

JABSOM Policy on Interactions with Industry

Purpose of Policy

The purpose of this policy is to establish guidelines for interactions of University of Hawaii at Manoa, John A. Burns School of Medicine (JABSOM) faculty members, staff, and trainees with Industry representatives. Interactions with Industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices, and hospital and research equipment and supplies, on-site training of newly purchased devices, the development of new devices, educational support of medical students and trainees, and continuing medical education. Faculty and trainees also interact with Industry off-campus in a variety of circumstances including consulting and scholarly activities of various sorts. Many aspects of these interactions are positive and very important for promoting the educational, clinical and research missions of JABSOM. However, these interactions must be ethical and cannot create conflicts of interest (COI) that could endanger patient safety, data integrity, the integrity of our education and training programs, or the reputation of either the faculty member or JABSOM. Individuals must separate any clinical care or research design and analysis decisions from any perceived or actual personal or institutional benefits expected from any company. It is unacceptable for such decisions to be influenced by the possibility of personal or institutional financial gain.

Statement of Policy

It is the policy of JABSOM that clinical decision-making, medical education, and research activities be free from influence created by improper financial relationships with, or gifts provided by, Industry. For the purpose of this policy, the term “Industry” is defined as vendors whose product sales might be influenced by our clinical decision-making, research findings, or teaching practices. Common examples include pharmaceutical manufacturers, biotechnology or medical device companies, or hospital equipment supply entities and their representatives. In addition, clinicians, professors, researchers, and their staff should not be the target of commercial blandishments or inducements – great or small – the costs of which are ultimately borne by our patients, our research, and the public at large. These general principles should guide all potential relationships or interactions between JABSOM faculty members, staff, trainees and Industry representatives. The following limitations and guidelines are directed to certain specific types of interactions. For other circumstances or when the cultural setting may require a unique culturally sensitive approach, JABSOM personnel should consult in advance with their immediate supervisor to obtain further guidance and clarification. Charitable gifts provided by Industry in

connection with fundraising done by or on behalf of the University of Hawaii (UH) or JABSOM may be subject to other policies adopted from time to time by the UH, JABSOM or foundations fundraising on their behalf. When conflicts of interest do arise they must be addressed according to JABSOM / UH policy. (See appendix)

Scope of Policy

For the purpose of this policy, JABSOM faculty is defined as any full or part-time faculty member paid with funds from JABSOM or RCUH (G-funds, Intramural or Extramural funding). It also includes physicians in all JABSOM approved clinical faculty practices (e.g. UCERA). This policy applies to any faculty, staff, or trainee of JABSOM. Where the word department is used in this policy it refers to all SOM departments, centers or institutes.

Gifts and Compensation

Considerable evidence from social sciences suggests that gifts of negligible value can influence the behavior of the recipient. Faculty members, staff, and trainees are discouraged from accepting gifts or meals from Industry. The perception of accepting such gifts as conflict of interest should be carefully considered in each situation. Gifts or meals with value of greater than 10 dollars should not be accepted. Philanthropic gifts may only be accepted through approved foundations, such as the University of Hawaii Foundation.

Specifically, gifts or compensation may not be accepted for:

- Listening to a sales talk by an industry representative
- Prescribing or changing a patient's prescription or
- Attending a CME or other conference when not speaking, presenting, or otherwise actively participating in on the organization of the event.

Site Access by Sales and Marketing Representatives

Sales and marketing representatives are not permitted in clinical settings of JABSOM or UCERA except to provide in-service training on already purchased devices and other equipment and then only by appointment. Sales or marketing representatives are permitted in non-patient care areas by appointment only. Events scheduled by the department for the purpose of comparing multiple vendors

and products prior to purchase are permitted. Industry representatives should wear identification and all materials provided should be educational and not promotional.

Drug Samples

Free drug samples should not be prescribed for self or family by JABSOM faculty, staff, or trainees. Distributing free drug samples to patients is discouraged as use of drug samples has been documented to increase the overall cost of medications. However, if used to support care for indigent patients, Joint Commission standards (see appendix) should be met in accepting, monitoring and dispensing such medications to patients. Local hospital policies should be considered in planning the use of drug samples.

Provision of Scholarships or Travel Funds to Participate in Educational Programs

Industry support for faculty, staff, or trainees who participate in educational programs should be free of an actual or perceived conflict of interest, must be specifically for the purpose of education and must comply with all of the following provisions:

- The JABSOM department, program, division or institute selects the trainee.
- The funds are provided to the School, department, program, division, or institute and not directly to the trainee or to the individual faculty member.
- A JABSOM department has determined that the funded conference or program has educational/scientific merit.
- The recipient is not subject to any implicit or explicit expectation of providing something in return for the support, i.e. a “quid pro quo”.

This provision does not apply to national or regional merit awards. Travel awards to presenting attendees at national or regional conferences are permitted to the individual so long as they come through the conference organizers or JABSOM.

Support for Educational and other Professional Activities

JABSOM educational events that are partially or fully supported by Industry must follow these guidelines and the Accreditation Council on Continuing Medical Education Standards for Commercial Support. (see appendix) This activity includes all support such as food, refreshments, materials, and speakers.

- Support from Industry may be accepted and managed by a JABSOM department but not an individual faculty member or trainee.
- The JABSOM Department must remain in control of the planning, content and execution of the educational activities at all times (consistent with ACCME SCS) (see appendix)
- Industry support for education must be exclusively spent on education.
- Industry support may not influence curriculum in any way.
- Industry promoting or marketing is permitted so long as the displays are away from the main conference entrance described by the ACCME guidelines.
- Industry employees will normally not serve as educators at such activities, although exceptions related to technical expertise with full conflict of interest disclosure may be permitted.
- When a faculty or planning committee member (or immediate family member) has a financial interest with Industry this should be disclosed to the learners.

Industry Sponsored Fellowships

JABSOM does not allow industry sponsorship of fellowship positions for clinical fellowships. Competitive scientific research fellowships may receive industry support so long as the program is completely managed by JABSOM and independent of industry influence on the research itself.

Consulting or Advisory Relationships(excluding scientific research and speaking)

Consulting on behalf of industry is discouraged. Contracts for consultative work should be approved by department chair or appropriate supervisor and should include clear deliverables and fees that represent fair market value for the work provided.

Industry Supported Meetings and Conferences

JABSOM faculty, students, staff and trainees should be cognizant of the potential for a conflict of interest especially when playing a leadership role in organizing or presenting at the event. This activity is permitted providing that the following guidelines are met.

- The activity is designed to promote evidence-based clinical care and/or advance general health/disease knowledge or scientific research.
- Financial support by Industry is fully disclosed to the learners by the meeting sponsor within CME industry standards for currency and magnitude of support.
- The lecturer - not the Industry sponsor - determines and prepares the meeting or lecture content.
- The lecturer is expected to promote a fair and balanced assessment of educational or research activities and discourse. Whenever possible, the JABSOM department leadership should review materials to assure objectivity.
- The JABSOM 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.
- When the lecturer is speaking as part of consulting activities, he or she makes clear that the content reflects views of the individual and not those of JABSOM.
- The use of the JABSOM name in a non-JABSOM event is limited to the identification of the individual by his or her title and affiliation. It should be clear that use of the JABSOM logo or other JABSOM identifiers (such as backgrounds on slides) represents this faculty affiliation only and does not suggest approval of the content.
- Attendees do not receive vendor specific gifts or other compensation for attendance. Food provided to all attendees as part of the conference is acceptable. Attendees should not accept reimbursement for travel or other remuneration by industry.

Participation in the following activities is not permitted.

- Industry-sponsored "speaker bureaus" (these are contractual relationships to give talks in which the topic and content are provided by the company).
- Dedicated marketing and training programs designed solely or predominantly for sales or marketing purposes.

Disclosure to JABSOM of relationships with Industry – Enforcement

(See UH Executive Policy E5.214 and Disclosure Forms)

The University of Hawaii has specific policy and procedure requiring annual disclosure of potential or actual conflicts of interest. These annual statements are collected on a standard form and provided to one's supervisor. The Dean summarizes the individual reports in an annual report to the Chancellor's office. In addition to annual disclosures, updated disclosure forms must be submitted during the year if changes occur that may result in a conflict of interest, alter the details of a previously disclosed conflict, or eliminate a previously disclosed conflict. Conflicts of interest identified through disclosure must be managed in such a way as to protect the public. In situations where faculty participation is essential despite a COI, the impact of the COI should be managed in such a way as to minimize the potential for bias. It is the responsibility of the supervisor reviewing the conflict documents to assure the COI is resolved appropriately. When assistance is needed, the Conflict of Interests Committee (COIC) can be called upon to review and provide advice on the management of cases involving conflict of interest. The COIC is comprised of University of Hawai'i faculty and administrators, appointed by the Vice Chancellor for Research and Graduate Education.

Disclosure of Relationships to Industry in Publications or Presentations

The following provisions about scholarly or educational activities apply to JABSOM faculty, staff, students and trainees.

- Individuals are prohibited from engaging in ghostwriting; i.e. publishing articles under their own names that are written by Industry employees.
- In scholarly publications, individuals must disclose their related financial interests in accordance with the International Committee of Medical Journal Editors. In presentations, all relevant personal financial interests should be disclosed following CME industry standards for currency and magnitude of support.
- Publications or presentations resulting from independent consulting activity by faculty members should state clearly that this activity was done independent of their JABSOM academic role.
- Faculty members responsible for student curriculum should ensure that a stated faculty member's conflict or potential conflict of interest does not affect their teaching or the content of the curriculum.

Involvement in Purchasing Decisions at JABSOM or Health Systems

Individuals who have a direct role in making institutional decisions on equipment or drug procurement must disclose to the purchasing unit or selection committee any potential conflict of interest following institutional standards for magnitude and currency of conflict(s), prior to making any such decision. Specifically, any financial interest they or their immediate family members have in companies that might substantially benefit from the decision must be declared and managed. Individuals involved in Health System purchasing should also abide by hospital specific policies regarding conflict of interest.

Training regarding potential COI

All JABSOM faculty members, staff and trainees will receive this policy document as well as training regarding potential conflict of interest with industry.

Continuing Medical Education (CME)

JABSOM CME programs will be conducted in compliance with guidelines outlined by the Accreditation Council on Continuing Medical Education.

Appendix of Related Policy Sites

JABSOM Faculty Development Site

This site provides the most recent University of Hawaii Conflict of Interest Executive Policy, COI Disclosure form, COI procedures, and a sample Memo/Report from the Chair.

<http://jabsom.hawaii.edu/facudev/Forms/ConflictOfInterest.asp?tab=Forms>

UH Executive Policy E5.214 – Conflicts of Interest.

<http://www.hawaii.edu/svpa/ep/e5/e5214.pdf>

American Medical Association (AMA) Code of Ethics on Gifts to Physicians from Industry

<http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.shtml>

Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support

http://www.accme.org/dir_doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf

The Joint Commission (TJC)

<http://www.jointcommission.org/Standards/>

NIH Conflict of Interest web page

<http://grants.nih.gov/grants/policy/coi/resources/htm>

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