

School of Medicine Policy On Industry Relationships

Responsible Office:
Office of Faculty Affairs

POLICY STATEMENT AND PURPOSE

Academic Medical Centers have opportunities to engage in professional activities with industry that contribute to the missions of research, education, and clinical care, reflect the faculty's talent, expertise, knowledge and skills as well as enhance their national and international recognition. Such interaction may create perceived conflicts of interest. Transparency is key to oversight of conflicts of interests and requires ongoing internal reporting and external disclosure. This document outlines the School of Medicine's policy concerning relationships and interactions with Industry in a manner that avoids real or perceived conflicts.

WHO SHOULD READ THIS POLICY

All faculty, credentialed healthcare providers, staff and students in all programs and units in the Virginia Commonwealth University School of Medicine (VCU SOM) should read and comply with this policy.

RELATED DOCUMENTS

VCUHS Policies:

7202.03 Vendor, Visitation, and Gifts.
Pharmacy & Therapeutics Committee yearly COI disclosure
TJC policies (LD.02.02.01, LD.04.02.01,
Use and Control of Medication Samples (#4512.01)
Non-Pharmaceutical Vendor Policy (#7202.02)

State and University Policies:

State and Local Government Conflict of Interests Act Va. Code 2.1-639.6.C.7
SOM Outside Professional Activity Policy
45 CFR Part 94.1: Responsible Prospective Contractors
Conflict of Interest Policy
Policy on Corporate-Sponsored Research Agreements

CONTACTS

The Office for Faculty Affairs officially interprets this policy and will prepare revisions as needed to meet the changing needs of the School of Medicine. All revisions shall be subject to approval by School of Medicine leadership.

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DEFINITIONS

“Industry” refers to any person or company seeking to do or doing business with Virginia Commonwealth University Health System (VCUHS) including any pharmaceutical, medical device, medical publishing or medical equipment companies.

“Conflict of interest” (COI) exists whenever an individual or an institution has a primary allegiance that requires certain actions and, simultaneously, has a secondary interest that (a) could abrogate that primary allegiance and (b) is sufficiently tempting to raise a reasonable possibility that it might actually do so.

“Gift” means any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, or other item having monetary value. It includes services as well as gifts of transportation, local travel, lodgings and meals, whether provided in-kind, by purchase of a ticket, payment in advance or reimbursement after the expense has been incurred.

POLICY

1.0 GIFTS

Gifts from industry and/or representatives are prohibited. This encompasses *gifts* from equipment and service providers as well as pharmaceutical and device manufacturers.

2.0 Pharmaceutical Samples

Samples must be deposited with the Nurse Manager or other appropriate professional in each clinic/unit. Each clinic/unit must implement a reconciliation process and policy for handling pharmaceutical samples. The clinic administration and the department in concert with VCUHS/VCU Compliance must develop this process.

3.0 Site Access by Pharmaceutical Representatives

- 3.1 To protect *patients*, patient care areas, and work schedules, access by pharmaceutical representatives to individual physicians is restricted to non-patient care areas and nonpublic areas and should take place only by appointment or invitation of the physician.
- 3.2 Involvement of *students and trainees* in such individual meetings should occur only for educational purposes and only under the supervision of a faculty member.
- 3.3 *Pharmaceutical representatives* may be invited to a patient care area when the faculty provider requests training or demonstration of a product.
- 3.4 Each *department* is responsible for enforcement of central registration of industry representatives.

4.0 Site Access by Device Manufacturer Representatives

- 4.1 Access by *device manufacturer representatives* to patient care areas is permitted only when the representatives are appropriately credentialed by VCUHS and should take place only by appointment or invitation of the physician.

- 4.2 *Representatives* should not be allowed to be present during any patient care interaction unless there has been prior disclosure to and consent by the patient, and then only to provide in-service training or assistance on devices and equipment.
- 4.3 *Student interaction with representatives* should occur only for educational purposes under faculty supervision.

5.0 Continuing Medical Education

- 5.1 *All requests* for CME industry support and receipt of funds should be coordinated and overseen by the Continuing Professional Development and Education Studies (CPDE) office for VCU SOM.
- 5.2 The *CPDE* will institute audit mechanisms to ensure compliance with Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of CME. CPDE requires financial disclosure/COI management for those involved in planning and/or presenting a CME activity.
- 5.3 Faculty must disclose personal and professional relationships with industry in formal lectures to students, residents, and other health care professionals.
- 5.4 Faculty, residents, and students are strongly discouraged from attending industry-supported medical education that is non-CME or that are not offered by hospitals, health systems, specialty societies, and medical schools accredited by ACCME or the Medical Society of Virginia Intrastate CME Accreditation Committee. This does not apply to required training or instruction associated with new devices or equipment.

6.0 Participation in Industry-Sponsored Programs

- 6.1 Faculty participation in industry-sponsored speakers' bureaus is strongly discouraged, with the exception of settings in which investigators are presenting results of their industry-sponsored studies to peers and there is opportunity for critical exchange.
- 6.2 Faculty and staff who participate in industry-sponsored, FDA-regulated programs, should adhere to the following standards:
 - 6.2.1 There should be full transparency and disclosure to the institution when participating in such programs; and

6.2.2 Payments received should be only at fair market value.

6.3 Faculty and trainees are strongly discouraged from attending non-ACCME accredited industry events billed as CME.

6.4 Faculty and trainees are prohibited from engaging in the following activities:

6.4.1 Accepting payment for attendance at industry-sponsored meetings; and

6.4.2 Accepting personal gifts from industry at such events.

7.0 Industry-Sponsored Scholarships and Educational Funds

7.1 All scholarships or other educational funds from industry must be given to a central coordinating office designated by administration.

7.2 No *quid pro quo* is to be involved in any way.

7.3 The evaluation and selection of recipients of such funds must be the sole responsibility of the designated office/official based on institutional guidelines and with no involvement by the donor industry.

8.0 Food

8.1 Industry-supplied food and meals can be provided in connection with ACCME-accredited programming and in compliance with ACCME guidelines. There are no exceptions that permit industry-supplied food and meals within the medical center.

8.2 Faculty and trainee participation in industry-sponsored off-site functions (e.g., satellite symposia, meetings, dinner talks) is strongly discouraged.

9.0 Professional Travel

9.1 Faculty, trainees, and students are directly prohibited from accepting travel funds from industry, other than for legitimate reimbursement or contractual services.

9.2 The centrally designated administrative office must coordinate travel funds/scholarships for faculty, trainees and students.

10.0 Ghostwriting

- 10.1 VCU prohibits faculty, trainees, and students from allowing their professional presentations of any kind, oral or written, to be ghostwritten (i.e., written by someone who is not an author) by any party, industry or otherwise.

11.0 Purchasing

- 11.1 Faculty and personnel with any financial interest in any particular manufacturer of pharmaceuticals, devices, or equipment, or any provider of services, are required to disclose such interests according to institutional policies and to recuse themselves from involvement in purchasing decisions relevant to the conflicting interests.
- 11.2 To the extent that an individual's expertise is necessary in evaluating any product, that individual's financial ties to any manufacturer of that or any related product must be disclosed to those charged with the responsibility for making the decision.

12.0 Physician/Patient Interactions and Conflicts of Interest

- 12.1 Relationships that tie compensation to individual or institutional use of products or devices are prohibited.
- 12.2 All credentialed Providers must file a disclosure statement of personal interest in a contract or transaction pursuant to engagement in such activities.
- 12.3 Relationships between all credentialed healthcare providers and industry must be disclosed to patients at or before the establishment of the physician-patient relationship and made available to the public.

13.0 Faculty Members as Consultants to Industry

- 13.1 Faculty members may qualify as consultants if they are engaged for an exchange of information about important treatments or developments, to review and comment on a product, to discuss independent research projects or their results and to explore the potential for research.

- 13.2 Faculty members whose activity qualifies as consulting must comply with the related policies governing fair market value compensation for services performed and specified in advance, guidelines on potential conflicts of interest, publications and disclosure requirements.
- 13.3 Disclosure and approval of this relationship must occur through the *Outside Professional Activity Request Process*.

14.0 Policy Authority

The Executive Vice President for Medical Affairs and Dean authorizes this policy.

15.0 Cognizant Office

The Dean's Office should be contacted for interpretations, resolution of problems and special situations that relate to this policy.

Date Approved:

Vice President for Health Sciences and CEO VCUHS: February 17, 2009
Executive Vice President for Medical Affairs and Dean: February 17, 2009
VCU Board of Visitors: May 15, 2009
VCUHS Board of Directors: June 16, 2009

Effective Date: July 1, 2009