



**USF Health - Morsani College of Medicine
GME POLICY & PROCEDURE**

Title: Vendors and/or Industry Relations	GME-314
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Scope: Applies to all University of South Florida Morsani College of Medicine (“USF MCOM”) trainees in Accreditation Council for Graduate Medical Education (“ACGME”) accredited and non-accredited/non-standard programs.

Background: Relationships with outside entities are vital to USF MCOM’s mission to advance health through research, education, clinical practice, and community partnerships.

The USF MCOM Graduate Medical Education program recognizes that, inherent to this relationship, there is the possibility of conflict of interest or apparent conflict of interest in interactions with corporations, representatives of corporations, or other individuals supported by corporations. At the same time, USF MCOM recognizes that several medically related industries provide legitimate and appropriate support for educational activities.

The USF MCOM Graduate Medical Education program follows the USF Systems policy USF9.019, concerning vendor interactions and adheres to the guidelines (see attached) as referenced below.

USF 9.019 identifies potential, real or perceived outside interests that may be viewed as a conflict and appropriately manages such conflicts in interactions with the Pharmaceutical, Medical Service, and Biotechnical Industries. This over-arching policy provides guidance regarding conflicts of interest and is intended to supplement, but not replace, state and federal laws governing conflicts of interest for nonprofit and charitable organizations.

The University recognizes that its affiliated hospitals have their own specific policies regarding corporations and vendors, and the University will actively support and enforce these policies. Where a conflict exists between this policy and that of another organization, it is the overarching policy of USF MCOM that the stricter or more stringent policy will apply to a given situation within that organization.

The following areas are addressed and further defined in the attached:

- Gifts and Individual Financial Relationships with Industry
- Meals
- Consulting Relationships

- Industry-Funded Speaking Relationships
- Disclosure
- Pharmaceutical Samples and Devices
- Purchasing and Formularies
- Restrictions on Industry Representatives
Purchasing and Formularies
- Education
- Relations with Industry Representatives in Publications
- Medical School Curriculum
- Enforcement and Penalties
- Annual Review and Revision

ProcedureResponsible PartyAction

GME Responsibility

Ensures compliance with the attached regulations as defined for USF Health Community Members, which includes residents and fellows ("Residents").

Program Director

Program leadership should be aware of and discuss with Residents any interaction with representatives from vendors to ensure that any contacts are within the scope and spirit of this policy. Interactions that appear to place the resident in a position of obligation to, or influence by, the vendor should be explicitly discouraged. Programs should provide training to residents on vendor relations and conflicts of interest, including reference to this policy and other relevant institutional and affiliate policies. The Program Director must communicate this policy to trainees as part of program orientation, and reinforce it through inclusion in program handbooks and other information sites for Resident reference.

GME Community

When in doubt about right or appropriate action, contact your supervisor, Department Chair or Division Director, as applicable, call the USF Helpline at (813) 974-2222 or visit the USF Health Professional Integrity Office website. Promptly report any possible violations of law or improper activity to a supervisor or call the Helpline at (813) 974-2222.

APPROVED:



 Sr. Associate Dean, Graduate Medical Education/DIO

c:p&p\vendors

APPROVED 8/2008

Reviewed, Revised, Approved 9/2010; 3/2012, 12/2019



Number: USF9.019
Title: Limiting Conflicts of Interest in Interactions with the Pharmaceutical, Medical Device, and Biotechnology Industries
Responsible Office: USF Health

Date of Origin: 12-8-11

Date Last Amended: 8-4-16 (technical)

Date Last Reviewed: 8-4-16

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

- a) “**MCOM**” means the University of South Florida, Morsani College of Medicine.
- b) “**MCOM 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 MCOM appointment and/or assignment; the term also includes MCOM medical students, graduate students, and postgraduate physicians-in-training. If a section of this Regulation applies to faculty or staff only, it is so designated.
- c) “**Industry**” means the pharmaceutical, medical device, and biotechnology industries and their representatives.

(2) Introduction. MCOM personnel must devote particular attention to potential conflicts of interest in any interactions with Industry 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 MCOM personnel and Industry. Therefore, the MCOM 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 MCOM 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 Regulation 10.107](#) and [USF Policy 0-027](#) 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 MCOM personnel and Industry must be consistent with this Regulation.

- b) All MCOM personnel are expected to become familiar with and adhere to this Regulation. MCOM faculty should consult with the MCOM's Vice Dean for Faculty & Academic Affairs or Human Resources for staff with any questions or to obtain further guidance. MCOM personnel ultimately are individually accountable for their actions.

(5) Gifts and Individual Financial Relationships with Industry.

- a) **Gifts.** The MCOM recognizes that the acceptance of gifts, even in modest amounts, may exert a conscious or unconscious influence on the recipients' behavior, which may affect patients' care by adding cost. Accordingly, MCOM 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 MCOM personnel, or by another person on behalf of the MCOM 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. MCOM 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 MCOM Departmental meetings, retreats or social events. In general, acceptance of meals provided by Industry at off-site locations is discouraged, except for approved meetings conducted by sponsors of clinical research when launching a new study or reviewing an existing study, or attendance assigned by the departmental chair at medical device "hands on" training sessions. Such meetings are typically related to research, the development and/or initiation of clinical trials, or training conducted by device manufacturers (i.e., education and training directly related to research and/or procedures to be performed in USF Physician Group). Attendance at these investigator or device-training meetings by the principal investigator, clinical physician and their designated staff is an important mechanism to document that the site at USF Health has the appropriate training and experience to conduct the study or utilize the device for the clinical benefit of patients. In this narrow instance, with prior approval by the Dean of the College of Medicine or their Designee, the Department, USF Physicians Group or Industry Sponsor may provide transportation, lodging and meals for attendees.
 - 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 is encouraged to support the educational mission of the MCOM 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 MCOM or its Departments and monitored/distributed pursuant to USF and/or USF Foundation regulations, policies and procedures.

c) Consulting Relationships.

1. The MCOM recognizes that MCOM personnel may be sought after as consultants to Industry and that such a relationship 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 MCOM 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 MCOM Departments providing such consultation services as a part of Departmental assigned activity) under the following conditions:
 - a. The relationships must be disclosed via the appropriate outside activity reporting process (Reporting Outside Activities Database – ROAD – for faculty or eDisclose for staff) 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 MCOM personnel's Departmental assignment; and
 - b. The MCOM personnel must submit a request for annual leave if the participation is designated as Outside Activity and 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 or staff 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 MCOM'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 MCOM personnel may provide the approved outside activity report form in response to such requests.
4. In accordance with [USF Policy 0-309](#), MCOM personnel who participate in a USF Research Project involving the Industry Sponsor 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 Research Project through the eDisclose research system: <https://arc.research.usf.edu/Prod>.
5. Outside employment, consulting activities, and financial interests of MCOM personnel may be disallowed if they result in conflicts with the employee's assigned duties,

responsibilities, and obligations to the MCOM as set forth in USF regulations and policies and that employee's USF contract. Failure to request approval for compensated outside activity in ROAD (or eDisclose) may result in progressive discipline up to and including termination of employment in accordance with University policy and regulations ([USF Policy 0-027](#)). It is the responsibility of the MCOM personnel to ensure that no consulting or employment agreement that he or she enters into violates any USF regulation and policy, as well as local, state and federal laws. Faculty and staff members seeking to challenge administrative decisions or disciplinary actions related to the application of this Regulation may pursue all avenues of complaint or grievance under applicable Faculty Council and/or University processes.

d) Industry-Funded Speaking Relationships.

1. The MCOM recognizes that MCOM 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 MCOM recognizes that MCOM personnel spend time and effort apart from their assigned MCOM duties in preparing for such presentations, and that compensation by the Industry Sponsor for the MCOM personnel's time may be offered. The MCOM also recognizes that speaking relationships must not function as de facto gifts from Industry or marketing of Industry products.
2. MCOM personnel participation as speakers on behalf of an Industry company relative to its products must be conducted as an approved outside activity. The MCOM personnel must disclose the activity via the appropriate outside activity reporting process (Reporting Outside Activities Database – ROAD – for faculty or eDisclose for staff) prior to engaging in the outside activity. Approval will not be unreasonably withheld, but will be dependent upon whether the MCOM 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 MCOM 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 or other USF assigned duties.
3. Payment to the MCOM personnel must be commensurate with the tasks performed considering the MCOM 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 MCOM 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 MCOM personnel shall retain full control of the educational content and ensure the ethical and scientific integrity of the information he/she presents. FDA mandated

audiovisual and other materials must meet FDA regulations and must be produced by and/or fully vetted for scientific accuracy, completeness and educational value by the faculty or staff member. As the MCOM remains concerned about the educational and scientific integrity of the program materials, appropriate third party review in accordance with accreditation processes are required. Program content must be either CME Accredited with USF or professional organizations, or programs will be subject to audit and review by USF Health as follows.

- a. For faculty involvement, each Department in which faculty are participating in Industry Speaker's Bureaus will be required to establish a standing committee, consisting of the Chair and a minimum of two additional faculty appointed by the chair, who will convene in person or by electronic means (e.g., e-mail, teleconference) not less than quarterly and either prospectively or retrospectively review the programmatic content of an appropriately sized representative sample of the industry sponsored speaking engagements performed by the departmental faculty.
- b. The committee will select one or more faculty member(s) participating in Industry Sponsored Speaking to provide the program materials used by them, including slides for review with FDA regulated program materials to be identified as such and included in the review.
- c. The committee will independently review the materials and determine if the program is scientifically accurate and provides appropriate evidence-based educational value. If the program does not meet these criteria, the committee will meet with the faculty member to share their initial concerns and ask for additional information.
- d. The committee will then make a final determination, which will be documented and maintained on file by the Department. Programs not meeting criteria will be either disallowed (if prospectively reviewed) or tagged as inappropriate (if retrospective), and the next audit will include another review of that faculty member's programs. Faculty with three disallowed or inappropriate programs within 12 months will be suspended from Industry Speaking for a minimum of three years. Faculty participation in Industry Speaking activities is at the Department Chair's discretion, and faculty must be appropriately fulfilling all their assigned USF clinical, educational, research and other duties as a prerequisite for participation in this kind of outside activity.
- e. Compliance with this review process will be documented by minutes maintained on file by this departmental Outside Activity Review Committee, and these minutes will be subject to review by the MCOM Dean at any time, and will be submitted as part of the annual departmental review process by the senior leadership team. In addition, at each quarterly meeting, the committee will review a report of the total Outside Activity of all faculty members within that department during the preceding quarter, drawn from the ROAD database. These summaries and the minutes of each quarter's meeting and committee activity will be copied to the Vice Dean of Faculty Affairs.
- f. Maintenance of this process is requirement for the participation of the faculty of a given Department in Industry Speaking, and is ultimately the responsibility of the Chair.
- g. For staff involvement, the Department Chair shall initially determine compliance with the standards outlined above.

5. If an industry engagement requires that a faculty or staff member use industry prepared materials on drug products due to FDA regulation, 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 in accordance with FDA requirements.
6. Participation in an Industry-sponsored speaker’s bureau may create a conflict of interest for the MCOM 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 MCOM shall not sponsor or host any Industry speaker’s bureau activities.

e) **Disclosure.**

1. MCOM personnel wishing to engage in activities or hold financial interests that are required to be reported under [USF Regulation 10.107](#) have 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 MCOM and to the University of South Florida. Each MCOM personnel is responsible for complying with the regulations and laws concerning outside activities and financial interests.
2. MCOM 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 MCOM or the USF. MCOM personnel may not use the University's resources, including its name or addresses, without express written approval from an administrator designated by the USF President to approve such use. A request for the use of University resources must be submitted pursuant to the [USF Regulation 10.107](#).
3. MCOM personnel disclosures of outside activities are to be reported via the Reporting Outside Activities Database (ROAD) for faculty and via eDisclose for staff which is to be reviewed by the Department Chair or immediate supervisor and forwarded to the MCOM Dean or the MCOM 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. MCOM 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 MCOM faculty and staff at the USF are open to the public under Florida law. This information is publicly available via the MCOM’s website. Additionally, MCOM 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. MCOM faculty, residents and staff who have no outside activities or financial interests to report are required to provide an annual attestation to that effect via the appropriate reporting process for each; namely, ROAD or eDisclose.

(6) Pharmaceutical Samples and Devices

a) Dispensing of Sample Medications and Devices

1. In general, faculty should encourage Industry Representatives to provide patient vouchers for discounted or free sample medications or devices, instead of physical samples processed through USF Health whenever possible.
2. All vendors entering the clinical practice site must do so outside of business hours and have the medications accepted and signed for under a physician's authority. A copy of the receipt of the samples must be maintained in a log. Vendor representatives maintain responsibility for obtaining documented authorization from the physician with whom they are supplying the medications.
3. Sample medications may only be dispensed under the verbal or written order of or by a licensed practitioner legally authorized to prescribe medications. The dispensing of samples by the practitioner will be confined to those medications within their scope of prescription authority.
4. An RN, LPN or MA may follow the authorized licensed practitioner's order and prepare samples (label with patient name, dose, frequency) to provide to USF Health patients only.
5. All sample medications must be documented in the patient's medical records, along with the corresponding written or verbal order for the sample medication.
6. Personnel are NOT to request, take or dispense sample medications from clinical areas without a written prescription or authorization from a physician. In the event that MCOM personnel requests, takes or dispenses sample medications inappropriately, they may be subject to disciplinary action, up to and including, termination of employment.

b) Inventory and Management

1. Each clinical practice site will maintain a secured and locked location, where sample medications are kept.
2. Sample medications are to be neatly arranged in therapeutic grouping or some easily accessible method. (For example, all anti-hypertensive medications located together, all antibiotics placed together, etc.)
3. All sample medications are to be clearly marked with the drug's name, strength, dosage and expiration dates. At the time they are dispensed, they should also be labeled with the patient's name, prescribed dosing regimen and the date dispensed.
4. Upon receipt of the sample medications from the Pharmaceutical Representative, all sample medications must be signed as received by an appropriate provider. A copy of the receipt of the sample medication must be logged.

5. Sample Medications are checked monthly by assigned staff for expiration. Expired sample medications are to be disposed of by placing in a black pharmaceutical waste container.
6. Monthly physical count of sample medications must be completed by assigned staff and reconciled to the log (total received less dispensed / expired should equal count).
7. All orders must be documented in the patient's medical record under the current medication section- Annotate NDC#, Lot #, Expiration Date, Date, Medication, Dosage and Quantity Dispensed.
8. The effective management of sample medications will be audited for appropriate tracking in logs, labeling, dispensing, removal of expired medications and recording in medical records. Areas not in compliance may forfeit the right to utilize sample medications in their practice.

c) Device Samples

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 MCOM clinical site.
2. The MCOM'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.

(7) Restrictions on Industry Representatives

a) General Regulations and Procedures

1. To improve the security and welfare of our patients, staff and property of the Centers for Advanced Healthcare, Pharmaceutical Representatives and Vendors who conduct business at these Centers are required to adhere to the following procedures.
2. Pharmaceutical, medical device and other industry representatives are NOT permitted to visit any USFPG clinical locations during business hours.
3. This prohibition does NOT apply to vendor representatives that come into the practice at the request of the provider in an effort *to support the care team* (i.e., device management, ALS clinics, Healthy Start services provided by the Florida Department of Health, implant deliveries to the ASC, etc.) *in providing clinical care to our patients*.
4. All Representatives and Vendors are required to sign in and obtain a visitor identification badge. The badge must be displayed during the visit and returned to the point of entry at the completion of the visit.
5. No Representatives or Vendors are permitted to come in contact with patients or patient's Protected Health Information (PHI), except in cases in which the representative is authorized to do so for patient care with appropriate patient consent, or under an IRB approved research protocol.

6. All Representatives and Vendors wishing to visit the USF Health Campus *are required to have scheduled appointment* with a provider or faculty member, outside business hours. Should they arrive during business hours or without an appointment, they will be asked to schedule an appointment with that Department and return at that time.
7. All Representatives and Vendors must wait in an area with no possibility of patient contact or access to PHI to obtain a signature from a Provider for drug samples (see below), outside business hours, or if their prior scheduled appointment with Provider is delayed.
8. No Representatives or Vendors are permitted to place educational materials, products, or product information in exam rooms or in the patient waiting areas. This information should be given directly to the Provider or nursing staff.
9. All Representatives or Vendors presenting educational sessions will hold these sessions in a conference room away from patient care areas, before or after business hours.
10. No Representatives or Vendors are permitted to cater meals or provide any food for Providers or Staff per University Regulation USF9.019 “Limiting Conflicts of Interest in Interactions with the Pharmaceutical, Medical Device, and Biotechnology Industries”.
11. On-site locations include all USF Health controlled and utilized locations, including the Morsani Center, the ASC, the Faculty Office Building, the South Tampa Center, and others.
12. Notification of the revised policy will be available at the check in locations for all Representatives or Vendors.
13. In addition, each USF Health clinical site may have its own site-specific procedures. Currently, those procedures are found at: (a) for the Morsani Center: [PG041 Pharmaceutical Rep Vendors - Morsani](#); (b) for the South Tampa Center: [PG041 Pharmaceutical Rep Vendors - South Tampa Center](#); (c) for the Eye Institute: [PG041 Pharmaceutical Rep Vendors - Eye Institute](#); and (d) for the Psychiatry Center: [PG041 Pharmaceutical Rep Vendors - Psychiatry Center](#).

(8) Purchasing and Formularies.

- a) MCOM personnel engaged in University purchasing are subject to the provisions of the USF’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 MCOM personnel has a material financial or managerial interest. If there is a requisition prepared to purchase from an enterprise in which a MCOM personnel has a material interest, the MCOM personnel with the interest cannot approve the requisition. If the purchase is allowed under state law, the approval of the MCOM 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.

(9) Education.

a) On-Site Educational Activities

1. Teaching Aids/Books/Devices/Educational Materials/Equipment.

- a. MCOM personnel are generally not permitted to directly accept books, instruments, equipment, or teaching aids from Industry.
- b. Industry may support the educational mission of the MCOM by providing unrestricted educational grants or gifts of the above listed items to the MCOM 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 MCOM or its Departments and monitored/distributed pursuant to USF and/or USF Foundation regulations, policies and procedures.
- c. Educational materials may be donated by Industry to the MCOM for use by MCOM personnel and students provided such materials are preapproved in advance by the MCOM'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 MCOM faculty, residents, staff, students, and patients.

2. Educational Presentations.

- a. 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:
 - (1) Interactions must only involve presentation of published literature and FDA approved indications.
 - (2) Time allowed for open questions shall be not greater than 10% of the allocated presentation time.

3. Patient Education Materials.

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

4. Other On-Site Educational Activities.

- a. MCOM personnel may engage in educational activities on-site in conjunction

with Industry under the conditions set forth in this section.

- b. 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) Support for Off-Site Educational Meetings.

1. MCOM 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.
2. Grants from Industry to the institution may be used in part to support travel for MCOM personnel attending professional meetings; however, the decision to use gift funds for travel expenses will be made at the discretion of the applicable MCOM Department Chair and/or the MCOM Dean. A Department Chair's use of such funds for his/her own travel must be approved in advance by the MCOM Dean.
3. 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 MCOM Department control the selection of the recipient of travel support.
4. Industry Support for Scholarships/Fellowships and Funds for Trainees. MCOM 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 MCOM 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 MCOM/Department and not by Industry.

(10) Relations with Industry Representatives in Publications.

- a) The professional presentations, books, articles, reports, or other materials, oral or written, of MCOM personnel must have appropriate authorship attribution.
- b) MCOM 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 Policy 0-301, Misconduct in Research](#).

(11) Medical School Curriculum.

The MCOM Curriculum Committee shall ensure that MCOM 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.

- a) MCOM directors, department chairs and immediate supervisors are responsible for reviewing disclosures and for ascertaining that MCOM 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.
- b) MCOM personnel who fail to abide by the provisions of this Regulation are subject to appropriate disciplinary action in accordance with University regulations and/or policies. 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 MCOM Faculty Council, USF MCOM Chapter of the American Medical Student Association representatives, and the administration of the MCOM 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 MCOM and the University.

Authority: Art. IX, Sec. 7, Fla. Constitution; Fla. Board of Governors Regulation 1.001.

History—New (BOT approval) 12-8-11; Amended 9-16-15, 8-4-16 (technical).