

Executive Summary

Policy on Conflicts of Interest and Interactions between Commercial Entities and Healthcare Professionals of the RUSH University Medical Center and its Affiliated Entities

This policy has been created to establish more explicit standards for the relationships between Rush University Medical center personnel (including non employed faculty) and commercial entities. This policy is complementary to the Research Conflict of Interest policy has as its focus all other medical center/commercial entity relationships not covered in the research conflict of interest policy. This new **Policy on Conflicts of Interest** was developed by a University Committee, appointed by Provost Thomas Deutsch, chaired by Dr. David Ansell, Chief Medical Officer and including representatives from the university leadership, medical staff, residents, and students. The policy has been widely discussed across the medical center and has been modified based on the input of many. This policy is divided into 10 sections listed below:

Gifts, Meals and Compensation

Samples

Support for Educational and Other Professional Activities

Display of Commercial entity Provided Promotional Items

Site Access by Vendor Representatives

Speakers' Bureaus and Ghostwriting

Consulting

Personnel and Faculty Disclosure

Patient Informed Consent

Consequences of Non-Compliance

Policy on Conflicts of Interest and Interactions between Commercial Entities and Healthcare Professionals of the RUSH University Medical Center and its Affiliated Entities

Final 1-29-09

The purpose of this policy is to establish standards for interactions with commercial entities (which includes, but is not limited to pharmaceutical, device, lab science and imaging companies) for faculty, staff, non-employed faculty, students, and trainees at the healthcare facilities associated with RUSH University Medical Center (hereafter referred to as RUSH personnel) which will minimize the likelihood for conflict situations that might influence patient care. This policy is based on the understanding that physicians and other healthcare providers have special obligations to patients and that these obligations should not be compromised by the presence or the appearance of conflicts with commercial interest or by commercial entity marketing practices. These policy will help RUSH personnel understand the implications of relationships with commercial entities and will help them manage these relationships in a manner which does not jeopardize patient care, professional integrity, or objectivity.

This policy supersedes existing RUSH policies governing conflicts of interest and relationships with commercial entities and complements RUMC policy XXX on Research Conflict of Interests. It is expected that RUSH personnel will be familiar with this policy and with the expectations for vendor compliance.

I. Gifts, Meals and Compensation

- A. RUSH personnel may not accept or use personal gifts from commercial entity representatives, regardless of the nature or value of the gift (including gifts of minimal value including pens, notepads, etc.).
- B. RUSH personnel may not accept gifts or compensation for listening to a sales talk by a commercial entity representative or for prescribing medications or changing a patient's prescription.
- C. RUSH personnel may not accept meals or other hospitality funded directly by a commercial entity on campus, may not be involved in the arrangement of such activities whether on or off campus, and are discouraged from participating in such activities off campus.

- D. RUSH personnel may not accept compensation from a commercial entity, including the defraying of costs, for simply attending an educational event or other activity (i.e. if the individual is not speaking or otherwise actively participating at the event).

II. Samples

- A. Pharmaceutical product samples may not be stored, dispensed, or administered in any patient care area or emergency room of the hospital. In addition, no samples will be available in any hospital owned clinics unless specifically approved by the Chief Medical officer.
- B. This policy applies to both legend drugs (prescription only) and non-legend (non-prescription or over the counter) sample drugs, regardless of source (mail, medical service representatives, physicians).
- C. Any pharmaceutical product samples found in the hospital patient care areas and emergency room will be removed by the Department of Pharmacy for proper disposal.
- D. Pharmacy personnel will monitor medication storage areas for drug samples on a monthly basis.
- E. For hospital-owned clinics, compliance is assessed by monthly inspections conducted by the clinic and faxed to the Department of Pharmacy.
- F. Private offices associated with RUSH are encouraged to abide by this policy as well.
- G. Non solicited laboratory samples from bioscience companies or their representatives are prohibited unless the use of the bioscience material is for consideration for future purchase.

III. Support for Educational and Other Professional Activities

- A. All educational events sponsored by RUSH must be compliant with ACCME Standards for Commercial Support whether or not CME credit is awarded.
 - 1. Educational grants which are compliant with the ACCME may be received from a commercial entity, but must be administered by departments, centers, institutes, or divisions.
 - 2. Divisions and departments must maintain records of compliance with ACCME Standards in a manner consistent with the guidelines of the institution and offices of continuing education.

- B. Provision of funds to RUSH personnel from commercial entity sources (i.e. scholarships, reimbursement of travel expenses, or other non-research funding in support of scholarship or training) must be free of any actual or perceived conflict of interest, whether or not the funds are provided directly to RUSH.
 - 1. A commercial entity may not earmark contributions to fund specific recipients or to support specific expenses.
 - 2. The funds must be provided to the department or the sponsoring professional organization rather than directly to the trainee.
 - 3. The RUSH personnel must be selected according to clear criteria approved by the department.
 - 4. The department must determine that the conference or training has educational merit.
 - 5. The recipient of the funds must not be subject to any implicit or explicit *quid pro quo*.
 - 6. The Departmental Chairperson must approve these arrangements.

- C. RUSH personnel must ensure that support of RUSH clinical trainees by the commercial entities through funding mechanisms such as scholarships, reimbursement of travel expenses, or other non-research funding in support of scholarship or training are free of any actual or perceived conflict of interest. The commercial entity funding of trainees should comply with all of the following:
 - 1. The trainee is selected by RUSH.
 - 2. The funds are provided to the department rather than directly to the trainee.
 - 3. RUSH has determined that the conference or training has educational merit.
 - 4. The recipient of the funds is not subject to any implicit or explicit *quid pro quo* (i.e. “no strings are attached”).

IV. Display of Commercial entity Provided Promotional Items

- A. Promotional items which incorporate or display a product or company logo may not be used or displayed on the RUSH campus without explicit approval of the Chief Medical Officer. This prohibition shall include exhibitions by commercial entity representatives at, or adjacent to, certified CME activities.

- B. While on the RUSH campus and while off-campus during activities when representing RUSH, RUSH personnel are discouraged from displaying upon their persons any visible article of clothing, uniform, badge, pin, sign, or other item which displays the name of a non-RUSH health care service, health care product, or company logo. This restriction may be waived for special charitable or philanthropic events with the consent of the Chief Medical Officer.

V. Site Access by Vendor Representatives

- A. All vendor representatives must have a scheduled appointment to visit RUSH, and are required to register at the *4th floor Atrium security desk or other designated sites* at the time of the appointment. They must also provide a copy of the invitation from the physician requesting the appointment.
- B. Registration by the representative will acknowledge that the representative has read and understands this policy.
- C. All meetings must be conducted in non-patient care areas. Vendor representatives are restricted from all patient care areas, which include, but are not limited to: inpatient units, nursing stations, conference rooms, physician lounges, outpatient clinics, preoperative and operative areas, and the Emergency Department.

VI. Speakers' Bureaus and Ghostwriting

- A. Speaker's bureaus (a speaker's bureau is defined as a commercial entity sponsored event or presentation where the company's product is being promoted as part of that talk or another presentation) sponsored by a commercial entity must be considered an extension of the marketing department of the companies which support the programming. RUSH personnel are prohibited from participating in "speakers bureaus" or other commercial entity sponsored events if the faculty talk or the talks of other participants promote a specific commercial entity's product. Those faculty members who currently participate in "speaker bureaus" or commercial entity sponsored symposia under the conditions listed above must sever those relationships within 24 months of the implementation of this policy.
- B. Ghostwriting by commercial entity representatives must be considered academic dishonesty and is prohibited. RUSH personnel may not be listed as co-authors on papers ghostwritten by commercial entity representatives.

VII. Consulting

- A. Consulting arrangements which pay RUSH personnel a guaranteed amount without any associated duties (e.g. scientific advisory boards that do not meet regularly and provide scientific advice) shall be considered gifts and are consequently prohibited.

- B. These guidelines are not meant to discourage constructive scholarly interchange, commercial entity sponsored research, and development efforts. However, while pursuing such activities, RUSH personnel must follow University guidelines relating to consulting and may accept only fair market compensation for specific, legitimate services provided to a commercial entity with payment commensurate with time and effort.
 - 1. All consulting relationships must be disclosed by faculty and staff using the appropriate annual COI disclosure tool (see VIII below.)
 - 2. The terms of the arrangements, services provided, and compensation must also be approved annually, in writing by the Departmental Chairperson and their Dean.
- C. Upon implementation of this policy, RUSH personnel who have existing relationships with commercial entities which are not compliant with this policy must take action to sever any such relationships or to modify them to become compliant within one year.

VIII. Personnel and Faculty Disclosure

- A. Annually, every employee including and above Director level and all active faculty members will be required to complete a Conflict of Interest Disclosure Form if they receive any direct or in-kind compensation for an activity associated with a consulting, marketing or promotional activity. This will include the identity of the sales agent and company engaged in the marketing or promotional activity, the nature of the marketing or promotional activity and the item or service being promoted or marketed.
- B. The Faculty COI Disclosure form will be made available to Hospital and Medical Staff personnel on appointment of a faculty member to a hospital wide committee, a medical staff committee, or when petitioning the University or hospital committee on product selection. Serving as a paid consultant for a vendor must be disclosed before participating in product selection when that vendor markets such product or competing products.

IX. Patient Informed Consent

- A. If a faculty member is utilizing a device or pharmaceutical for a patient treatment and that faculty has a financial relationship with the company (through device royalties, research, company consultation or speaking arrangements,) the patient must be informed about the relationship during the consent process for the procedure or treatment and this should be documented.

X. Consequences of Non-Compliance

- A. In most instances, the first episode of non-adherence to this policy will be met with an educational response directed at the individual circumstance.
- B. Repetitive and/or flagrant disregard for this policy may be considered misconduct and will subject RUSH personnel to disciplinary action.