



College of Medicine

## **Policy and Guidelines for Interactions between The University of Arizona College of Medicine and Commercial Interests (“Industry”)**

### **Purpose of Policy**

The purpose of this policy is to establish guidelines for interactions with Industry representatives for medical staff, faculty, staff, students, and trainees of The University of Arizona College of Medicine. Interactions with Industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices, and research equipment and supplies; training for newly purchased devices; the development of new devices; educational support of medical students and trainees; and continuing medical education. Faculty and trainees also participate in interactions with Industry off campus and in scholarly publications. Many aspects of these interactions are positive and important for promoting the educational, clinical and research missions of the College of Medicine. However, these interactions must be ethical and cannot create conflicts of interest that could endanger patient safety, data integrity, the integrity of our education and training programs, or the reputation of either the College of Medicine or its personnel.

Individuals must consciously and actively divorce clinical care decisions from any perceived or actual benefits expected from any commercial interest. It is unacceptable for patient care decisions to be influenced by the possibility of personal financial gain.

Management of conflict of interest in health sciences offers additional and unique challenges in comparison to other areas of research. This policy for the College of Medicine is intended to complement and not supersede or conflict with overall research integrity policies at the University of Arizona, including, but not limited to, The University of Arizona’s Individual Conflict of Interest in Research Policy and Conflict of Commitment Policy. In research involving human subjects, potential financial conflicts may affect, or appear to affect, judgment regarding clinical care decisions, selection of human subjects, use of protected health information, adverse event reporting, data collection, and ultimate dissemination of findings. However, many new ideas and development of those ideas stem from interactions between academic and Industry contemporaries. Consulting and commercialization of intellectual property derived from academic pursuits are major drivers of practice-changing procedures, drugs, and devices. Thus, these conflicts of interest are unavoidable but can be minimized with appropriate oversight and management.

### **Definitions**

*Conflict of interest (COI)*: That situation which exists when a faculty, staff, student or trainee of The University of Arizona College of Medicine may have a significant financial or other personal consideration that may compromise, or have the appearance of compromising, their professional judgment or integrity in clinical responsibilities, teaching, conducting or reporting research, or performing other College obligations.

Commercial interests (Industry): Any proprietary entity producing health care goods or services, with the exception of non-profit or government organizations and non-health care related companies.

## **Statement of Policy**

It is the policy of The University of Arizona College of Medicine that interactions with Industry should be conducted so as to avoid or minimize conflicts of interest. When conflicts of interest do arise they must be addressed appropriately, as described herein.

## **Scope of Policy**

This policy incorporates the following types of interactions with Industry:

- I. Gifts from Industry
- II. Meals from Industry
- III. Industry-sponsored promotional speaking relationships
- IV. Industry support of ACCME-accredited CME
- V. Attendance at Industry-sponsored promotional events
- VI. Industry-funded scholarships and awards
- VII. Ghostwriting and honorary authorship
- VIII. Consulting and advising relationships
- IX. Access of pharmaceutical sales representatives
- X. Access of medical device representatives
- XI. Conflict of interest disclosure
- XII. Conflict of interest in the medical school curriculum
- XIII. COI policies and adjunct/courtesy faculty and affiliated hospitals/clinics
- XIV. Enforcement and Sanctions

### **I. Gifts from Industry**

- a. Personal gifts from Industry may not be accepted anywhere at The University of Arizona College of Medicine or at any clinical facility operated by the College. In addition, University of Arizona College of Medicine faculty, staff and trainees may not accept gifts at any non-College-operated clinical facility such as other hospitals or outreach clinics. Non-faculty medical staff are strongly discouraged from accepting gifts at non-College-operated clinical facilities but are not proscribed by this policy from doing so.
  - i. No form of personal gift from Industry may be accepted under any circumstances. Individuals should be aware of other policies, such as the AMA Statement on Gifts to Physicians from Industry (<http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/about-ethics-group/ethics-resource-center/educational->

[resources/guidelines-gifts-physicians.page?](#)) and the Accreditation Council for Continuing Medical Education Standards for Commercial Support ([www.accme.org](http://www.accme.org)), which apply by reference to faculty, staff and trainees under this Policy.

- ii. Individuals may not accept gifts or compensation for listening to a sales talk by an Industry representative.
- iii. Individuals may not accept gifts or compensation for prescribing or changing a patient's prescription.
- iv. Individuals may accept product samples from commercial interests only for patient use, provided no financial gain, or appearance of financial gain, exists.

b. 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). Travel reimbursement, for travel conducted according to UA Travel policies, is acceptable for individuals attending specific training activities for use of a new medical device when the travel is necessary for appropriate training on that device. Under The University of Arizona's Conflict of Interest in Research Policy, if an individual's research is sponsored by a Public Health Service Agency, the individual must report the value of all sponsored or reimbursed travel costs received by that individual from a third-party organization (regardless of whether it is a for-profit or non-profit entity) through the University's Online Conflict of Interest Disclosure and Training Form (<https://uavpr.arizona.edu/COI/>).

## **II. Meals**

Meals or other types of food or drink directly funded by Industry may not be provided at University of Arizona College of Medicine activities or at associated clinics. Exceptions for general 'educational support' are allowed under circumstance where: 1) the company is not acknowledged for providing support; 2) company representatives are not in attendance; 3) no promotional materials for company products are distributed or made available at the event; and 4) the event or meeting is a regularly scheduled scholarly activity and not an ad hoc event scheduled due to availability of a company-sponsored meal or promotion of company products or ideas.

## **III. Industry-sponsored promotional speaking relationships**

- a. Faculty, staff, students and trainees are strongly discouraged from participating in "Speakers' Bureaus", as an appearance of undue influence on content by Industry damages the integrity and validity of the work of UA faculty members. Financial compensation to faculty from Biomedical Companies for talks potentially considered promotional must be approved by the Department and reported to the College of Medicine.
- b. In addition, a faculty member's department head and dean must approve of the faculty member's time and effort devoted to participating in a "Speaker's Bureau" under the University's Conflict of Commitment Policy. The faculty member should complete and submit a Request for Approval of External Professional Commitment or Outside

Employment form (provided on the Conflict of Interest Program's website) to his or her department head and dean for approval before committing to participation.

- c. Faculty must retain intellectual independence over the content of any educational material they present.
- d. Faculty are prohibited from being compensated for participation in speakers' bureaus or any other "educational" or informational event sponsored by Industry at which Industry exerts influence or control over the content, tone, or views presented. Without an open exchange of information, such events have the appearance of company marketing and are inappropriate venues for faculty presentations. A faculty member who conducts research at The University of Arizona must disclose if he or she has received more than \$5,000 when aggregated from any publicly traded or non-publicly traded entities, including participation in a speaker's bureau, to the Conflict of Interest Program through the University's Online Conflict of Interest Disclosure and Training Form: <https://uavpr.arizona.edu/COI/>.

#### **IV. Industry support of ACCME-accredited CME**

- a. ACCME Standards for Commercial Support bind all such activities at the College of Medicine. They provide guidelines for evaluating all forms of Industry interaction, both on and off campus, and include both University of Arizona College of Medicine events, as well as other events. The Standards are found at [www.accme.org](http://www.accme.org).
- b. All educational events offered by The University of Arizona College of Medicine must be compliant with ACCME Standards for Commercial Support whether or not CME credit is awarded. Industry funding is not accepted for support of CME activities unless:
  - i. The Course would be prohibitively expensive or an essential part of training that would not be possible without the support of Industry.
  - ii. Educational grants, compliant with the ACCME Standards may be received from Industry but must be placed in a general designated account, and administered by the Dean of the College of Medicine or his designated representative. They may not be administered by individual departments, divisions, or individual faculty. The Dean of the College of Medicine, the Director of Continuing Medical Education, or their designated representative(s) must maintain records of fund distribution in compliance with ACCME Standards.
- c. Faculty and medical staff should carefully evaluate their own participation in meetings and conferences that are fully or partially supported by Industry because of the high potential for perceived or real conflict of interest. Furthermore, faculty conducting research at The University of Arizona, particularly those faculty members who have research that is sponsored by a Public Health Service Agency, should review The University of Arizona's Conflict of Commitment Policy, the Individual Conflict of Interest in Research Policy, and the Institutional Conflict of Interest Policy to ensure that all outside interests are properly disclosed to The University of Arizona's Conflict of Interest Program.
- d. This provision does not apply to faculty attending meetings of professional societies that may receive partial Industry support, or other meetings governed by ACCME Standards.

## **V. Attendance at Industry-sponsored promotional events**

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 prior to the activity and at the beginning of the presentation by the meeting supporter.
- b. The meeting or lecture content is determined by the speaker and not the commercial supporter.
- c. The lecturer is expected to provide an impartial and objective assessment of therapeutic options and to promote objective scientific and educational activities and discourse.
- d. The College participant is not required by the commercial supporter to accept advice or services concerning speakers, content, etc., as a condition of the commercial supporter's contribution of funds or services.
- e. The lecturer makes clear that content reflects individual views and not the views of The University of Arizona College of Medicine.
- f. The use of The University of Arizona College of Medicine name in a commercially supported event is limited to the identification of the individual by his or her title and affiliation.
- g. Financial support by Industry must be properly disclosed to The University of Arizona's Conflict of Interest Program in accordance with The University of Arizona's Conflict of Commitment Policy, the Individual Conflict of Interest in Research Policy, and the Institutional Conflict of Interest Policy. The individual must also comply with any and all directives or management plans issued to the individual by the University's Institutional Review Committee or the Executive Review Committee.

## **VI. Industry-funded scholarships and awards**

Industry support of students and trainees should be free of any actual or perceived conflict of interest, must be specifically for the purpose of education, and must comply with all of the following provisions:

- a. The College of Medicine department, program, or division selects the student or trainee.
- b. The funds are provided to the department, program, or division and not directly to the student or trainee.
- c. The department, program or division has determined that the funded conference, program, or other educational activity has educational merit.
- d. The recipient is not subject to any implicit or explicit expectation of providing something of benefit to the Industry sponsor in return for the support, i.e., a "quid pro quo."

## **VII. Ghostwriting and honorary authorship**

Individuals are prohibited from publishing articles under their own names that are written in whole or material part by Industry employees.

## **VIII. Consulting and advising relationships**

Consulting and advising relationships with Industry are allowed under the following circumstances:

- a. Relationships are disclosed to and approved by the department head and Dean of the College of Medicine. In addition, under the University's Conflict of Commitment Policy, a faculty member's department head and dean must approve of the faculty member's time and effort devoted to consulting and advising relationships with Industry. The faculty member should complete and submit a Request for Approval of External Professional Commitment or Outside Employment form (provided on the Conflict of Interest Program's website) to his or her department head and dean for approval prior to participating in the consulting or advising relationship.
- b. Relationships are in compliance with all other sections of the College of Medicine conflict of interest policy.
- c. Relationships are properly disclosed to the University's Conflict of Interest Program in accordance with The University of Arizona's Conflict of Commitment Policy, the Individual Conflict of Interest in Research Policy, and the Institutional Conflict of Interest Policy. Individuals must comply with any and all determinations, directives or management plans issued to the individual by the University's Institutional Review Committee or the Executive Review Committee. Please see Section XV: Information Regarding Related Policies of this policy for more information. Please contact the Conflict of Interest Program by email at [coi@email.arizona.edu](mailto:coi@email.arizona.edu) with any questions.

## **IX. Access of pharmaceutical sales representatives**

Sales and marketing representatives of pharmaceutical companies are permitted in non-patient care areas by appointment only. Appointments may be made on a per visit basis or as a standing appointment for a specified period of time, at the discretion of the faculty member, his or her division or department, or designated hospital personnel issuing the invitation and with the approval of appropriate hospital or clinic management.

## **X. Access of medical device representatives**

Medical device representatives are permitted in non-patient care areas by appointment only, for evaluation by College personnel of new purchases of equipment, devices, or related items. Medical device representatives are permitted in patient care areas under the following circumstances:

- a. By appointment only, for in-service training of College personnel regarding research or clinical equipment or devices already purchased.

- b. When requested by College personnel to assist or advise in the technical use of equipment during surgical cases or research studies.

## **XI. Conflict of interest disclosure**

- a. In scholarly publications, individuals must disclose their related financial interests in accordance with the International Committee of Medical Journal Editors (<http://www.icmje.org>).
- b. Faculty with supervisory responsibilities for students, residents, trainees or staff should ensure that the faculty's conflict or potential conflict of interest does not affect or appear to affect his or her supervision of the student, resident, trainee, or staff member. Faculty with a significant financial interest, as defined by The University of Arizona's Individual Conflict of Interest in Research Policy and the Institutional Conflict of Interest Policy, must disclose these relationships to trainees including students, residents, and fellows, prior to any training or educational activities related to the commercial interest.
- c. Individuals having a direct role making institutional decisions regarding equipment or drug procurement must disclose to the purchasing unit, prior to making any such decision, any financial interest they or their immediate family have in companies that might substantially benefit from the decision. Such financial interests could include equity ownership, compensated positions on advisory boards, a paid consultancy, or other forms of compensated relationship. They must also disclose any research or educational interest that might substantially benefit either the Department or the individual by making the decision. The purchasing unit will decide whether the individual must recuse him/herself from the purchasing decision. This must be done in accordance with UA policies on Purchasing and Contracting Services (PACS, [http://pacs.arizona.edu/manual\\_page01#Conflict](http://pacs.arizona.edu/manual_page01#Conflict)).
  - i. This provision excludes indirect ownership such as stock held through mutual funds.
  - ii. The term "immediate family" includes the individual's spouse or domestic partner or dependent children.
- d. For disclosure requirements related to educational activities, see the ACCME Standards for Commercial Support ([www.accme.org](http://www.accme.org)).
- e. Faculty, staff and trainees who are engaged in teaching, research, administration or business operations in the College of Medicine also must comply with The University of Arizona's Individual Conflict of Interest in Research Policy, the Institutional Conflict of Interest Policy, if applicable, and the Conflict of Commitment Policy (<http://policy.arizona.edu/research/conflict-commitment-policy>). In addition to the annual reports required under those policies, faculty, staff and trainees must annually report all grants, contracts, speakers' bureaus, consulting arrangements, gifts, or financial interests they may have with biomedical companies.

## **XII. Conflict of interest in the medical school curriculum**

All students, residents, trainees, and staff shall receive training regarding potential conflicts of interest in interactions with Industry. Conflict of Interest education will be part of new faculty orientation. Faculty will receive yearly reminders with a link to the Conflict of Interest Policy. Education for College of Medicine graduate trainees will be coordinated through the GME Office; education for medical students will be coordinated through the Office of Medical Student Education.

## **XIII. COI policies and adjunct/courtesy faculty and affiliated hospitals/clinics**

This policy applies to all faculty and staff members of The University of Arizona College of Medicine, including members practicing at affiliated hospitals and clinics. This policy is in addition to, and does not supersede, the conflict of interest policies of Banner-University Medicine or The University of Arizona's Individual Conflict of Interest in Research Policy, the Institutional Conflict of Interest Policy, or the Conflict of Commitment Policy..

## **XIV. Enforcement and sanctions**

- a. Faculty and staff will complete disclosure reports during their annual evaluations. Department Heads are responsible for assuring that all faculty complete a yearly Conflict of Interest form. Failure to complete a disclosure form may result in disciplinary action by the Department and Dean's office. The duty to disclose is ongoing and not limited to an annual disclosure form.
- b. Students, trainees, staff and faculty are encouraged to report any violation of this Conflict of Interest Policy or concerns about educational conflicts to the Dean's office through the College of Medicine's Professionalism Conduct Comment form (<http://medicine.arizona.edu/webform/professionalism-conduct-comment>). Any concern about a possible Conflict of Interest Policy violation will be investigated by the Dean's Office. Corrective action will be taken when necessary to assure compliance with the Policy.

## **XV. Information Regarding Related Policies**

- a. Conflict of Commitment Policy: <http://policy.arizona.edu/research/conflict-commitment-policy>
- b. Individual Conflict of Interest in Research Policy: <http://policy.arizona.edu/research/individual-conflict-interest-research>
- c. Institutional Conflict of Interest Policy: <http://policy.arizona.edu/research/institutional-conflict-interest-policy>
- d. Conflict of Interest Program Contact Information: COI@email.arizona.edu