



University of the Virgin Islands School of Medicine

Policy Name and Section: <i>UVISOM Conflict of Interest Policy</i>	Effective Date:	UVISOM Policy Number: <i>001</i>
Responsible Authority: <i>Chair, Department of Medical Sciences</i>	UVISOM Documents where Policy is available: <i>UVISOM Faculty Handbook, Appendix F, Appendix G</i>	Approval Body and Date: <i>Executive Council, Self-Study Committee, Curriculum Committee March 2016</i>

UVI School of Medicine (UVISOM) Faculty is provided with guidelines to report potential conflicts of commitment and conflicts of interest in three areas.

1. **Conflict of interest in research:** Conflict of interest in research, disclosure, and review procedures are detailed in the UVI Conflict of Interest Policy (available at http://www.uvi.edu/files/documents/Administration_and_Finance/Human_Resources/COI_Policy.pdf).
 - a. For Policy specifically related to Biomedical research, UVISOM has developed the following:

Policy on Financial Conflict of Interest (FCOI) in Biomedical Research

The National Institutes of Health and other U.S. Public Health Service (PHS) agencies represent the largest source of funding of research activities conducted at medical schools across the nation. To address the increasing complexities of the financial interests held by biomedical and behavioral researchers and the resulting interactions among government, research institutions, and the private sector, the PHS has promulgated comprehensive financial conflict of interest regulations that promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by the PHS under grants, cooperative agreements or contracts will be free from bias resulting from the financial conflicts of interest of an Investigator. The UVISOM acknowledges the importance of adhering to these PHS standards in the conduct of all of its extramural funded activities. This policy is for the purpose of applying these important regulations (hereinafter, the FCOI Policy) to all of its sponsored research activities. All Investigators applying for any extramurally funded activities shall comply with the requirements of this FCOI Policy. This FCOI Policy shall be made available by the Provost & Vice President of Academic Affairs on a publicly available website. The PHS agencies include: National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), The Health Resources and Services Administration (HRSA), the Substance Abuse

and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ). The PHS regulations are entitled:

- a. Responsibility of Applicants for Promoting Objectivity in Research issued at 42 CFR Part 50. Subpart F (the “FCOI Regulations”).
See: <http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol11/xml/CFR-2011-title42-vol11-part50-subpartF.xml>
- b. The NIH Office of Extramural Research Conflict of Interest Web site contains helpful information and resources about the FCOI Regulations.
See: http://grants.nih.gov/grants/policy/coi/coi_faqs.htm

Disclosure to the UVISOM is required of all “Significant Financial Interests” that reasonably appear related to the Investigator(s) Institutional Responsibilities. “Significant Financial Interests” include all travel reimbursements of any amount, any equity interest in a privately-held entity, and all other financial interests having a value in excess of \$5,000.

2. Conflict of private interests of faculty with academic/teaching/responsibilities, with regard to outside employment

It is required that full-time faculty members will devote their time and service to the University on a full-time basis. However, a faculty member may engage in other commercial and public service activities in addition to his/her work at the University. Such activities should be tied to the University’s mission and do not simply have the character of a second position or another job. Where professional commitments of this sort are being considered, a faculty member should consult with the Unit Manager to ensure that their responsibilities will not be diminished by this outside activity. Faculty members are required to sign a conflict of interest form annually.

Outside activity or employment which interferes with faculty obligations to the university, or which represents a conflict of interest, are prohibited. In order to comply with the rules and standards governing the code of ethics, the University requires disclosure of potential conflicts of interest and disclosure of outside activity or employment before the activity is undertaken. Outside activity or employment must be reported and approved annually. If activities change during the year, the change must be reported and approved. If university facilities, equipment, personnel or services are used in this outside activity, permission must be granted approving this use before such use is undertaken. During the review process, some activities will be permitted, others will be denied, and others may result in a monitoring and management plan to ensure that conflicts do not occur.

The general requirements of these provisions are summarized in the UVI Conflict of Interest Policy available online at

http://www.uvi.edu/files/documents/Administration_and_Finance/Human_Resources/COI_Policy.pdf

3. Industry Relations Policy and Guidelines

1. Introduction and Scope of Policy

UVISOM strives to be a leader in assuring the highest levels of ethics and professionalism in all dealings with the health care industry, which includes, but is not limited to, the pharmaceutical, biotechnology, medical device, and medical equipment supply industry (“Industry”), and in establishing a culture of ethical behavior and accountability for its administrators, faculty, staff, students (“UVISOM Personnel”). The UVISOM greatly values its industry partners and works openly in collaboration with these partners and vendors to promote positive, productive and ethical relationships. As leaders in science and medicine, UVISOM experts participate in appropriate industry advisory roles, industry-funded scientific studies, and development of new health care discoveries and resources. As a leader in health care transformation, the UVISOM develops collaborative partnerships and business arrangements with industry partners. As a non-profit educational institution, the UVISOM seeks and accepts philanthropic support from Industry. This policy will guide all UVISOM Personnel in structuring and participating in industry relationships to assure integrity of professional judgment, the highest ethical behaviors, and the objectivity of medical education.

This policy applies to all individual and institutional financial relationships, business arrangements, and interactions with Industry vendors and developers of products and services that are marketed and sold to medical schools, academic health science centers, researchers, educators, and clinicians. This policy applies to all UVISOM Personnel and covers relationships and activities that occur during both work and non-work hours.

Indirect minority investment interests, such as investments in a mutual fund that owns shares in a pharmaceutical company, are not considered conflicting interests for purposes of this policy.

2. Statement of Policy

It is the intent of the UVISOM to work collaboratively with Industry partners that share a heightened commitment to maintaining the highest ethical standards. All UVISOM relationships and interactions with Industry will be structured, managed, and monitored to assure adherence to such ethical standards. Individual and institutional decisions, actions, and relationships must be free from even the appearance of bias relating to vendor/Industry relationships. Clinical judgments, business agreements, education, and research activities must not be impacted by undue influence resulting from financial relationships with, or gifts provided by, Industry. All collaborations and financial relationships with Industry must be based on the goals of advancing science, education, and clinical care consistent with the UVISOM mission and values.

For questions or further guidance, UVISOM Personnel should consult with a member of the UVISOM UVISOM Industry Relations Committee or with the Dean. It is the responsibility of each individual to seek necessary guidance and approvals in advance of participating in an Industry relationship. Philanthropic gifts provided by Industry are subject to this Policy and may be subject to additional policies of the UVISOM or affiliated entities or foundations fundraising on its behalf. In addition to review for ethical issues, all financial and business relationships with Industry must be carefully reviewed for compliance with all applicable legal, regulatory, reimbursement, and accreditation requirements. Associated contracts must be reviewed, approved and signed in accordance with UVISOM and University procedures.

3. GIFTS AND INDIVIDUAL FINANCIAL RELATIONSHIPS WITH INDUSTRY

3.1 GIFTS AND MEALS

UVISOM Personnel shall not accept or use personal gifts (including food) from representatives of Industry, regardless of the nature or dollar value of the gift.

Gifts from Industry that incorporate a product or company logo on the gift (e.g., pens, notepads, or office items such as clocks) introduce a commercial, marketing presence that is not appropriate to a non-profit educational and healthcare system¹. However, food provided in connection with an educational program accredited by the Accreditation Council for Continuing Medical Education (ACCME), or a professional society-sponsored meeting with paid registration, may be accepted.

Meals or other food and hospitality funded directly by Industry may not be offered in any UVISOM facility. UVISOM Personnel may not accept free meals or other food or hospitality funded by Industry, whether on-campus or off-campus, and may not accept complimentary tickets to sporting or other events or other such benefits from Industry, unless otherwise provided in this policy.

3.2 CONSULTING RELATIONSHIPS

Consulting arrangements with Industry must be reviewed in accordance with this policy and approved in advance by the individual's Chair, Director, or Associate Dean, or the Dean or the Dean's Designee.

Consulting arrangements must be set forth in written agreements, or narrative description if agreement is not available, clearly specifying expert services to be paid for at fair market value. Participation on Industry advisory boards is permitted so long as the board regularly meets and provides scientific advice and other guidance that advances academic values and promotes ethical relationships between academic health sciences and Industry. Agreements must be reviewed, approved, and documented through usual UVISOM procedures. UVISOM Compliance will periodically audit consulting agreements for compliance with this provision. A list of Industry consulting agreements of UVISOM employees shall be made available annually to the Executive Council. These procedures apply whether the consulting fees are received by UVISOM, or the individual, or donated to another organization.

For individual consulting relationships with fees that exceed \$10,000 per company per year, annual reports describing activities, payments, and time spent must be submitted to UVISOM Compliance as long as the relationship lasts.

1. Exception: This provision does not prohibit acceptance of items bearing Industry logos provided as part of an off-site educational program (such as a meeting of a professional society), including name tag, lanyards, and totes in which the items are provided and used incidental to attendance, the items are of nominal value, and the items are not used in any UVISOM facilities.

3.3 Industry Funded Speaking Relationships, Meetings, and Publications

The UVISOM must assure that participation in Industry-funded speaking relationships, meetings, and publications serves to advance scientific knowledge and patient care and are not primarily Industry marketing activities. Industry-funded speaking arrangements must be approved in advance by the individual's Chair, Director, or Associate Dean or the Dean or the Dean's Designee. Honoraria for speaking engagements, whether received by the individual or by UVISOM, must be modest and consistent with fair market value of the time spent in preparing and presenting the talk and reasonable travel expenses.

UVISOM Personnel are responsible for the scientific integrity of material presented in any talk or publication and shall decline to participate in educational presentations or scientific publications if the content is controlled by or requires prior approval by Industry, if the content is not based on the best available scientific evidence, or if significant portions are written by someone who is not the purported author or is not properly acknowledged.

UVISOM Personnel may participate in Industry-sponsored meetings wherein investigators are presenting results of their Industry-sponsored studies to peers and there is opportunity for critical exchange. If an individual is speaking at such an Industry-sponsored meeting, acceptance of a modest honorarium and travel expenses is permitted as described above. Otherwise, UVISOM personnel may not accept payment, gifts, or financial support from Industry to attend lectures and meetings other than through an approved consulting or business arrangement.

3.4 Travel Fund

UVISOM shall allow Industry and others that wish to do so to contribute, through the Foundation for the University of the Virgin Islands (FUVI), to a central UVISOM fund to be used at the Dean's discretion to provide travel assistance to UVISOM personnel, including students, for professional development; or (ii) other approved Department account for use at the particular Department Chair's discretion to provide travel assistance to Department personnel, including students, for professional development. Contributions to such fund shall be disclosed and acknowledged.

3.5 Educational Symposia Fund

UVISOM shall allow Industry and others to contribute, through UVI, to a central UVISOM fund to be used in the Dean's discretion to provide UVISOM-sponsored educational programs and symposia; or (ii) other approved Department account for use at the particular Department Chair's discretion for the Department-sponsored educational programs and symposia. Contributions to such fund shall be disclosed and acknowledged.

3.6 Disclosure of Financial Interests

UVISOM Personnel shall report their outside relationships with Industry through the regular University conflicts of interest disclosure process, at least annually and more often as needed to disclose new, or change in, relationships. The general conflicts of interest review process will identify personal financial relationships with health care vendors, including pharmaceutical, medical device, and biotechnology companies, equipment companies, and other health care vendors.

UVISOM Personnel shall disclose all relevant personal financial interests, including financial interests of immediate family members, in speaking engagements and scholarly publications and when presenting to students or colleagues.

Individuals normally having a direct role in making institutional decisions on equipment, drug or medical device procurement must, prior to participating in any such decision, disclose to the purchasing unit or selection committee any financial interest they or their immediate family have in companies that might substantially benefit from the decision and shall recuse themselves from involvement in purchasing decisions relevant to the conflicting interests.

4. Pharmaceutical and Medical Device Samples

The UVISOM prohibits acceptance of samples of pharmaceuticals or medical devices by individual UVISOM practitioners or faculty members except through approved dispensing facilities or for research use. Such samples may not be used personally by UVISOM Personnel or their families.

5. Purchasing and Formularies

UVISOM Personnel are not eligible to participate in Pharmacy and Therapeutics or product evaluation decisions if they, or members of their immediate family, have, or have had within the prior 5 years, a personal financial relationship or funded research with a related pharmaceutical or medical device company that is being considered or discussed. UVISOM Industry Relations Committee members who have conflicting interests may share informed opinions regarding the drug or device, provided that the conflict is fully disclosed in advance and the member recuses himself/herself from participating in the decision.

6. Site Access to Industry Sales Representatives

Visits to UVISOM facilities by representatives of Industry may be appropriate for exchange of scientifically valid information and other data, improving patient care, and providing essential training and instruction in use of medical equipment and devices. UVISOM shall not allow use of its facilities or other resources for Industry marketing activities.

Sales or marketing representatives of Industry may access UVISOM facilities only if their company has registered with the UVISOM and they have been specifically invited to meet with a UVISOM representative for a particular purpose. Individual physicians or other UVISOM Personnel may request a presentation by or other information from a particular company. When entering the UVISOM facilities, all Industry representatives must sign in and, while in the facilities, must be identified by name and current company affiliation. Meetings with sales or marketing Industry representatives shall not be held in direct patient-care areas and education areas. Involvement of students or trainees in

meetings with Industry Representatives should occur only for educational or training purposes and only under the supervision of a faculty member.

Access by medical device or equipment representatives to patient-care areas is permitted only when (1) a UVISOM representative requests essential instruction in use of the equipment or device, (2) the representative is appropriately credentialed by the Dean's Office, and (3) all necessary patient consents have been obtained and documented.

All Industry personnel seeking sales or vendor relationships must work directly with their designated UVISOM representative and shall not solicit other UVISOM Personnel.

7. Education

7.1 Support of Continuing Medical Education and On-site Educational Activities

All continuing medical education (CME) events hosted or sponsored by the UVISOM must comply with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of Educational Programs (or other similarly rigorous, applicable standards required by other health professions), whether or not CME credit is awarded for attendance at the event. The UVISOM will maintain a central CME office through which all requests for Industry support and receipt of funds for CME activity are coordinated and overseen and programs are periodically audited for compliance with ACCME requirements and standards.

If Industry is interested in sponsoring a CME program hosted by UVISOM, the strongly preferred structure is through a contribution to the UVISOM Educational Symposia Fund, enabling a UVISOM-sponsored program. Presentations structured and presented by UVISOM through this Fund may include modest food and beverage.

All CME programs hosted by UVISOM must be academically oriented. Industry may not restrict program content or specify who is selected as presenters. Industry funding sources should be directly acknowledged in all announcements and literature about the related CME offering.

Industry funding may not be accepted for social events that do not have an educational component. Industry funding may not be accepted to sponsor UVISOM meetings or retreats (either on or off-campus).

Such meetings and events may be supported through a general Dean's discretionary fund, and Industry is encouraged to contribute to the Dean's Discretionary Fund.

UVISOM facilities (clinical and non-clinical) may not be rented by or used for Industry funded and/or directed programs, except for programs structured in accordance with this policy.

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

The UVISOM solicits and welcomes Industry contributions for scholarships, fellowships, and other support for trainees, so long as the funds are given centrally to the administration of UVISOM, either directly or through an affiliated entity or foundation; there is no expectation of benefit to the donor; the evaluation and selection of recipients is in the sole discretion of the UVISOM; and the allocation and distribution of funds is managed by the UVISOM.

7.3 TRAINING OF UVISOM PERSONNEL

ALL UVISOM PERSONNEL SHALL RECEIVE TRAINING REGARDING POTENTIAL CONFLICTS OF INTEREST IN INTERACTIONS WITH INDUSTRY AND THE REQUIREMENTS OF THIS POLICY.

The UVISOM medical school curriculum includes instruction for students in understanding and addressing individual and institutional conflicts of interest in relationships with Industry.

7.4 Education of UVISOM Industry Partners and Vendors

UVISOM Industry Partners and vendors shall be provided copies of this policy and instructions regarding appropriate UVISOM contracts and registrations procedures.

7.5 Industry Educational Materials

Educational materials for UVISOM faculty, residents, staff, students, or for patients, supplied by Industry representatives or vendors, is permitted provided such materials are pre-approved by the Module Director or Clerkship Director, and are not “branded” by the supplier of the materials. Such materials may not be distributed directly to UVISOM faculty, residents, staff and students or to patients by Industry representatives or vendors. Any questions regarding the appropriateness of such materials may be directed to the individual’s Director.

8. Philanthropy

The UVISOM welcomes and solicits charitable donations from Industry that support the UVISOM missions. The Foundation for the University of the Virgin Islands (FUVI) and other tax exempt entities will assist UVISOM in soliciting, receiving, and managing funds. Such donations must be free of any implication or expectation of a benefit to the donor, not tied to any purchase or business arrangement, and openly acknowledged. Each donation from Industry will be reviewed in accordance with this policy and any additional standards that may be developed by the UVISOM Industry Relations Committee and approved by the Dean, and the UVISOM Industry Relations Committee may recommend to the Dean steps needed in structuring and acknowledging such gifts to avoid or minimize conflicts of interest or the appearance of conflicts. Information regarding donations and gifts from Industry shall be provided to UVISOM Compliance. In addition, information regarding all donations and gifts over \$10,000 shall be submitted to the UVI Office of Institutional Advancement, which will review it with the Dean’s Office.

9. UVISOM Partnerships and Business Arrangements with Industry

The UVISOM may enter into a variety of business arrangements and partnerships with Industry when such arrangements advance the UVISOM missions. These are relationships that extend beyond purchasing the standard Industry product or service and may include, for example, shared research, development, and/or ownership of a health care product or service. As in purchasing, any individuals with a conflicting personal financial relationship or interest must disclose such interests and recuse themselves from the decision on adopting by the UVISOM of a proposed Industry partnership or business arrangement. Each proposed partnership or business arrangement will be reviewed in accordance with this policy and any additional standards that may be developed by the UVISOM

Industry Relations Committee and approved by the Dean. The UVISOM Industry Relations Committee may recommend to the Dean any steps needed in structuring the partnership or business arrangement to avoid or minimize conflicts of interest or the appearance of conflicts.

UVISOM Industry partners and vendors shall be provided copies of this policy and an acknowledgement of receipt and review must be obtained prior to commencement of a partnership or vendor relationship.

10. Research with Human Subjects

UVISOM Personnel may not conduct research with human participants if such personnel have a Significant Financial Interest in an existing or potential product or a company that could be affected by the outcome of the research. Any exceptions to this policy must be reviewed by the UVISOM Industry Relations Committee and the responsible Institutional Review Board (IRB) and be approved by the Dean. Exceptions to this policy may be permitted only if (a) the individual's participation is essential for the conduct of the research and

(b) an effective mechanism is established for managing the conflict and protecting the integrity of the research.

11. Enforcement

Suspected violations of this policy shall be referred to the individual's Supervisor, Chair, Director or Associate Dean, who shall review the matter and, if warranted, refer the matter to the UVISOM Compliance for investigation. UVISOM Compliance may consult the UVISOM Industry Relations Committee before advising the Dean or other senior management on proposed enforcement actions, as appropriate. Violations of this policy by UVISOM Personnel may result in the following actions (or in any combination), depending upon the seriousness of the violation, whether the violation is a first or repeat offense, whether the violator knowingly violated the policy or attempted to hide the violation and other appropriate considerations: (a) counseling of the individual involved; (b) written reprimand, entered into the violator's employment or faculty record; (c) banning the violator from any further outside engagements for a period of time; (d) requiring that the violator return any monies received from the improper outside relationship; (e) requiring the violator to complete additional training on conflicts of interest; (f) removing the violator from supervision of trainees or students; (g) fines; and/or (h) termination for cause.

12. UVISOM Industry Relations Committee

The Dean shall appoint an advisory UVISOM Industry Relations Committee to assist in implementation of this policy and management of UVISOM Industry relations. The UVISOM Industry Relations Committee shall include faculty members representative of UVISOM. *Ex officio* voting UVISOM Industry Relations Committee members shall consist of the UVISOM Chief Legal Officer, the UVISOM Associate Dean for Clinical Affairs, the UVISOM Executive Dean for Finance & Administration, and the UVISOM Assistant Research Director. UVISOM Industry Relations Committee members, other than the *ex officio* members, and a chair or co-chairs shall be appointed by the Dean for three-year terms. An *ex officio* member may be appointed as a chair or co-chair for three-year terms. The UVISOM Industry Relations Committee shall meet at least two times per year, or more often as needed, to review, monitor, and advise the Dean regarding implementation and enforcement of this policy and the financial and business arrangements that require review. The UVISOM Industry Relations Committee shall keep minutes and records of its reviews and recommendations. The UVISOM Industry Relations Committee shall review the policy regularly and propose updates as appropriate.

13. Continuing Evolution of UVISOM Industry Relations Policy

The UVISOM recognizes that oversight, guidance and debate around Industry relationships and conflicts of interest must continue to evolve at local and national levels. This policy will continue to evolve as issues are considered further by the UVISOM and the UVISOM Industry Relations Committee.