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##### Introduction

Relationships between commercial entities and academic medical centers have become increasingly intertwined and complex. The substantial financial assets of corporations and the broad intellectual resources of academic centers create natural opportunities for joint pursuit of common objectives. Yet occasionally the commitments and fiduciary duties of industry may conflict with the core scientific and education missions of the Medical Center. Furthermore, while offers of "free" goods, gifts, donations or grants for teaching programs may serve a beneficial purpose, they may violate the federal Anti-Kickback Statute and similar New York State laws. These laws prohibit the knowing solicitation or receipt, offer or payment of anything of value in return for patient, product or service referrals and punish any violator with significant fines, jail terms and exclusion from federal and state health care programs. In light of these potentially conflicting missions and regulatory prohibitions, it is critical that all members of the Mount Sinai community remain acutely sensitive to avoiding any actual or perceived conflict of interest.

Mount Sinai does business with corporations associated with a wide range of activities, including but not limited to: the sale of products and services to the institution; referral and receipt of patients for health care services; and sponsorship of scientific research. Vendors include: pharmaceutical, biotechnology, office supply, and medical device/supply companies; research supply and equipment companies; building contractors; consultants; medical service providers; billing and collection companies; and other service companies. For purposes of this policy, the term "vendor" encompasses all commercial entities that do business with Mount Sinai and its faculty, staff, and trainees.

All decisions relating to purchasing or other business processes must promote the best interests of Mount Sinai without favor or preference based on personal considerations. All actions must reflect Mount Sinai's commitment to the highest ethical standards of conduct as described in the Compliance Manual and the Code of Ethics and Business Conduct, and must be consistent with all institutional policies, including but not limited to the Section 16 - Purchasing Policy, the Policy on Business Conflicts of Interest and policies in the Faculty Handbook, e.g., Financial Arrangements with Extramural Entities and Use of Mount Sinai Name Guidelines promulgated by the Federal Office of the Inspector General (OIG) and the PhRMA Code must also be observed. Maintaining rigorous practices will ensure our commitment to the well-being of our patients, the integrity of our research and the soundness of our educational programs. The following guidelines apply to all faculty, staff, and trainees of Mount Sinai School of Medicine, The Mount Sinai Hospital, and The Mount Sinai Medical Center, and are designed to assist in avoiding potential conflicts of interest between Mount Sinai and industry.



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##### Gifts

A gift is defined as anything of value that is given by a business or individual that does or seeks to do business with Mount Sinai to either the recipient or his/her close family members, and for which the recipient neither paid nor provided services.

Gifts from vendors are strictly prohibited regardless of value, including but not limited to:

- Cash in any amount
- Any product or service, or discounts on products or services
- Prizes
- Gift certificates
- Tickets
- Loans
- Meals
- Transportation
- Hotel accommodations
- Use of a company's vehicles or vacation facilities
- Stocks or other securities, or participation in stock offerings
- De minimis gifts, e.g. trade show trinkets distributed to large numbers of people by vendor representatives. Excluded from this prohibition are materials of modest cost which have a clear educational value, such as patient-friendly booklets describing organ systems.
- Group gifts from vendors meant to be shared by all members of the staff, e.g. flowers, chocolates, etc.
- Vendor invitations to be their guests at charitable events sponsored by Mount Sinai, e.g., the Crystal Ball, to which the vendor has purchased tickets.

If unsolicited gifts arrive via the post office or private carrier, the department head or administrator will advise on the best method for returning the gift.



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##### Vendor Support for Medical Center Educational Events

Vendor support for Mount Sinai-sponsored educational events, whether held on campus or off-campus, will only be accepted in accordance with the following provisions:

- A. Deposit to General Fund
- B. Food and Beverages
- C. Continuing Medical Education
- D. Program Content
- E. Acknowledgment of Vendor Support
- F. Vendor Support for Trainees
- G. Education and Training on Vendor's Own Products



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##### Deposit to General Fund

With the exception of CME events (see [Section III-C](#) of this policy), any vendor contribution must be in the form of a general educational grant paid directly to a School or Hospital fund. No direct payments may be made to any Mount Sinai faculty member, trainee, or employee. Mount Sinai shall retain exclusive responsibility for all aspects of educational events. Corporate sponsors may not make commercial exhibits, distribution of promotional materials or the inclusion of company representatives a requirement for support. A letter of agreement outlining expectations and restrictions will be signed by both the department Chair and the vendor.



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##### Food and Beverages

Direct provision by vendors of food and beverages, or subsidies for food and beverages, is prohibited.



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##### Continuing Medical Education

Vendor support for accredited continuing medical education (CME) programs must be submitted in accordance with the policies and procedures of Mount Sinai's Page and William Black Post Graduate School for Continuing Medical Education. Vendor support for CME programs will be managed in accordance with the [Standards for Commercial Support](#) of the Accreditation Council for Continuing Medical Education (ACCME), including:

- Independence from commercial interests in course goals, content and methods
- Resolution of personal conflicts of interest
- Bias-free content and format
- Disclosures relevant to potential commercial bias
- Management of commercial promotion



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#### Program Content

Programs must have true educational value and can never be designed to influence purchasing decisions. The [Standards for Commercial Support](#) of the Accreditation Council for Continuing Medical Education (ACCME) are applicable to all educational events, whether or not they fall under the auspices of the Post-Graduate School; guidelines include:

- Curriculum content, faculty selection and program quality will be the sole responsibility of Mount Sinai department management and/or faculty involved in the event.
- Speaker selection and educational content will be at the discretion of the department.
- Guest speakers must sign a standard [Disclosure Statement](#) indicating compliance with institutional conflict of interest policies.
- All presentations must be free of commercial bias for or against any vendor's products or services. Generic rather than trade names of drugs must be used at conferences.
- Vendor representatives may not address the audience unless specifically invited by the Mount Sinai event organizers.
- Promotional materials from commercial sponsors may not be displayed in the room before, during or after the activity.
- Vendors may apply for exhibit space outside the room(s) in which the educational event is held. The granting of such requests is at the discretion of the conference organizers and fees may be levied. In the event that exhibit space is approved, exhibitors will be subject to gift restrictions as described in [Section I](#) of this policy, as well as to the [PhRMA Code](#).
- Refreshments, study materials, etc. should be appropriate to the event.



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##### Acknowledgment of Vendor Support

Commercial support may be acknowledged in printed materials, but specific products may not be mentioned.



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#### **Vendor Support for Trainees**

Vendor support can never be made directly to or earmarked specifically for an identified individual. Vendor support for trainee education, including salary support, must be in the form of educational grants to Mount Sinai.



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##### Vendor Support for Off-Campus Educational Events

Faculty and staff with special expertise may be invited to give lectures or otherwise participate in conferences and seminars in a variety of venues outside Mount Sinai, including: other academic institutions; professional conferences; international symposia; expert training in device use or new technologies; and presentations to lay audiences. The Department Chair will have overall responsibility for monitoring the frequency and nature of faculty and staff participation in these off-campus activities. In all cases, speakers must be aware of and abide by institutional policies on Use of Mount Sinai Name.

If off-campus events are sponsored by industry, employees and trainees are encouraged to participate only when Continuing Medical Education (CME) credit is offered. For events that fall outside the realm of CME, following are guidelines for participation:

- A. Educational Value of Event
- B. Speaking Engagements
- C. Paid Engagements
- D. Vendor Support to Participate in Events



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##### **Educational Value of Event**

Discretion must be employed in determining whether to attend, based on whether the event has a legitimate educational value. For example, industry sponsors often organize their own conferences and invite faculty or trainees to attend; it is incumbent upon the invitee and his/her Chair to determine whether it is truly a learning event or is designed primarily to influence participants to favor the vendor's products. The setting for and cost of the event should be appropriate to its purpose.



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#### Speaking Engagements

Some pharmaceutical companies, device companies or other commercial entities maintain Speakers Bureaus and/or sponsor events designed to disseminate information relating to their products and services. These companies often seek to hire medical school faculty as lecturers because they are experts in particular disease entities and can add credibility to an event. Because events sponsored by commercial entities may be perceived as venues to influence participants in their relationship with the company, it is essential that faculty and staff participate in such events only when there is a legitimate educational purpose, the individual's role is meaningful and substantive, and the content is within the individual's field of expertise. For full-time faculty, all paid speaking engagements are subject to prior approval as described in the MSSM Policy on Relationships with Outside Entities ([scroll down to section E](#)) and must be disclosed on their on-line Annual Report of Outside Relationships.

Continuing Medical Education (CME) events are subject to strict guidelines issued by the Accreditation Council for Continuing Medical Education, so you can be confident of the educational value of the activity. Sometimes CME events are coordinated by "medical education and communication" companies which must uphold the standards required of all CME courses.

If the proposed event does not offer CME credits, then you will be expected to provide alternative evidence to your Chair or supervisor that there is a legitimate educational value to the event. Key considerations in evaluating a corporate invitation to give a presentation that is not part of a CME event include:

- Is there a marketing message in the talk that you are being asked to give and/or in the overall event? A fair and balanced presentation can typically be distinguished from one that resembles a marketing tool for the company. MSSM faculty and staff are prohibited from performing product or company endorsements. Although legitimate presentations sometimes involve reporting research project results and mentioning a particular product or technology, this is quite different from talks and events that are marketing in nature.
- As a speaker would you be able to use your own materials without control of the content by the sponsor? Talks in which sponsors exert significant control over the content are prohibited. Use of materials that are not your own is strongly discouraged; occasionally an illustrative slide prepared by the vendor might be acceptable if it has an educational and not a marketing value, but the majority of the presentation should be your own. The use of ghostwritten materials is strictly prohibited.
- Is the proposed payment to you fair and reasonable? Faculty and staff are expected to accept compensation only if it reflects fair market value, i.e., the payment is reasonable in relation to the services rendered, and resembles what others with similar expertise might be paid for a similar work effort. The "fair and reasonable" test also applies to coverage of travel expenses such as airfare and hotel. Your Chair can help to assess whether the proposed payment seems appropriate.
- Will the payment for your services come directly from a commercial entity, or will it be paid by an academic medical center? Direct payments from vendors may indicate that the event is designed to promote the goals and objectives of that vendor and are discouraged. Clear disclosure of the source of payment for your presentation must be made to your Chair/supervisor and to your audience in order to promote transparency.
- Is the program venue appropriate to the purpose? Typically events that are truly educational take place in settings that are appropriate to the learning experience. If the proposed event will be in an extravagant or exotic location, it is less likely that education is the primary purpose of the event, and it should be avoided.



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##### Paid Engagements

Faculty who receive compensation for participating in off-campus events outside the scope of CME will be subject to the [MSSM Policy on Financial Arrangements With Extramural Entities](#), and must submit written agreements for approval by the Department Chair prior to participation. Faculty must also adhere to CME guidelines concerning disclosure. For engagements involving expert training, the individual must also abide by the guidelines of the relevant professional organizations.



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##### **Vendor Support to Participate in Events**

Mount Sinai faculty, staff and trainees may not accept scholarships or other special funding directly from a vendor. Vendors may make donations a general departmental education fund; the department will use its own criteria to select trainees to receive support for participation in educational events. Under no circumstances can a trainee be paid by a commercial sponsor to attend an educational event.



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##### Authorship

Authorship on articles and scientific presentations must be in accordance with [Mount Sinai's Responsibilities of Authors](#) and [AMA guidelines on authorship](#). An author's role in content and contributions must be verifiable. Having one's own name appear as author of a document conceived, researched and written by others is unacceptable, e.g. an article prepared by industry for publication under an MSSM faculty member's name is not permitted.



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##### Purchasing Decisions

All purchasing decisions must be made in a manner consistent with Mount Sinai's Purchasing Policy in order to promote the best interests of Mount Sinai.

- A. Disclosure of Financial Interests
- B. Personal Incentives
- C. Departmental Incentives
- D. Placement of Vendor Equipment at Mount Sinai
- E. Site Visits to View Vendor Products and/or Services
- F. Pharmacy and Therapeutics Committee



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##### Disclosure of Financial Interests

Mount Sinai faculty and staff involved in decisions regarding the purchase of equipment or supplies - including individuals who serve on formulary committees - must submit an annual conflict of interest disclosure form identifying any financial interests that they have with vendors or potential vendors. Anyone with a conflict of interest may not participate in discussions and decisions on:

- Purchases from a company in which they have a financial interest
- Purchase of products of a competitor of the company in which they have a financial interest



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#### Personal Incentives

Occasionally, vendors offer an incentive if a buyer agrees to purchase the company's goods or services. Personal incentives, e.g., merchandise, tickets to special events, vacation trips, etc. are considered gifts as described in [Section 11](#) of this policy and cannot be accepted under any circumstances.



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##### Departmental Incentives

A vendor may offer the Hospital, School or an individual department a discount on the purchase price of a product or service. The Purchasing Department will only consider any discount as a factor in the initial formal purchasing/bidding process.



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#### Visits by Vendor Representatives

Vendor representatives from pharmaceutical, biotechnology and other industries may visit healthcare providers or researchers to talk about and demonstrate their new products. While generally acceptable as straightforward sales visits, an appointment is always required; representatives are not permitted on campus on a drop-in basis. Visits to health care providers must comply with Mount Sinai's policy on Medical Sales Representatives. Sales representatives are not permitted in patient care areas and may not access any patient-specific information. Refreshments and gifts from vendors, however modest, are prohibited during visits by representatives as described in [Section II](#) and Section III of this policy.

Scheduled appointments are required for vendor visits to train physicians, researchers or others in device use or new technologies.



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##### **Placement of Vendor Equipment at Mount Sinai**

Vendors may offer to place a new device or piece of equipment on-campus on a trial basis. Such arrangements require Finance Department approval of a no-charge Purchase Order that describes the item and the timeframe for evaluation. The vendor will be expected to deliver and retrieve the item within the designated time period.



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##### Site Visits to View Vendor Products and/or Services

Site visits to observe vendor products and/or services are sometimes an appropriate part of a purchasing decision. When such visits are necessary, they must be approved by the department head. Vendor offers to pay for site visits cannot be accepted because these offers may be designed to influence a purchasing decision or the institution's relationship with other vendors; the cost of the trip should be paid with departmental funds.



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##### Pharmacy and Therapeutics Committee

The Pharmacy and Therapeutics Committee policy manual includes standards and procedures for introducing new agents to the formulary. All requests to the committee for the addition of a drug, vaccine or other biological agent require that the requestor complete and submit a conflict of interest disclosure form.



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#### Pharmaceutical Samples

Physicians and staff may not accept pharmaceutical samples for their own personal use or for distribution to patients or family members. Distributing sample drugs would place physicians in a drug dispensing role, subject to applicable laws and regulations.

There will be only two circumstances that warrant an exception to this prohibition:

- If there is a compelling medical necessity to treat an urgent condition, where immediate treatment prior to leaving the physician's office will alter the clinical outcome
- If there is a need to demonstrate appropriate use of a product

In these exceptional cases, the minimum possible sample should be given. Appropriate documentation of the medication dispensed or the device utilized must be entered in the patient's medical record.



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##### **Patient Referrals**

Mount Sinai physicians refer patients to outside companies for services such as home care, home nutritional support, direct pharmacy services, etc. These companies do not necessarily sell products or services to Mount Sinai or its physicians. However, they depend on Mount Sinai for their business through patient referrals, for which they bill the patients or carriers directly. Mount Sinai cannot accept gifts, e.g. equipment, research grants, salary support, etc. from these vendors in exchange for such referrals. Such gifts would constitute illegal kickbacks in violation of the Federal Anti-Kickback Statute. Any gifts or donations offered by these companies must be directed to Mount Sinai's Office of Development for review and approval to ensure compliance with all regulatory requirements.



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#### Consulting/Relationships with Outside Entities

There is a potential for a conflict of interest in any business relationship between a member of the Mount Sinai faculty or staff and an outside company or organization. Relationships can take many forms, including: membership on boards of directors or scientific advisory boards; review/evaluation of efficacy of new products or devices for vendors; consulting with institutions on behalf of a vendor; expert witness testimony, etc.

Faculty and staff with decision-making authority for procuring specific products or services for Mount Sinai may not have an outside business relationship with a company that provides those products or services to the institution.

Full-time faculty must have all of their outside relationships reviewed and approved in accordance with the Policy on Financial Arrangements With Extramural Entities. This policy includes a description of time restrictions relating to arrangements with outside entities.

Members of the management staff must submit a written description of the arrangement, including estimated time required and remuneration, to the Chairman or Senior Vice President in charge of their department. Staff can only take time off from their regular duties if prearranged through the appropriate Chair or Senior Vice President.



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#### Role of Development Office

As a not-for-profit organization Mount Sinai may, through its Office of Development, solicit and accept charitable donations in furtherance of Mount Sinai's mission. In order to ensure compliance with federal and state laws regarding charitable donations, individual departments can partner with Development to solicit corporate contributions; departments should not, on their own, directly seek donations from vendors with which they do business.

Departments should consult with the Office of Development if questions arise concerning possible contributions from commercial entities.