a conflict of interest for the COM personnel if he/she is invited to speak on a similar topic for a professional meeting certified for CPE (continuing professional education) credit unless such CPE activity is conducted in association with or on behalf of activities of the Health Professional Conferencing Corporation (HPCC).

7. The COM shall not sponsor or host any Industry speaker's bureau activities.

(e) **Disclosure.**

1. COM personnel wishing to engage in activities or hold financial interests that are required to be reported under University of South Florida Regulations 10.206 and 10.107 have

¹ http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf Section 7

an obligation to disclose and receive approval prior to engaging in these activities and to assure that such activities do not infringe upon their responsibilities and obligations to the COM and to the University of South Florida. Each COM personnel is responsible for complying with the regulations and laws concerning outside activities and financial interests.

2. COM personnel 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 South Florida. COM personnel may not use the University's resources, including its name or addresses, without express written approval from an administrator designated by the University of South Florida President to approve such use. A request for the use of University resources must be submitted pursuant to the University of South Florida Regulations 10.206 or 10.107.

3. COM personnel disclosures of outside activities are to be reported via the Reporting Outside Activities Database (ROAD) which is to be reviewed by the Department Chair or immediate supervisor and forwarded to the COM Dean or the COM Dean's designee for authorization. This report should be completed and filed prior to such time as the outside activity or financial interest begins and at the beginning of each fiscal year. If a material change in the information presented occurs during the year, a new report must be submitted. All reports associated with continuing outside employment/activity must be renewed on a fiscal year basis. The report shall include the amount of financial compensation for the outside employment/activity.

4. COM faculty who present formal lectures to students or residents of the University of South Florida must disclose any and all outside activities, financial interests or personal relationships with Industry that are pertinent to the lecture subject at each presentation.

5. All reports of outside activities by COM faculty at the University of South Florida are open to the public under Florida law. This information is publicly available via the COM's website. Additionally, COM personnel are expected to take appropriate steps to disclose their financial ties with Industry to patients when such a relationship might represent an apparent conflict of interest.

6. Annual Attestation. 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.

(6) Pharmaceutical Samples and Certain Medically Necessary Devices.

(a) COM personnel may not directly accept pharmaceutical samples from Industry except under certain narrow circumstances approved by the COM that protect the interests of patients and prevent the use of samples as a marketing tool. Pharmaceutical sales

representatives are prohibited from giving samples directly to physicians, except at the COM clinical site for control and dispensing as provided by this Regulation. The COM and COM personnel shall not accept remuneration of any kind for either receiving or dispensing sample medications. COM personnel shall not accept sample medications for personal use, and are not authorized to request, take or dispense sample medications without a written order of a licensed practitioner legally authorized to prescribe medications.

(b) Pharmaceutical samples can benefit patient care by allowing patients to try a medication for effectiveness and absence of side effects prior to incurring a related cost, and by expediting the patient's medical intervention. With these benefits comes 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.

(c) Sample medications are to be signed for by a physician and stored in a locked central location within the COM clinical site and with the COM's designated pharmacy/clinic manager responsible for security of access. Any Schedule II or III medications are to be kept in a separate locked storage space/cabinet. Sample medications may be dispensed only under the written order of a licensed practitioner legally authorized to prescribe medications, and must be recorded in the patient's medical record along with the corresponding written order for the medication. The medical record documentation should include the order date, medication and quantity dispensed; and dosing instructions, which should be provided to the patient. Sample medications are to be checked by the designated clinic manager for expiration dates on a monthly basis. Expired medications are to be disposed of as hazardous waste and not distributed or dispensed for use by anyone. The medication inventory is to be updated whenever medications are received, dispensed or disposed of. Certain dermatological sample preparations in the dermatology clinical area such as skin crèmes, ointments, gels, treatments, and emollients under 30 g total or 30 cc total per package and non-prescription elective and/or cosmetic agents are exempt from the inventory control accountability enumerated above.

(d) Authorized sample devices for patient use are listed on an annually updated clinic list approved by the Dean of the College of Medicine. Devices to be considered for approval must be commonly utilized for patient care for intensive care management such as, but not limited to, glucose meters utilized in diabetes care management.

1. Receipt of such devices from a device representative are to be signed for by a physician/designee and must be stored in a locked central location within the COM clinical site.

2. The COM's clinic manager or designee shall be responsible for security and/or access in accordance with the policy for use of such devices together with the accompanying continuing care supplies which are to be used for initiation of management as authorized by the patient's third party carrier or for humanitarian reasons may be provided to patients otherwise unable to pay or unable to obtain the initial device and necessary supplies.

3. Sample supplies, if initially dispensed for the convenience of the patient at initiation of care management, must be dispensed under the written order of a licensed practitioner legally authorized to prescribe medications or devices and must be recorded in the patient's medical record along with the corresponding written order for the supplies. The medical record documentation should also include the initial order date, specific supplies, and quantity dispensed as well as instructions for use and the frequency of use; appropriate documentation and instruction should also be provided to the patient by a member of the care coordination team. The inventory of sample supplies with a date of expiration must be checked periodically by the designated clinic manager and destroyed if the expiration date is exceeded.

(7) Purchasing and Formularies.

(a) COM personnel engaged in University purchasing are subject to the provisions of the University of South Florida's regulation and applicable state and federal law regarding the disclosure of outside activities, financial interests and conflict of interest. In addition, formulary committees and committees overseeing purchases of medical devices shall exclude those who have financial relationships with Industry from voting on applicable purchases. Expert clinicians may advise such committees provided that all conflicts of interest are disclosed.

(b) An approved disclosure form must be attached to each applicable Requisition to Purchase from an enterprise in which COM personnel has a material financial or managerial interest. If there is a requisition prepared to purchase from an enterprise in which a COM personnel has a material interest, the COM personnel with the interest cannot approve the requisition. If the purchase is allowed under state law, the approval of the COM personnel'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.

(8) Industry Representatives (Including Sales and Device Representatives).

(a) Industry representatives are required to schedule an appointment to meet with a COM personnel for educational purposes relative to the representative's company's products, and must limit their interaction to only that COM personnel. Industry representatives are required to check in at a designated area to sign in as a visitor at a USF Health/COM site; receive a visitor pass to be worn throughout their visit; and return the visitor pass upon signing out when leaving the site. On their initial visit to a USF Health/COM site, Industry representatives are to be notified of this Regulation and other applicable USF Health/COM policies, standards, and procedures and sign an agreement acknowledging their commitment to comply with such. An Industry representative's failure to comply with these registration and other Regulation requirements can result in penalties including denial of any future access.

(b) Industry representatives are not allowed access to patients or Protected Health Information (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. Pharmaceutical representatives shall not have access to patient information nor be allowed to observe examinations or therapeutic discussions of patients. Except as allowed above, device representative's access to patient information, examinations, and therapeutic discussion shall be limited to only that which is necessary for appropriate education of the medical staff during planned or active use of the represented device.

(c) Educational materials or product information that may be useful to patients may be directly accepted by the physician and designated clinic staff. Industry representatives are not permitted to place educational material in patient care areas or waiting areas. Any educational sessions presented by Industry representatives are to be held away from patient care areas wherein PHI is not viewed or heard.

(9) Education.

(a) On-Site Educational Activities.

1. *Teaching Aids/Books/Devices/Educational Materials/Equipment.* COM personnel are generally not permitted to directly accept books, instruments, equipment, or teaching aids from Industry. Industry may support the educational mission of the COM by providing unrestricted educational grants or gifts of the above listed items to the COM under the conditions stated in this section. Such unrestricted grant or gift funds will be placed in an appropriate USF or USF Foundation account as controlled by or accessible to the Senior Vice President, USF Health, the COM or its Departments and monitored/distributed pursuant to USF and/or USF Foundation regulations, policies and procedures. Additionally, educational materials may be donated by Industry to the COM for use by COM personnel and students provided such materials are preapproved in advance by the COM's Vice Dean for Educational Affairs or Dean and have no branding beyond a logo on the cover or device. Such materials must not be distributed directly by industry to individual COM faculty, residents, staff, students, and patients.

2. *Educational Presentations.* Industry representatives are allowed to provide educational materials and presentations to medical students and postgraduate physicians in-training only if the interaction is approved by the Vice Dean for Educational Affairs (for medical students) or the relevant residency program director (for residents) subject to the following conditions:

a. Interactions must only involve presentation of published literature and FDA approved indications.

b. Time allowed for open questions shall be not greater than 10% of the allocated presentation time.

c. The Industry representative may not provide promotional items to any medical students or resident physicians, regardless of value, nor gifts such as meals, food, and beverages except as authorized under the specific provisions of paragraph (5) (b) 3 above.

3. *Other On-Site Educational Activities.* COM personnel may engage in educational activities on-site in conjunction with Industry under the conditions set forth in this section. CME courses must conform to Accreditation Council for Continuing Medical Education (ACCME) standards and must be processed through and approved by the USF Health Office of Continuing Professional Development (OCPD). Any non-CME educational activities that involve the participation of Industry shall be conducted in accordance with this Regulation and in such a manner as to ensure that Industry-participation is fully disclosed.

(b) Payment for Travel or Attendance at Off-Site Lectures and Meetings.

COM personnel may not accept payments from Industry to attend off-site lectures or meetings except under the following limited circumstances: (i) for legitimate reimbursement for travel to provide contractual services to Industry pursuant to an approved consulting activity or other approved outside activity; (ii) to view capital equipment *in situ* if the equipment is being considered for purchase or for training in the use of equipment, in which cases travel should be reimbursed through and in compliance with University policies; or (iii) to participate in meetings directly related to ongoing sponsored research in which case travel should be reimbursed through and in compliance with University policies. Unrestricted grants from Industry to the institution may be used in part to support travel for COM personnel attending professional meetings; however, the decision to use gift funds for travel expenses will be made at the discretion of the applicable COM Department Chair and the COM Dean. A Department Chair's use of funds for his/her own travel must be approved in advance by the COM Dean. Students and trainees may accept travel funds from scientific societies, whether or not Industry is the source of the funds, provided the society and/or COM Department control the selection of the recipient of travel support.

(c) Industry Support for Scholarships/Fellowships and Funds for Trainees. COM personnel may not accept scholarships or fellowships to support training initiatives directly from Industry; however, scholarship and fellowship funds may be provided to USF or the USF Foundation and placed in accounts controlled by or accessible to the Senior Vice President, USF Health, the COM or its Departments, as appropriate to support these initiatives. There shall be no *quid pro quo* associated with such funding, and recipients of scholarships and fellowships shall be chosen by the COM/Department and not by Industry.

(10) Relations with Industry Representatives in Publications.

The professional presentations, books, articles, reports, or other materials, oral or written, of COM personnel must have appropriate authorship attribution. COM personnel may not submit material(s) for publication (or for consideration for publication) in professional works as

their own created product if those material(s) are primarily created by another person such as but not limited to employees of any Industry company. Such conduct may be referred for consideration as research misconduct (possible plagiarism) under USF System Policy 0-301, Misconduct in Research.

(11) Medical School Curriculum.

The COM Curriculum Committee shall ensure that COM medical students are trained to understand the importance of federal, state, and institutional conflict of interest laws, rules, policies and procedures, and how Industry promotion can influence clinical judgment.

(12) Enforcement and Penalties.

COM directors, department chairs and immediate supervisors are responsible for reviewing disclosures and for ascertaining that COM personnel and activity under their supervision are in compliance with this Regulation and initiating enforcement and corrective action to address any instance of non-compliance with this Regulation. COM personnel who fail to abide by the provisions of this Regulation are subject to appropriate disciplinary action in accordance with University regulations. Examples of sanctions are: disallowance or limiting outside activities, changes in assignment, limitations on research activities, fines, reduction in pay, demotion, written reprimand, suspension without pay, and termination for cause.

(13) Annual Review and Revision.

The COM Faculty Council, USF COM Chapter of the American Medical Student Association representatives, and the administration of the College of Medicine will review this document annually to revise and propose changes as may be both appropriate and necessary as this is envisioned to be a dynamic shared governance regulation consistent with professionalism standards for the COM and the University.

Authority: Art. IX, Sec. 7, Fla. Constitution; Fla. Board of Governors Regulation 1.001. History—New 12-8-11.