

**Florida International University Herbert Wertheim College of Medicine
Industry Relations Policy and Guidelines 2/16/15**

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Florida International University Herbert Wertheim College of Medicine Industry Relations Policy and Guidelines

1. Introduction and Scope of Policy

Florida International University (FIU) Herbert Wertheim College of Medicine (FIU-HWCOM) Faculty Council created an ad hoc committee to create a policy for FIU-HWCOM regarding Industry relations. This was composed of faculty from the FIU Health Care Network (FIU-HCN), ethics division, general faculty, clinical department chairs, and included two medical student representatives. After reviewing existing policies at Florida medical schools and the Association of American Medical Colleges (AAMC) reports on conflicts of interest (COI) in academic medicine <https://www.aamc.org/initiatives/research/coi/>, the committee created a policy to be presented to the full FIU-HWCOM Faculty Assembly.

The FIU-HWCOM has many opportunities to engage in professional activities with Industry that contribute to the college's mission of research, education, and clinical care. Such interaction may create perceived COI. Transparency is the key to oversight of COI and requires ongoing internal reporting and external disclosure.

Appropriate collaboration between physicians at Academic Health Centers (AHCs) and the pharmaceutical and medical device industries is necessary for the advancement of medicine; however, such interactions can also create conflicts of interest that threaten the quality of patient care.

This document outlines the FIU-HWCOM policy concerning relationships and interactions with Industry in a manner that avoids real or perceived conflicts.

2. Definitions

"HWCOM personnel" means any employee of Florida International University (whether full-time, part-time), including Other Personnel Services (OPS) employees, who have a HWCOM 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.

"Immediate family member" means a husband or wife, birth or adoptive parent, child, or sibling; stepparent, step-child, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; spouse of a grandparent or grandchild)

A *"gift"* is means anything of value that is given by a business or individual that does or seeks to do business with HWCOM or HCN to either the recipient or his/her immediate family members, and for which the recipient neither paid nor provided services.

"Industry" means any individual or entity that sells items covered by the Medicare Medicaid or other State or federal health care program. This includes pharmaceutical companies and medical device manufacturers.

A *"Significant Financial Interest"* is a payment of \$10,000 or more (per company per FIU fiscal year).

3. Statement of Policy

It is the policy of the FIU-HWCOM that relationships with Industry be conducted so as to avoid real and perceived conflicts of interest. Should a conflict of interest arise, it must be addressed appropriately, as described in this policy.

4. Scope

4.1 Faculty, Residents, Staff and Students

This policy applies to all COM faculty, residents, staff and students. This policy does not supersede Florida International University's policy regarding the disclosure of outside activities, financial interests and conflict of interest, which is applicable to all FIU employees. It is a supplement to the FIU Conflicts of Interest/Outside Activities policy found at: http://hr.fiu.edu/index.php?name=conflict_of_interest

Under Florida Ethics laws, gifts to FIU faculty and staff by University lobbyists (e.g. vendors who do or seek to do business with the University) are limited to less than \$100/year per individual, if the individual is procurement employee. Gifts to University Reporting Individuals by lobbyists/vendors is prohibited.

All transfers of value to a FIU faculty or staff member must be reported to FIU through the Conflicts of Interest/Outside Activity Reporting processes.

At all times, the FIU-HWCOM policies are subordinate to the FIU policies.

COI reports must be made for any outside compensated professional activity (such as consulting) or when the FIU faculty or staff member reasonably concludes that the proposed outside activity may create a COI.

4.2 Sites and hours

This policy addresses conduct both at FIU sites as well as off-site activities, seven days/week, all hours.

5. Gifts and Individual Financial Relationships with Industry

5.1 Gifts and Meals

FIU-HWCOM Personnel shall not accept personal gifts from representatives of Industry, regardless of the nature or dollar value of the gift. Gifts from vendors are strictly prohibited regardless of value.

5.2 Continuing Medical Education (CME)

Provisions and materials received in connection with an educational program accredited by the Accreditation Council for Continuing Medical Education (ACCME), programs sponsored by FIU-HWCOM Division of Continuing Medical Education (CME), or a professional society-sponsored meeting may be accepted by FIU-HWCOM Personnel as a part of the meeting attendance provided all attendees if items are made available to all program participants.

6. Samples and Purchasing of Pharmaceuticals

6.1 Sample Medications and Vouchers

Sample medications are not permitted in HCN managed sites. In order for patients to receive complimentary starter medications from a pharmacy of their choice, HWCOC and HCN administrative leaders may determine use of vouchers to be permissible and must develop processes for securing and distributing vouchers, including the use of logs, which must be periodically audited for adherence with the processes. Dispensing of vouchers is limited to HWCOC personnel who are a prescribing provider with active prescription privileges. If vouchers are not available, sample medications may be used in only HWCOC HHS clinical sites. Limitations on Sample medications and vouchers apply to patient care and non-patient care areas.

6.2 Personal Use Prohibited

FIU-HWCOC personnel may NOT accept samples of pharmaceuticals, vouchers, medical devices, or medical supplies for their personal use. Free vouchers may never be sold

6.3 Purchasing and Formularies

FIU-HWCOC Personnel who have fiscal ties with Industry or who have immediate family members with such ties may not participate in decisions relating to purchasing of products or services provided by such companies. FIU-HWCOC Personnel may serve as a resource for information about certain products, but if a financial COI is present, they should not participate in the actual decision with regard to expenditures.

7. Site Access to Sales and Marketing Industry Representatives

7.1 Patient Care Areas

Access by Sales and Marketing Industry representatives to patient care areas is permitted when:

- a. FIU-HWCOC representative requests essential instruction in use of the equipment or device,
- b. If a specific patient is involved in the instruction of the equipment or device, a prior disclosure to the patient and patient authorization must be obtained.

Vendors must wear visible identification. Medical students and trainees may be included for educational purposes. These interactions must occur under the supervision of a faculty member.

Industry marketing information may not be placed in patient care areas or waiting rooms.

7.2 Non-Patient Care Areas

Sales and marketing representatives are permitted in non-clinical areas by appointment only.

Appointments will normally be made for such purposes as:

- a. In-service training of personnel for research or clinical equipment or devices already purchased;
- b. Evaluation of new purchases of equipment, devices, or consideration of addition of new pharmaceuticals to the medication formulary.

7.3 Oversight

While appointments may be made at the discretion of any faculty member, the overall activity of sales and marketing representatives is subject to the oversight of division chiefs, department chairs, medical staff leadership, and other designated officials of HWCOC and HCN.

8. Industry Support of Education

8.1 Support by Industry of Continuing Medical Education and On-site Educational Activities.

All Continuing Medical Education (CME) events hosted or sponsored by the FIU-HWCOM must comply with the Accreditation Council of Continuing Medical Education (ACCME) standards. HWCOM CME Office will provide reports to the Industry Relations Workgroup of any vendor contribution exceeding \$10,000 in support of CME per year per vendor.

8.2 Payment for Attending

Individuals may not accept compensation, including the defraying of costs, for simply attending a CME or other activity or conference (that is, if the individual is not speaking or otherwise actively participating or presenting at the event).

8.3 Evaluation of Offered Sessions

HWCOM Personnel should carefully evaluate their own participation in meetings and conferences that are fully or partially sponsored or run by industry because of the high potential for perceived or real conflict of interest. This provision does not apply to meetings of professional societies that may receive partial industry support, meetings governed by ACCME Standards, and the like. Individuals who actively participate in meetings and conferences supported in part or in whole by industry (e.g., by giving a lecture, organizing the meeting) should follow these guidelines:

- a. Financial support by industry is fully disclosed by the meeting sponsor.
- b. The meeting or lecture content is determined by the speaker and not the industrial sponsor:
- c. The lecturer is expected to provide a fair and balanced assessment of therapeutic options and to promote objective scientific and educational activities and discourse
- d. The FIU HWCOM Personnel participant is not required by an industry sponsor to accept advice or services concerning speakers, content, etc., as a condition of the sponsor's contribution of funds or services.
- e. The lecturer makes clear that content reflects individual views and not the views of FIU HWCOM or FIU HCN.
- f. The use of the FIU name in non-FIU event is limited to the identification of the individual by his or her title and affiliation

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

The FIU-HWCOM solicits and welcomes Industry contributions for scholarships, fellowships, and other support for trainees, so long as the funds are given to FIU HWCOM through an affiliated entity or foundation (e.g. FIU Foundation); there is no expectation of benefit to the donor; the evaluation and selection of recipients is in the sole discretion of the FIU-HWCOM; and the allocation and distribution of funds is managed by the FIU-HWCOM.

9. Industry Consulting and other Outside Relationships (e.g., consulting, advisory board, speaking, publishing, attending meetings or other financial interests)

Outside Arrangement means a written or verbal arrangement with Industry for FIU-HWCOM Personnel to perform consulting services, to serve on advisory boards, to speak at or attend an Industry sponsored events, to publish in Industry-funded publications.

9.1 Disclosure of Outside Arrangements Involving Industry using the University Conflict of Interest Review process

FIU-HWCOM Personnel shall report their Outside Arrangements with Industry through the regular university COI process, using the Request for an Exemption/Disclosure under Section 112.313(12) (h), Florida Statutes, available online at, http://hr.fiu.edu/index.php?name=conflict_of_interest at least annually and as often as needed to disclose new relationships. All such reports are open to the public.

9.2 Consulting or Service Agreements

Consulting arrangements that simply pay HWCOM Personnel a guaranteed amount with minimal or no associated duties or deliverables (such as participation on scientific advisory boards that do not regularly meet and provide scientific advice) or excessive compensation for the services provided shall be considered gifts and are consequently prohibited. All consulting agreements must meet the following requirements to be acceptable:

- a. **Contract.** Consulting should be supported by a written contract with specific deliverables, which must be restricted to scientific issues, not marketing, and which require FIU HWCOM Personnel's technical and professional judgment or assessment.
- b. **Scientific Issues.** The specific and substantive deliverables in the written agreement must be restricted to scientific issues such as:
 - 1) design of a new clinical trial or conduct of an existing clinical trial with which FIU is involved;
 - 2) development of a new diagnostic, therapeutic or technical product; or
 - 3) development of an educational product
- c. **Compensation and Reimbursement.**
 - 1) The compensation paid must be reasonable and reflect fair market value for the services and time provided;
 - 2) The compensation paid must not be considered excessive when looked at overall for all time expended for consulting or honoraria;
 - 3) All services must be performed on personal time unless the consulting income is paid to FIU; and
 - 4) Travel and expense reimbursement must be reasonable and necessary for the provision of the above services.

9.3 Submission of Consulting Agreements

Consulting agreements must be submitted via the FIUCOI/ Outside Activities reporting process for review by the FIU HWCOM COI Work group, including Legal Affairs.

9.4 Advisory Board

Membership on Industry advisory boards by HWCOM Personnel is permitted so long as 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 FIU-HWCOM, must be modest and consistent with fair market value. In addition, the individual may receive reasonable travel expenses (such as airfare, mileage, lodging, tips, meals and other transportation costs) as approved by the FIU COI approval process.

9.5 Industry-Funded Speaking Relationships, Meetings, and Publications

- a. **General Guidelines.** FIU-HWCOM Personnel must assure that participation in Industry-funded speaking relationships, meetings, and publications serves to advance scientific

knowledge or patient care and are not primarily Industry marketing activities. Honoraria for speaking engagements, whether received by the individual or by the FIU-HWCOM, 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, tips, meals and other transportation costs) as approved by the FIU COI approval process.

b. If FIU HWCOM Personnel are Presenting. FIU-HWCOM Personnel are responsible for the scientific integrity of material presented in any talk or publication. FIU-HWCOM Personnel shall not participate in educational presentations or scientific publications if:

- 1) the content is controlled by or requires prior approval by Industry,
- 2) the content is not based on the best available scientific evidence, or
- 3) substantial portions are written by someone who is not an author or if all authors are not properly acknowledged.

c. Speaker's Bureau. Participation by FIU-HWCOM Personnel in "Speakers' Bureau Activity" is strictly prohibited. "Speakers' Bureau Activity" means any speaking engagement in which FIU-HWCOM Personnel would be speaking on behalf of Industry. The FIU-HWCOM shall not sponsor and/or host any Speakers' Bureau Activities.

10. Disclosure to Students, Residents, Colleagues and Patients

FIU-HWCOM 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 FIU-HWCOM Personnel is participating in an individual capacity and not on behalf of the FIU-HWCOM or University.

11. Research with Human Subjects

Gifts or contributions by Industry for research purposes must be managed in accordance with processes established by the FIU Division of Research.

12. Philanthropy

FIU-HWCOM welcomes and solicits donations from industries that support the FIU-HWCOM's mission, goals, and objectives. Such funds should be directed to the FIU Foundation, which, under the direction of the Dean of the HWCOM, will distribute the funds to support HWCOM's missions.

The FIU Foundation and other tax exempt entities such as the direct support organizations (DSO) assist the FIU-HWCOM in soliciting, receiving, and managing charitable donations. All charitable donations must be free of any implied or explicit expectations of benefit to the donor. Corporate sponsors may not make commercial exhibits, distribution of promotional materials or the inclusion of company representatives a requirement for support.

13. Training of FIU-HWCOM Personnel

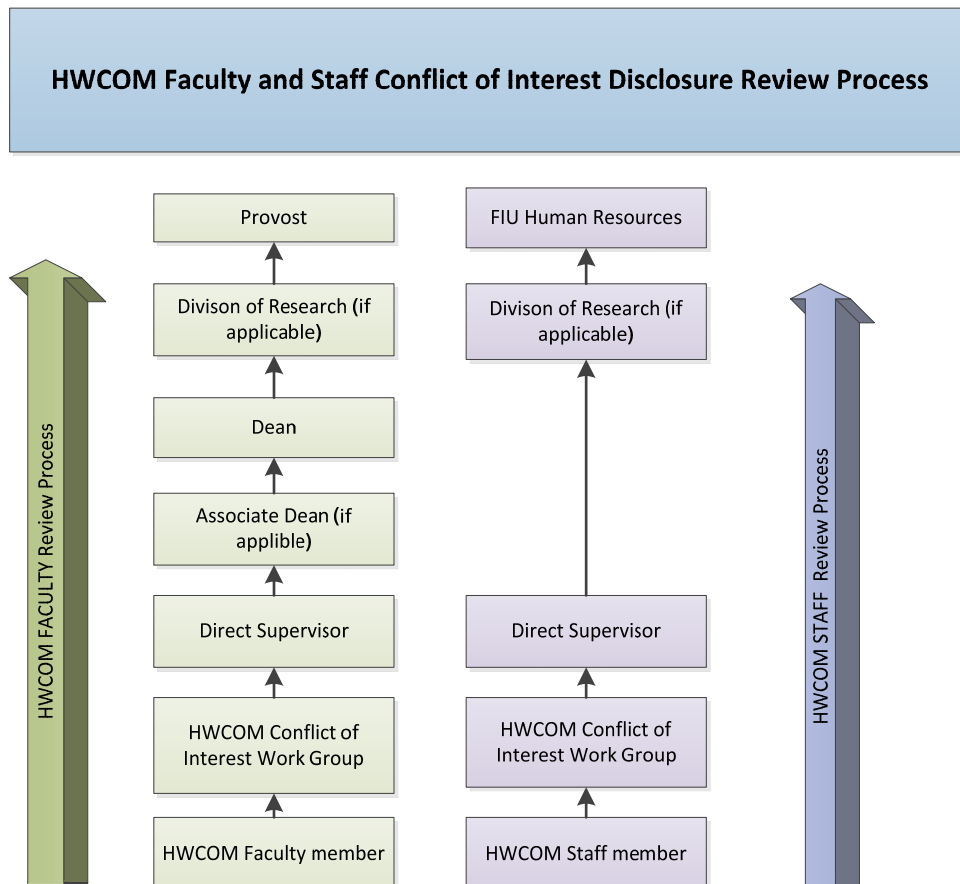
FIU-HWCOM medical school curriculum includes instruction for medical students in understanding and addressing individual and institutional COI in interactions with Industry and how the potential for COI impacts/influences education, research and patient care/clinical judgment. Medical students and FIU-HWCOM Personnel are required to receive specific instruction regarding this policy.

14. Ghostwriting

The FIU-HWCOM has zero tolerance for plagiarism and for publication of articles under the authorship of individuals who did not, in fact, contribute to the production of the manuscript. All persons who participate in the production of an article should receive credit for a publication, but must make a substantial contribution to the preparation of a manuscript by meeting the standards established by the International Committee of Medical Journal Editors (ICMJE). An academic researcher should not apply his/her name to an article to which they did not make a substantial contribution. This violates the principles of ethical authorship and research integrity outlined in the ICMJE guidelines <http://www.icmje.org/conflicts-of-interest/> and other scientific standards for authorship and is absolutely prohibited.

15. HWCOM Conflict of Interest Work Group (HWCOM COI Workgroup)

The HWCOM COI work group, as part of the FIU COI process will evaluate and make determinations of reported relationships made in accordance with this policy.



16. Sanctions

HWCOP faculty, residents, staff and students who fail to abide by the provisions of the HWCOP's Policy on Industry Conflicts of Interest/Industry Relations are subject to appropriate administrative or disciplinary action. 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 take action in accordance to applicable University policy. Vendors who violate this policy may be barred from doing business with HWCOP.