

NOTICE OF CHANGE IN PROPOSED REGULATION

Date:

REGULATION TITLE:

College of Medicine: Policy on Pharmaceutical and Medical Device Industry Conflicts of Interest and Industry/Academic Relations

REGULATION NO.:

5.0764

SUMMARY OF CHANGES: The University of Florida, in response to comments received concerning the above regulation, has changed the regulation as follows:

The following change was made to paragraph (1)(d):

“Industry” means ~~the~~ pharmaceutical, medical device, biotechnology, ~~industries and~~ hospital and research equipment supply industries and their representatives.

The “URL” in Section (5) has been changed to

“http://med.ufl.edu/admin/UF_COI_Policy_2011.pdf”.

The following change was made to the last sentence in paragraph (5)(h):

Any such contribution or grant will be reviewed by the CIC or by the CIC’s designee.

The following sentence was added as the last sentence in paragraph (6)(b):

Disclosures of such interests may be expected in other circumstances, such as to other COM personnel (including but not limited to residents and other trainees) and patients.

THE FULL TEXT OF THE PROPOSED REGULATION IS ATTACHED TO THIS NOTICE.

REGULATIONS OF THE
UNIVERSITY OF FLORIDA

5.0764 College of Medicine Policy on Pharmaceutical, Medical Device, and
Biotechnology Industry Conflicts of Interest

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

(a) “COM” means the University of Florida College of Medicine in Gainesville (the “COM-GNV”) and the University of Florida College of Medicine in Jacksonville (the “COM-JAX”).

(b) “COM personnel” means any employee or appointee of the University of Florida (whether full-time, part-time or courtesy), including but not limited to Academic Personnel (AP), Technical, Executive, Administrative and Managerial Support (TEAMS), University Support Personnel System (USPS), and Other Personnel Services (OPS) employees, who has a COM appointment. Academic Personnel are defined in University of Florida Regulation 7.003 and include without limitation faculty members, residents, fellows, graduate assistants and post-doctoral associates.

(c) “Gifts” mean 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, without limitation, food or beverages, transportation, lodging, parking, membership dues, admission fees, flowers, personal services, preferential rates or terms on a debt, loans, goods or services, forgiveness of a debt, and the use of real property. Any prohibition against gifts does not extend to gifts from a relative.

(d) “Industry” means pharmaceutical, medical device, biotechnology, hospital and research equipment supply industries and their representatives.

(e) “Industry-COM Conflict of Interest Committee” or “CIC” means the Industry Academic Relations Committee for COM personnel under the jurisdiction of the COM-GNV or the JAX Industry COM Conflict of Interest Committee for COM personnel under the jurisdiction of the COM-JAX. The compositions of the committees as well as the committee’s designees for any purposes set forth in this regulation are as set forth on the committees’ website at <http://coi.med.ufl.edu/contact-us/industry-academic-relations-committee/> and <https://www.hscj.ufl.edu/medicine/administrative-affairs/conflict-of-interest.asp>.

(f) “On-site” means facilities and grounds owned, operated or controlled by the University of Florida, the COM, or any affiliated patient-care facility.

(g) “Off-site” means facilities and grounds that do not fall under the definition of “On-site.”

(h) “Relative” means the spouse, domestic partner or fiancé of a COM personnel as well as the father, mother, son, daughter, brother, sister, uncle, aunt, first cousin, nephew, niece, grandfather, grandmother, great-grandfather, great-grandmother, grandchild, great-grandchild and the spouse, domestic partner, or fiancé of any of them, or any other natural person living in the same household as the COM personnel.

(i) “Speaker Bureaus” means any speaking engagement in which COM personnel are speaking on behalf of Industry as determined by the terms, conditions and intent of the agreement with the COM personnel when the following conditions apply: (i) the speech is not completely original to the COM personnel and all or part of the speech content is provided or dictated by or

on behalf of Industry-- or (ii) the content of the speech is subject to Industry approval.

(2) Introduction. COM personnel must pay particular attention to potential conflicts of interest in connection with Industry in order to protect the integrity of professional judgments and to preserve public trust in physicians, researchers, and academic medical institutions.

(3) Applicability of Policy. The COM Policy on Pharmaceutical, Medical Device, and Biotechnology Industry, Conflicts of Interest (“COM Industry Conflicts Policy”) applies to all COM personnel. The policy is supplemental to and does not supersede the University of Florida’s policy regarding the disclosure of outside activities, financial interests and conflict of interest, which is applicable to all University of Florida employees as set forth in University of Florida Regulation 1.011.

(4) General Statement of Policy

(a) The goal of the COM Industry Conflicts Policy is to increase transparency respecting 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 the policy.

(b) All COM personnel must become familiar with the COM Industry Conflicts Policy and are expected to understand and adhere to it.

(5) The COM Industry Conflicts Policy covers the following gifts and activities and, as in effect at any particular time, is more fully set forth at http://med.ufl.edu/admin/UF_COI_Policy_2011.pdf. To the extent of any conflict or ambiguity between this or another University Regulation and the policy posted at the referenced Web site, this and other University Regulations shall govern. It shall not be a conflict, however, that the

posted policy merely imposes additional requirements and provides additional detail.

(a) COM personnel may not accept gifts from Industry regardless of the monetary value of the gift unless such a gift is specifically allowed under the COM Industry Conflicts Policy.

(b) COM personnel may not accept pharmaceutical samples and educational materials from Industry unless their acceptance is specifically allowed under the terms and conditions of the COM Industry Conflicts Policy.

(c) On-site access by Industry is restricted to areas open to the general public unless otherwise allowed under the COM Industry Conflicts Policy.

(d) Participation by COM Personnel in Continuing Medical Education (CME) and other educational activities is allowed only under the conditions set forth in the COM Industry Conflict Policy. The policy applies to both on-site and off-site educational activities and any training for or by Industry.

(e) COM Personnel participation in Industry-sponsored speakers bureaus is prohibited.

(f) Food/ Entertainment

1. COM personnel may not accept meals or any other gifts of food for themselves or others if sponsored or provided by Industry unless allowed by the COM Industry Conflicts Policy. The Policy applies to both onsite and offsite food or entertainment.

2. Industry requesting to support the educational mission of the COM may provide educational grants and gifts to the University. Such grants and gifts will be placed in an appropriate University or University of Florida Foundation, Inc. account and monitored and

distributed pursuant to applicable University and University of Florida Foundation, Inc. regulations, policies and procedures.

(g) No Ghostwriting. The professional presentations, books, articles, reports, or other materials, oral or written, of COM personnel must have appropriate authorship attribution.

(h) Scholarships/Fellowships. COM personnel may not accept scholarships or fellowships to support training initiatives from Industry. Scholarship and fellowship funds from Industry may be provided to the University of Florida or the University of Florida Foundation, Inc. as appropriate. Any such contribution or grant will be reviewed by the CIC or by the CIC's designee. There shall be no quid pro quo associated with such funding.

(6) Disclosure and Notification.

(a) Outside activities and financial interests must be reported pursuant to the requirements of University of Florida Regulation 1.011. COM personnel who have no outside activities or financial interests to report are required to provide an annual attestation to that effect.

(b) COM personnel who present formal lectures to students or residents of the University of Florida must disclose at any presentation all outside activities, financial interests and relationships with Industry that relate directly or indirectly to the subject matter of the presentation. Disclosures of such interests may be expected in other circumstances, such as to other COM personnel (including but not limited to residents and other trainees) and patients.

Authority: BOG Regulation 1.001.

History: New