



Stony Brook Medicine Graduate Medical Education

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Responsible Department/Division/Committee:

Graduate Medical Education Committee

Policy:

PURPOSE

To establish an institutional policy regarding institutional interactions with pharmaceutical vendors or corporations

POLICY

The GMEC adopted the School of Medicine Guidelines as outlined below:

The goal of these guidelines is to establish policies and normative practices which will minimize conflicts of interest or appearances of conflicts that may otherwise unduly influence clinical decision making, research and education. Although the SOM recognizes that the pharmaceutical/medical device industries play a critical role in advancing therapeutics and medical knowledge, the interactions between clinicians and industry representatives should be governed by a mutual interest in education and research. Because marketing and sales initiatives by industry may potentially compromise the objectivity of evidence-based medicine these guidelines are intended to identify and/or prohibit those interactions that have a significant potential for abuse or for adversely influencing clinical practice. The guidelines are

intended to govern the behavior of all School of Medicine faculty, trainees and staff.

There already exist a number of University, Hospital, and SOM policies that also address some of the issues of conflict of interest, especially in the areas of procurement and research. See Appendix A.

These Guidelines are not intended to replace or supersede such policies but do serve as supplements that are specific to a particular arenas of potential conflict. Furthermore, in addition to extant institutional policies, these Guidelines are intended to operate consonant with:

- *The AAMC Task Force Recommendations on Industry Funding of Medical Education*
- *The ACGME Principles to Guide the Relationship between Graduate Medical Education and Industry*
- *The Accreditation Council for Continuing Medical Education (ACCME): Standards for Commercial Support*

A. SITE ACCESS BY PHARMACEUTICAL AND DEVICE MANUFACTURER REPRESENTATIVES.

1. Industry representatives may interact with professionals in non-patient care areas, including non-patient sections of professionals' offices and non-academic public areas (such as the cafeteria or lobby). They are not permitted in public areas in the Health Sciences Center proximate to lecture halls, classrooms, seminar rooms, or the library. Professionals may not interact with industry representatives in patient care areas, including inpatient units, nursing stations, conference rooms of patient care units, physician lounges, patient care areas of outpatient offices and clinics.

2. A representative may be permitted in patient care areas if all of the following conditions are satisfied:

- a) The representative is present to provide in-service training on devices and other equipment, including provision of essential guidance on the use of such equipment,
- b) The presence of the representative is expressly requested and approved in advance by a faculty member, and

c) The device representative is certified by their employer to provide the requested device training.

3. All representatives must be registered, either at the Security Desk of the Hospital or with the Office of Clinical Trials in the Health Sciences Center. The visitor will be issued a short term vendor badge that must be worn at all times the visitor is in the institution qua industry representative.

4. Sales and marketing representatives are permitted on the premises only by prior appointment with a faculty or professional staff member.

5. See UH Policy MM:0019 Pharmaceutical Representatives

B. GIFTS TO INDIVIDUALS

1. Any member of the faculty, staff or student body may not accept any form of personal gift from industry or its representatives regardless of its actual value. A gift is defined as anything of value that is not reasonable compensation for *bona fide* services. This includes money, entertainment, or any other products, services or subsidies that are not specifically authorized by the provisions detailed herein.

2. Individuals may not accept gifts, gratuities, meals, or compensation for listening to a sales talk by an industry representative, for prescribing or changing a patient's prescription, or for attending a CME or non-CME activity (unless the individual is a speaker or is otherwise actively participating or presenting at the event).

3. In circumstances where the gifts are in part supporting the mission of the University (e.g., food for conferences, payment for educational travel, textbooks, et al.), there are appropriate alternatives that can enable the vendors to continue to support the University's mission. Such gifts will be processed by Medical Center Advancement. For example, to replace the free food or payment for educational travel, vendors may donate funds to a unit of the University (e.g., department or division) to support meetings.

4. Individuals must continually strive to avoid the appearance that clinical care decisions are influenced by outside commercial interests, or by benefits expected or received from any company. All offices and clinical care areas (i.e., rooms in an outpatient clinic, patient waiting areas, or hospital space)

should be free of any materials that bear the name of a particular product or company (e.g., pens, papers, notepads, etc.).

5. See RI0002 Conflict of Interest: 4. Gifts, whether in the form of money, services, loan, travel, entertainment, hospitality, thing or promise, or in any other form, valued at seventy five dollars or more, per gift may not be accepted. Employees should not accept a gift from a disqualified source. Pharmaceutical companies are generally considered disqualified sources.

D. FOOD

1. Industry supplied or sponsored food and meals are considered personal gifts and will not be permitted or accepted within SBUH.

2. As described for Gifts to Individuals (3) above, industries have acceptable ways of supporting educational activities, and in particular through donations targeted to specific Departments, Divisions or programs and administered through the Medical Center Advancement system.

3. Faculty, residents, and students are discouraged from attending industry sponsored dinners or social events off campus unless these events meet the standards for accredited CME activities.

4. At no time should family members or guests of faculty accept gifts, meals, or other hospitality when faculty are attending industry sponsored functions.

5. Social events such as resident graduation, resident retreats, or departmental holiday parties should not be sponsored by industry.

E. OTHER EDUCATIONAL FUNCTIONS

1. Industry support of training should be through donations to a Department, Division or program education fund managed by the Medical Center Advancement office.

2. Industry support of training for faculty, staff or 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 School of Medicine department, program or division selects the student or trainee.

- b. The funds or educational materials are provided to the department, program, or division and not directly to student or trainee.
 - c. The department, program or division has determined that the funded conference, program or material has educational merit.
 - d. 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.'
3. CME or Grand Rounds activities may be supported by industry only if these activities are carried out in a manner consistent with the ACCME "Standards for Commercial Support."
4. Faculty, staff or trainees should not accept compensation for passive attendance at industry sponsored conferences or other "educational" events.
5. The use of departmental personnel, email or mailing lists, or other institutional resources to organize or promote unauthorized "off-campus" industry sponsored events is prohibited.

F. TRAVEL

1. Faculty and trainees may be sponsored to travel to professional meetings with the following provisos:
- a. The meeting is organized and sponsored by a professional group and the forum is not company or product specific. (Exception: see below, 1e.)
 - b. Travel, meals, and accommodations are appropriate to the venue.
 - c. Lavish accommodations and meals convey an appearance of impropriety and are likely to compromise evaluative objectivity.
 - d. There is no "quid pro quo." Faculty and trainees should not be required to attend promotional lectures or participate in product detailing events.
 - e. In the case of trainees support should be routed through institutional or departmental vehicles; trainees should not receive reimbursement directly from industry. Cf Policy C3.

f. It is recognized that because of the cost and specificity of medical devices faculty may depend on industry sponsorship to gain familiarity with and/or training in new procedures or technologies. Such travel and training should be conducted with an awareness of the impact that the marketing of new technology may have on the rising cost of health care.

Every effort should be made to select, acquire and utilize new technology in a manner consistent with the principles of cost-effective and evidence-based medicine.

G. PHARMACEUTICAL SAMPLES

1. It is recognized that there are some patients who are best served when sample medications are provided to enhance clinical outcomes. At the same time faculty and trainees are advised that the use of patented samples may encourage prescribing patterns that are not cost effective. It is imperative that faculty and trainees be familiar with generic and other low cost alternatives when establishing treatment algorithms in the hospital and clinic.

2. See SBUH policy MM0014 Sample Medications: Sample medication may not be used at Stony Brook University Hospital without prior approval by the Pharmacy Director. Outpatient areas shall be permitted to use sample medication after consultation with the Director of Pharmacy or designee and in accordance with procedures specified in the policy.

3. Samples should not be dispensed to faculty, staff, or their family members. Physician procurement of samples for personal use is prohibited.

H. PARTICIPATION IN INDUSTRY SPONSORED PROGRAMS, SPEAKERS BUREAUS AND CONSULTING

1. Clinicians may accept only fair market compensation for specific, legitimate services provided by him or her to industry. Individuals may not accept compensation, including defraying of costs, for simply attending a CME or other activity or conference.

2. Faculty may participate in "speakers' bureaus" on their own time but are strongly encouraged to ensure that all conflicts are fully disclosed and that

the reputation of the SOM is enhanced by presentations that are objective rather than industry biased.

3. Faculty must have the written approval of their Chair in order to participate in any industry sponsored or reimbursed speaking engagements and must adhere to CME guidelines concerning disclosure whether or not it is a CME authorized event. The terms of the arrangements, services provided, and compensation must be set forth in writing and, when appropriate, disclosed to the State according to the requirements of NY State law.

4. 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 by the meeting sponsor.
- b. The meeting or lecture content is determined by the speaker and not the industrial sponsor.
- c. The lecturer is expected to provide a fair and balanced assessment of therapeutic options and to promote objective scientific and educational activities and discourse.
- d. The 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.
- e. The lecturer makes clear that content reflects individual views and not the views of Stony Brook University Hospital.
- f. The use of the Stony Brook name in non-Stony Brook University event is limited to the identification of the individual by his or her title and affiliation.

1. Trainees may not receive industry compensation for any speaking engagement. (Any exceptions must be approved by the department chair and the Vice Dean for GME).

I. GHOST WRITING

Faculty, residents, or students are prohibited from engaging in or using any form of 'ghostwriting' of any presentations, publications, or other forms of media product.

"Ghostwriting" is the provision of materials by a vendor or intermediary that is officially credited to someone other than the actual writer(s) of the material.

J. PURCHASING

Individuals having a direct role making institutional decisions on equipment or drug procurement must disclose to the purchasing unit, prior to participating in 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 they or their department have that might substantially benefit from the decision. The purchasing unit will decide whether the individual must excuse him/herself from the purchasing decision.

I. RESEARCH

1. All clinical research in the SOM is governed by the policies of the SBU Institutional Review Boards (IRB) and CORIHS.

2. Industry sponsored research should always have intrinsic scientific merit. The use of SOM faculty, facilities, or other institutional resources to carry out research whose chief objective is to promote or market a product is prohibited.

Appendix A Related Policies

SUNY

Stony Brook University Policy P206. A Conflict of Interest Declaration (CID) is required for "all SBU investigators seeking internal or external funding to conduct research, training, or evaluated testing." Investigators are required to submit an Investigator Disclosure/Conflict of Interest Certification. The purpose of this disclosure is "to enable faculty to engage in sponsored

academic research while protecting the value of the results of that research from compromise by any financial interest that will or may be reasonably expected to, bias the design, conduct or reporting of the research.”

SBUH

RI0002 Conflict of Interest This policy pertains to conflicts that arise in connection with employment by the State of New York. Specifically note item #4: “Gifts whether in the form of money, services, loan, travel, entertainment, hospitality, thing or promise, or in any other form, valued at \$75 or more, per gift may not be accepted. Employees should not accept a gift from a disqualified source. Pharmaceutical companies are generally considered disqualified sources.”

See *MM0014 Sample Medications* This policy addresses the issue of drug samples and specifically bans drug samples “from the inpatient areas of the facility as well as the Emergency Department and Ambulatory Surgery Center.” It details a procedure for the acceptance, use, storage, and distribution of samples in outpatient and off-site locations.

See *MM0019 Pharmaceutical Representatives* This policy addresses the issues of access, permissible activities, and protocols for pharmaceutical representatives on hospital premises.

Definitions:

None

Procedures:

None

Forms: (Ctrl-Click form name to view)

None

Policy Cross Reference: (Ctrl-Click policy name to view)

[MM0014 Sample Medications](#)

[MM0019 Pharmaceutical Representatives](#)

[LD0101 Conflict of Interest](#)

Relevant Standards/Codes/Rules/Regulations/Statutes:

None

References and Resources:

None