

CONFLICT OF INTEREST & INDUSTRY INTERACTIONS

University of Florida
College of Medicine, Gainesville
2012 Overview



COI Program Overview



- This overview will:
 - Introduce you to the COI Program
 - Describe the policies you need to know
 - Provide background information regarding COI trends
 - Describe UF's Disclosure rules
 - Explain Outside Activity rules

COI Program Mission



- The COI Program (<http://coi.med.ufl.edu>) is focused on structuring appropriate, principled, transparent relationships with our valued Industry collaborators. These relationships are critical to the success of the University's effort to teach medical students, train residents and fellows, and to provide the best care for our patients.

Conflict of Interest Policies at UF



- 1. General conflict of interest policies at UF have been in place for many years. Please review Rule 6C-1.011 (<http://www.generalcounsel.ufl.edu/downloads/Appendices/AppendixA1.pdf>) for COI provisions pertaining to UF employees. You are responsible for knowing and following these provisions.
- 2. The COM's Conflict of Interest Policy (http://med.ufl.edu/admin/UF_COI_Policy_2011.pdf) This policy addresses academic/industry relationships specifically. You are responsible for knowing and following its provisions.

Code of Ethics for Public Employees



- Please also note that as faculty and staff of the University of Florida, you are bound by the State of Florida's statutory Code of Ethics for Public Employees.
- You should read and understand these statutory provisions. <http://www.ethics.state.fl.us/>

COI in the Spotlight



- Recognizing the special relationship that exists between doctors and patients, Academic Medical Centers are introducing specific measures to maintain the public's trust in academic medicine.
- Media coverage is extensive and government scrutiny is intensifying.

Los Angeles Times, October 4, 2008

- **Doctor accused in Congress' probe**
- *“A prominent Emory University psychiatrist received at least \$2.8 million in consulting fees from companies whose drugs he was evaluating and failed to report a third of it, congressional investigators studying medical conflicts of interest said Friday. The allegations against Dr. Charles B. Nemeroff, the latest in a series of such charges, are the most striking to emerge from the probe, which seems likely to alter the cozy relationships between prominent academics and the drug industry.”*

New York Times, December 2, 2008



- ***Cleveland Clinic Discloses Doctors' Industry Ties***
- *“The Cleveland Clinic’s Web postings are the most recent part of a conflict-of-interest effort at the clinic after some of its leading doctors came under fire several years ago when the news media disclosed some of their financial links.”*

Bloomberg, June 8, 2008



- ***Harvard Doctors Failed to Disclose Fees, Senator Says***
- “Harvard Medical School doctors who helped pioneer the use of psychiatric drugs in children violated U.S. government and school rules by failing to properly disclose at least \$3.2 million from drug-makers led by Johnson and Johnson and Eli Lilly & Co., a U.S. senator said.”

Physician Payments in the Sunshine Act is a direct result:



- Passed as part of Healthcare Reform
- Requires drug and medical device manufacturers to publically report gifts and payments made to physicians and teaching hospitals

Payments in the Sunshine



- How specific?

- Physician's name, address, national provider identifier; and the value, date, form and nature of the payment using standardized descriptions
- All of this information, except for the national provider identifiers, will be available to the public as of September 30, 2013.

Industry Online Databases



- Medtronic
 - Zimmer
 - Pfizer
 - Merck
 - Lilly
 - GSK
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- These companies disclose payments to doctors to the public using online tools. The list is growing.
 - **Discrepancies between these reports and internal UF records are investigated by appropriate University officials.**

UF's Approach



- The determination that an individual has a conflict of interest is a judgment about the situation and not about the professional who happens to be in that situation.

UF's Conflict of Interest Policy

Highlights and Key Points



- “Industry” includes, but is not limited to, pharmaceutical, medical device, equipment, biotechnology, service, software, supplies, biomedical investment, and for profit educational companies and foundations sponsored by companies such as drug and device companies
- Covers a broad array of individuals employed by UF (full-time, part-time and courtesy faculty)
- Includes Faculty, Residents, Fellows, AP, TEAMS, USPS & OPS
- Seeks to curb promotional and marketing activities as such activities are inconsistent with UF's mission
- Includes “conflict of commitment” provisions

Gifts & Food



- Gifts come in many forms: Food, beverages, pens, paper goods, transportation, lodging, parking, membership fees, 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. GIFTS ARE NOT PERMITTED, REGARDLESS OF VALUE.
- **Industry-purchased food is not permitted at the College of Medicine.**

Samples



- Generally, can't accept them from Industry
- May petition University of Florida Physicians Clinical Safety Committee for a waiver
- Must demonstrate clear and compelling benefit to patients in need and must provide safeguards for appropriate distribution and control

Teaching Materials; Equipment



- Generally not permitted to directly accept books, instruments, equipment, or teaching aids from Industry
- Want to encourage Industry and COM to use the UF Foundation, which is designed to accept grants from Industry
- Dean's Office will have oversight and audit function
- Materials/equipment may be donated to Foundation if properly transferred via a written agreement

CME & Other Educational Activities



- If CME, must comport to ACCME standards and be processed through the CME office
- Non-CME educational activities are monitored, evaluated and subject to full disclosure

On-Site Training



- Industry may provide on-site training with preapproval from the COM's CME office or the Industry Academic Relations Committee if non-CME. Industry may also receive on-site training from COM personnel in the safe and proper use of certain medical devices and/or equipment.

Off-site Events



- You may participate in or attend Industry-sponsored conferences and meetings and/or conferences and meetings of tax-exempt organizations funded or sponsored by more than one entity, which may include Industry under certain circumstances. Food/ beverages made available to the entire group are allowed. Note, however, that some companies report the provision of food/beverages and your name may appear in an Industry database.
- Travel expenses may not be paid by Industry unless you are speaking/presenting based on a written agreement.

Speakers Bureaus

- UF's College of Medicine defines a "speakers bureau" as any engagement in which you are speaking on behalf of Industry, where the content of the talk is not completely original to you; or the talk is subject to Industry approval; or the attendees of the event are selected by Industry or provided a gift or stipend to attend.
- **Speakers Bureau activities are prohibited.**
- Violations of this prohibition against Speakers Bureau activities will result in disciplinary action.
- As of January 1, 2011 you should not have any active Speakers Bureau relationships with Industry.

Ghostwriting



- The professional presentations, books, articles, reports, or other materials, oral or written, of COM personnel must have appropriate authorship attribution.
- **Collaboration with Industry during any phase of manuscript preparation should be appropriately disclosed.**

Scholarships/Fellowships



- Cannot be accepted directly from Industry
- HOWEVER, Scholarship and fellowship funds may be provided to the Foundation for education, travel to educational programs, and for other educational purposes. However, there shall be no *quid pro quo* associated with such funding.

Disclosure



- The disclosure of outside activities and financial interests must be reported on UF's form titled, **Disclosure of Outside Activities and Financial Interests** (University Form OAA-GA-L-267/Rev. 04/02) (<http://www.generalcounsel.ufl.edu/downloads/Appendices/appendixB1.pdf>) which is to be reviewed by the department chair or immediate supervisor and forwarded as necessary for authorization.

Disclosure (continued)



- This form 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 form must be submitted. All paperwork associated with continuing outside employment/activity must be renewed on a fiscal-year basis.

Outside Activity

- An “outside activity” is defined in the Rules of University of Florida, 6C1-1.011 as:
 - “Any private practice, private consulting, employment, teaching, research, business (including managerial interests or positions), or other activity, compensated or uncompensated, which is not part of the employee’s assigned duties and for which the University provides no compensation.”
 - * “Conflicts may arise even in instances in which the faculty or staff member will not receive any economic benefit from the outside activity.”
GUIDELINES, POLICIES, AND PROCEDURES ON CONFLICT OF INTEREST AND OUTSIDE ACTIVITIES, INCLUDING FINANCIAL INTERESTS -
<http://www.generalcounsel.ufl.edu/downloads/COI.pdf>

Outside Activity Issues



- Your personal external professional relationships include any professional services performed or products created and/or sold for any other person or entity (including, but not limited to, Industry and other entities).
- You must report these relationships **prior to engaging in them and they must first be approved by the Chair, the Dean's Office, and, if applicable, the Office of Research.**

Outside Activities (2)

- Your outside agreements must reference your home address and compensation must be paid to you as you are acting in a private capacity.
- You are responsible for any claims or damages arising from your personal external professional relationships.
- You must recognize you are performing the activity as an individual and you may not represent that you are acting on behalf of the university. *For example, you may not use University of Florida letterhead or a University of Florida email address in conducting outside activities.* You must take reasonable precautions to insure that the outside company understands you are engaging in the outside activity as a private citizen and not as an employee, agent, or spokesperson of the university.
- Reasonable travel expenses may be reimbursed by Industry or other entity.

Outside Activities (3)



- Under the majority of circumstances, you are not permitted to engage in the outside practice of medicine.
- The University has ownership in intellectual property rights so be mindful of contrary provisions in your outside agreements.