

COI Disclosure Requirements, Industry Interaction, Outside Employment, & Gift Policy

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Conflict of Interest (COI) Overview

- Purpose of COI Policies
- Applicable Federal/State Regulations & University Policies
- What Must Be Disclosed
- What Constitutes a COI
- Review & Management of COI/Conflict of Commitment
- UAMS Gift Policy
- “Foreign Influence” in US Biomedical System
- Scenarios and Q&A

Purposes of COI Regs/Policies

- Ensure that decisions are made based upon professional judgment and not the influence of potential financial gain.
- Protect patients and research subjects.
- Prevent unsafe drugs and devices from getting to market.
- Avoid publication of corrupt or biased data.
- Ensure public trust.
- Comply with federal and state laws and regulations.

What Regulations/Rules Apply?

- **Federal:** 42 CFR Part 50, Subpart F
 - ✓ Promoting Objectivity in Research - Promotes objectivity in research by establishing standards that provide reasonable expectations that the design, conduct, and reporting of research funded under Public Health Services (PHS) grants or cooperative agreements will be free from bias resulting from Investigator conflicts of interest -§50.601

What Regulations/Rules Apply?

State Level:

- Under Arkansas ethics laws, state employees may not participate (directly or indirectly) in any transaction at UAMS:
 - ✓ Involving an entity with which the employee or an immediate family member has a Financial Interest; or
 - ✓ Involving an entity with which the employee or an immediate family member is negotiating or has an arrangement concerning prospective employment.

What Regulations/Rules Apply?

State Level:

- Exception to ethics laws to facilitate the commercialization of university-generated technology or discovery.
 - ✓ Participation in a business incubator: provisions do not apply to faculty or staff of a state-supported institution of higher education participating in a business incubator within this state.

What Regulations/Rules Apply?

State Level:

- Exception to ethics laws to facilitate the commercialization of university-generated technology or discovery.
- Patents, copyrights or other proprietary information:
 - ✓ provisions do not apply to proprietary information in which the university and the employee have rights or interests.

University Policies

- **Industry Interaction:** parameters set by UAMS policy for engaging with the healthcare industry
 - UAMS Admin Guide 4.4.12, Industry Interaction
- **Outside Employment:** requesting permission to engage in the activity
 - UA Board Policy 450.1, Outside Employment of Faculty and Administrative Staff Members for Compensation
 - Faculty Group Practice 7000-0100-500 FGP P&R Financial Responsibility
- **Conflict of Interest:** disclosing the activity pursuant to COI policy
 - UAMS Admin Guide 4.4.13, Institutional Conflict of Interest in Research
 - UAMS Admin Guide 4.4.10, Conflict of Interest for Academic Staff Members
 - UAMS Admin Guide 4.4.11, Conflict of Interest for Non-Academic Staff Member
- **Gift Policy:** acceptance of gifts from outside sources
 - UAMS Admin Guide 4.4.09, Ethical Conduct/Gift Policy

Industry Interactions: HealthCare Industry Defined

- **Healthcare Industry:** individuals and organizations involved in the development, manufacture, supply, or delivery of health products or services.
 - Includes: pharmaceutical and medical device manufacturers, medical supply companies, patient transportation and ambulance services, hospitals, laboratories, medical imaging providers, and physician/nursing service providers.
 - Does NOT Include: domestic government agencies, domestic academic medical centers, or accredited public or non-profit, domestic institutions of higher education or their affiliated research institutes.

Types of Industry Interactions:

- **Industry Interaction:** consulting agreements, speaking engagements, service on advisory boards, paid authorships, business arrangements, and other non-UAMS activities for which remuneration is received.
 - Examples:
 - Surgeon conducts educational seminars sponsored by Medtronic.
 - Researcher serves on an advisory board for Novartis.
 - Nurse practitioner speaks at conference partially supported by Cardinal Health.
 - Administrator serves as a consultant for an HMO.

Industry Interaction Requirements:

- **Consulting relationships** must be defined by a formal, written agreement which:
 - Clearly defines the tasks to be performed;
 - Provides for compensation at fair-market value; and
 - Is for a defined contract period.
- **Speaking Engagements** at conferences or other activities supported in whole or in part by Industry are subject to restrictions to protect the integrity of employees and UAMS. They must meet all of the following requirements:
 - Financial support by Industry must be fully disclosed;
 - Content shall be determined solely by the presenter (Industry sponsor may not make revisions or approve presentation content);
 - Slides, abstracts, etc. shall be originated by the presenter;
 - Use of UAMS name must be limited to identification of the speaker;
 - Speaker shall not express or imply UAMS approval or endorsement of any product or service; and
 - Attendees shall not receive gifts or compensation for event attendance.

Industry Interaction Prohibitions:

UAMS employees are prohibited from:

- **Speakers' Bureaus:** any arrangement where the Industry sponsor (1) has right to control or dictate the content of the presentation, (2) creates the slides or presentation material, or (3) has final approval of the content and edits.
- **Ghostwriting:** inclusion of an author who has not met the qualifications of authorship or failure to include an individual who should be listed as an author
 - Employees may not lend their name as author, co-author or editor of any material prepared by Industry representatives or agents.
 - Employees must meet the criteria of the International Committee of Medical Journal Editors
- **Gifts and Meals:** employees may not accept or solicit gifts, including meals, from Industry
 - See Admin Guide Policy 4.4.09
 - FAQ on COI website

Outside Employment

- **UA Board of Trustees Policy 450.1:** all faculty members and UAMS institutional officials **must request permission in advance** of engaging in any Industry Interactions.
 - Approval is processed using the electronic outside employment system at: <https://secure.uams.edu/OutsideEmployment/Login.aspx>
 - Note: Industry Interactions are not the only outside activities covered by the UA Board Policy. For example, participation in a NIH study section is not considered an Industry Interaction but is considered Outside Employment.
- **UAMS Faculty Group Practice Policies:** Industry Interaction and other outside activities may be subject to FGP policies
 - Request by COM Faculty to Engage in Volunteer Clinical Activity, Moonlighting, or Other External Employment- 7000-100-510
- **Guide for UAMS Faculty on Outside Employment**
 - <https://coi.uams.edu/policies/>

Conflict of Interest & Outside Employment

- Two separate systems, but COI disclosures and Outside Employment requests may overlap.
- Outside Employment requests are reviewed and approved by Chairs and Deans.
- COI disclosures are provided to Chairs and Deans for review but are approved by the appropriate COI committee.

Disclosures Under COI Policies

What Must be Disclosed?

- **Significant Interests** of the Academic Staff Member (“ASM”) or their immediate family member that reasonably relate to or reasonably appear to be related to the ASM’s Institutional Responsibilities:
 - ✓ **Equity**
 - stock, stock options, or other ownership interests
 - ✓ **Intellectual Property**
 - licensed IP or income from IP rights, including IP assigned to or licensed through UAMS
 - ✓ **Payments or other Remuneration**
 - salary, consulting fees, honoraria, paid authorship, travel reimbursement
 - ✓ **Fiduciary Relationships**
 - service as a board member, officer, executive, advisor, or manager
 - ✓ **In-Kind Contributions**
 - Gifts, endowments, sponsored travel, or other in-kind contributions

Significant Interests Do NOT Include

- Compensation or other remuneration paid by UAMS (except for licensing fees or royalty income).
- Income from seminars, lectures, or teaching engagements sponsored by government agencies, academic medical centers, public or non-profit institutions of higher education.
- Income from service on advisory committee or review panels for government agencies, a academic medical centers, public or non-profit institutions of higher education.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as no direct control of investment decisions.

What is a Conflict of Interest?

- Conflict of Interest:

- ✓ a significant interest that could **inappropriately influence** or **reasonably appear to inappropriately influence** the integrity or objectivity of an Academic Staff Members' professional role or decision-making responsibilities. *UAMS Admin Guide 4.4.10*

What does a having a “conflict of interest” really mean?

- An outside interest that has the potential to, or could appear to, adversely affect our decisions or objectivity.
- A situation where objectivity could be compromised by the prospect of personal financial gain.

Identifying COIs

- Consider how the outside interest is related to job responsibilities:
 - ✓ Do I have ownership in a company that manufactures a device I'm researching?
 - ✓ Am I doing new research on technology I created that produces royalties?
 - ✓ Do I get paid to be a consultant for a company who sponsors my research?
 - ✓ Do I have a financial relationship with an entity that does business with UAMS?
 - ✓ Does my job at UAMS put me in a position to make decisions that would impact my outside interest?

Managing COIs

- Following submission, disclosures are reviewed by Chairs, Deans and the Conflict of Interest Committee.
- If the Committee determines that a staff member has a conflict, the staff member will be contacted and a management plan developed.
- The management plan will document steps being taken to prevent the outside interest from inappropriately influencing decision-making or impacting UAMS responsibilities.

Common Tactics Employed to Manage Conflicts of Interest

- Disclosure
- Recusal
- Monitoring / Oversight
- Role Restructure
- Divestment

Managing Conflict of Commitment

- ASMs may engage in external activities which contribute to professional development by enhancing knowledge, skills, and expertise.
- Such activities may include consulting, authorship, editorial services, involvement with professional societies, or participation on educational, advisory or scientific committees and review panels.
- Such activities, however, should not interfere with an ASM's Institutional Responsibilities.
- Therefore, external activities must be reviewed and approved by the appropriate UAMS Official(s) to assure they do not result in a conflict of commitment.

Sample Management Plan Terms

- The Investigator will disclose his/her interests in the Technology and the Company to the IRB for of any protocols involving research related to the conflict. The IRB may require disclosure in informed consent documents or other measures to protect human research subjects in addition to those described in this Management Plan.
- The Investigator will not be involved in the recruitment or consenting of human subjects for the Related Research.
- The Investigator will disclose his/her interests in the Technology and the Company to all other investigators, including students and trainees, working on the Related Research or other research projects related to the Technology and the Company in the form and manner described in Attachment A.
- Data analysis and oversight will be performed or validated by a non-conflicted investigator who has no financial interest in the Technology or the Company and is not under the Investigator's supervision.
- The Investigator will disclose his/her interests in the Technology and the Company in all applicable presentations and publications
- The Investigator's interests in the Technology and Company shall not place restrictions on the scholarly and research activity of UAMS personnel nor prevent or inhibit students from meeting applicable degree requirements.
- The Investigator's interests shall not place any restrictions on publications or presentations.
- The Investigator will continue to satisfy his/her work commitments to UAMS and shall not conduct Company business during UAMS working hours.
- UAMS employees and students shall not provide services to the Company unless pre-approved by the appropriate institutional officials (e.g., Department Chair and Dean).
- UAMS resources will not be utilized by or for the benefit of the Company absent a written agreement between the Company and UAMS that provides the Company will compensate UAMS at fair market value for such resources.

Conflict of Interest: Summary

- UAMS employees must disclose Industry Interactions and other significant interests.
 - **Who:**
 - Institutional Officials (cabinet level employees)—Admin Guide Policy 4.4.13
 - Academic Staff Members (faculty and research personnel)—Admin Guide Policy 4.4.10
 - Non-Academic Staff Members (non-classified positions)—Admin Guide Policy 4.4.11
 - **What:**
 - Significant Interests of the UAMS employee or his/her Immediate Family Member that are reasonably related to the employee's UAMS responsibilities, including:
 - Equity interests (stock, stock options, or other ownership interests)
 - Licensed intellectual property rights (patents, copyrights, etc.) or income from intellectual property rights (licensing fees, royalties, etc.)
 - Payments or other remuneration from outside organizations (salary, consulting fees, honoraria, paid authorship or travel reimbursement...Industry Interactions)
 - Fiduciary Relationships (service on board of directors)
 - Receipt of gifts, endowments, sponsored travel, or other in-kind contributions
 - **When:**
 - Within the first two weeks of employment; annually thereafter or within 30 days of a change
 - **Where:**
 - Muse-COI <https://muse2.uams.edu>

Gift Policy 4.4.09

- UAMS employees shall not solicit or accept a gift:
 - a. from a patient, visitor or a person or entity that contracts with, does business with or seeks to do business with UAMS; or
 - b. from healthcare industry vendors or representatives; or
 - c. given because of the employee's official position.
 - "Gift" includes everything of monetary value, except:
 - a one-time token of appreciation from a patient provided its value is less than \$25
 - rewards and prizes in contests open to the public
 - commercial discounts available to the general public or to all government or UAMS personnel
 - commercial loans, and pensions and similar benefits
 - anything for which the employee pays market value.

Gift Policy 4.4.09 Exceptions

- A gift may be accepted if:
 - gifts based on an outside family/personal relationship;
 - meals and gifts of a value of \$25 or less offered to UAMS employees by entities where the employee is present as a result of UAMS job duties;
 - UAMS employees whose scope of employment requires physical presence at non-UAMS facilities may accept meals and gifts of a value of \$25 or less provided such meals or gifts are given to similarly situated employees of that facility. Meals and gifts may not be accepted if provided by third parties.
 - Gov't group discounts offered generally from non prohibited sources;
 - awards that are part of a regular and established program of recognition for meritorious public service;
 - free attendance provided by the sponsor of a widely-attended gathering, speaking engagement, or other event where UAMS has determined it is in its best interest to attend the event;
 - food/refreshments/entertainment at certain social events extended by non-prohibited sources & no fee charged to attend;
 - unsolicited gifts for free attendance for UAMS employees (and spouses) at events sponsored by state or local governments or nonprofit, tax exempt civic organizations, where UAMS has determined it is in its community relations interests to attend the event;
 - unsolicited gifts of food, lodging, travel or attendance at events for UAMS employees (and spouses) when the employee is appearing in an official capacity for UAMS based on the employee's office or position and the purpose of the appearance is to further the UAMS mission;
 - travel costs may be accepted under limited circumstances.

Gift Policy 4.4.09 (Con't)

- Educational, marketing, and other promotional programs may not include meals for UAMS employees.
- Sponsors of educational programs must submit funds to the appropriate foundation account.
- Each college will establish procedures to implement this provision of this policy.

Foreign Influence in US Biomedical System

- NIH Letter to US Institutions, August 2018 & Areas of Particular Concern
 - Unauthorized Information Sharing
 - IP Theft
 - Failure to Disclose Foreign Interests in Grant Application and COI Disclosure Process
 - “Other Support” in Grant Application Process
 - “Significant Interest” in COI Disclosure Process

UAMS

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FOR MEDICAL SCIENCES

Scenarios

Scenario 1

- Dr. J, a full-time faculty member in the College of Medicine, Microbiology and Immunology Dept, has invented a novel method for inhibiting *H. Pylori* bacteria growth & UAMS has filed a patent on this method
- They are a 50% shareholder of *Dr. J Inventions, LLC*, a company they founded in order to commercialize this invention
- They have received no compensation from their company.
- In addition, Dr. J serves as a consultant for *BigPharma, Inc.*, a pharmaceutical company, which paid them \$8,000 this year.
- BigPharma would also like Dr. J to speak at an upcoming conference and, in order to facilitate the presentation, has provided Dr. J with all the slides & handouts to present at the conference.
- BigPharma will pay for all Dr. J's travel expenses.
- Dr. J wants to know what, if anything, they need to do regarding these activities and if there are COI concerns.

Discussion

- Discloseable “Significant Interests”
 - IP: Patent (not significant interest) vs License
 - Company shares
 - Consulting Fee
 - Travel
- Industry Interaction
 - Materials prepared by corporation
 - Is there a written consulting agreement?
- Outside Employment
 - Dr. J Inventions vs BigPharma
 - Conflict of commitment
- Conflict of Interest Committee Review
 - Do any of these outside interests constitute a conflict of interest?

Scenario 2

- Dr. Z, a full-time faculty member in the College of Medicine, Ophthalmology Dept, has invented a type of intraocular lens implant (entitled the Z-Implant) for treating myopia and UAMS has filed a patent on this invention
- This patent was recently licensed and Dr. Z is receiving royalty payments
- Dr. Z is a service line director and has procurement authority to decide which implants are purchased. Dr. Z plans on using the Z-implant in patients, if medically appropriate
- As an expert in intraocular implants, Dr. Z obtained an NIH grant as PI on a study regarding best practices for implanting their intraocular lens implant in cataracts patients
- In addition to the research, *Ocular, Inc.*, a leading manufacturer of implants has presented Dr. Z a written consulting agreement for one year, for consulting services in the amount of \$500 per hour. The contract contemplates no less than 20 hrs per week of consulting services
- Finally, a grateful patient has given Dr. Z a ceramic bowl he made by hand, as well as a gift certificate for \$100 to a local restaurant
- Dr. Z wants to know what, if anything, they need to do regarding these activities and if there are COI concerns

Discussion

- Discloseable “Significant Interests”
 - IP: Patent vs License (discloseable interest)
 - Consulting Fee
- Industry Interaction
 - Written consulting agreement
- Outside Employment
 - Ocular Inc. & Conflict of commitment
- Conflict of Interest Committee Review
 - Procurement of Z-implant & royalties
 - Use of Z-Implant in patients
 - Research re: ocular implant for myopia vs study on implants for cataracts
 - Could study results impact value of IP?
 - COI? Remedies?
- Gift
 - Bowl vs. gift certificate

Closing Remarks

- Transparency is the key
- Conflict of Interest is situation dependent and not a judgment of character. It does not imply wrong-doing.

Questions

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