THE MOUNT SINAI HEALTH SYSTEM, NEW YORK STANDARD: POLICY AND PROCEDURE

SUBJECT NO. ACS-C.21

DEPARTMENT: Assurance and Compliance Services, Corporate Compliance

SUBJECT: Policy on Staff Interactions with Vendors and Other Commercial Entities

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BACKGROUND

The Mount Sinai Health System (MSHS or Mount Sinai), which includes Mount Sinai Hospital (MSH), Mount Sinai Queens (MSQ), Mount Sinai Brooklyn (MSB), Mount Sinai Beth Israel (MSBI), Mount Sinai St. Luke's (MSSL), Mount Sinai West (MSW), New York Eye and Ear Infirmary of Mount Sinai (NYEE), and the Icahn School of Medicine at Mount Sinai (ISMMS), as well as other affiliated businesses, does business with commercial entities that offer a wide range of research, clinical, educational, and administrative products and services. All decisions relating to purchasing or other business processes must promote the best interests of MSHS without favor or preference based on personal considerations.

In order to avoid conflicts of interest in interactions with vendors or other commercial entities, staff at Mount Sinai is subject to the guidelines below as well as to other relevant institutional policies and external guidelines.

POLICY ON INTERACTIONS WITH VENDORS AND OTHER COMMERCIAL ENTITIES

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I. Introduction

Relationships between commercial entities, heath care providers, and academic medical centers have become increasingly intertwined and complex. The substantial financial assets of corporations and the broad intellectual resources of health care and academic centers create natural opportunities for joint pursuit of common objectives. However, occasionally the commitments and fiduciary duties of industry may conflict with Mount Sinai's core scientific and educational missions. Furthermore, while offers of "free" goods, gifts, donations, or grants for MSHS 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, 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/or 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 avoid 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/or 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 or seek to do business with Mount Sinai and its faculty, staff, and trainees.

All decisions relating to purchasing or other business processes must reflect Mount Sinai's commitment to the highest ethical standards of conduct as described in the Code of Conduct and must be consistent with all institutional policies, including but not limited to Section 16 of the Purchasing Policy, the Policy on Business Conflicts of Interest, the Policy on Financial Arrangements with Extramural Entities, and the Use of Mount Sinai Name Guidelines, as well as the requirements promulgated by the federal Office of the Inspector General (OIG) and in the Pharmaceutical Research and Manufactures of America (PhRMA) Code.

Maintaining rigorous practices ensures 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 staff, defined as Mount Sinai personnel who are not appointed faculty, and are designed to avoid potential conflicts of interest between Mount Sinai and industry.

II. Gifts

A gift is anything of value 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, and include but are not limited to:

- Cash in any amount;
- Any product or service, or discounts on products or services;
- Prizes:
- Gift certificates:
- Tickets;
- Raffles:
- 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. pens, notepads, trade show trinkets distributed to large numbers of people by vendor representatives, but excluded from this prohibition are materials of modest cost (e.g. less than \$10), 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.; and
- 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 a staff member or department is offered a gift; the offer must be decline and the vendor made aware of the policy

If a staff member of department receives a gift from a vendor, you must

- 1. Return the gift to the vendor using the Gift Refusal Letter (See Attachment A); or
- 2. Send the gift, if it is edible, to the mail room for distribution to a local food pantry.

As a last resort or if further guidance is required, you may contact the Compliance Department.

III. Vendor Support for Health System Educational Events

Any type of vendor support for Mount Sinai-sponsored educational events, whether held on or off the MSHS premises, requires department review and approval, as well as review by the Staff Conflicts of Interest Office, Office of Assurance and Compliance Services (Staff COI Office) prior to contacting any vendor. Staff must submit a Vendor Support Proposal for Health System Educational Events Form (Vendor Support Form) (See Attachment B) to the department Chair, vice president, or equivalent for approval. Vendor Support Forms must be in written format and include:

- A description of the planned educational event;
- The amount of support sought; and
- A description of the ways in which support will be used, e.g. honoraria for guest speakers, production of educational materials, etc.

Additionally, the proposal should be distributed to a broad base of potential funders (ideally 3 to 10 companies). The proposal and list of targeted vendors must be approved by the department Chair, vice president, or equivalent, then submitted to the Staff COI Office, which will review and give necessary guidance. Lastly, the department may distribute request(s) for proposed sponsorship to the prospective sponsors noted in the Vendor Support Form. The correspondence given to the potential sponsors must include language that reflects Mount Sinai's policies, such as the requirement that sponsorship be free of endorsements, and it must include the following wording, "This request for support does not in any way represent a commitment on the part of Mount Sinai to purchase any goods or services offered by your company."

If vendor support is offered, the Written Agreement for Commercial Support of Mount Sinai Health System Educational Activities Outside the Scope of CME (Written Agreement for Commercial Support) (See Attachment C), which outlines expectations and restrictions, and must be signed by both (1) the department Chair, vice president, or equivalent, and (2) the vendor. Vendor support is only accepted in accordance with the following provisions.

A. Deposit to General Fund

With the exception of Continuing Medical Education (CME) events (See Section III, Subsection C of this policy), any vendor contribution must be in the form of a general educational grant paid directly to ISMMS, a hospital fund, or a department. No direct or indirect payments may be made to any Mount Sinai staff member. Mount Sinai shall retain exclusive responsibility for all aspects of educational events. Corporate sponsors may not make commercial exhibits, distribution of promotional materials, or inclusion of company

representatives a requirement for support. You can contact the Development Office for more information about educational grants.

B. Food and Beverages

Direct provision by vendors of food and beverages or subsidies for food and beverages is prohibited. Vendor support may not be solicited / used for holiday parties or other activities whose primary purpose is not educational. Similarly, if MSHS offers food and beverages to voluntary faculty and/or other outside providers, that may create regulatory issues, so the Compliance Department must be contacted about proposed events prior to their occurrence.

C. Continuing Medical Education

Vendor support for accredited CME programs must be submitted to the CME Office 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. Vendor support must also be managed in accordance with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support, which includes, in part:

- 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; and
- Management of commercial promotion.

All staff is encouraged to participate in events where CME credit is offered.

D. Program Content

Programs must have true educational value and can never be designed to influence purchasing decisions. Applicable to all educational events, the ACCME Standards for Commercial Support include, but are not limited to, the following guidelines.

- Curriculum content, staff selection, and program quality are the sole responsibility of Mount Sinai department management, and/or the staff involved in the event and may not be delegated to the vendor.
- Speaker selection and educational content are at the discretion of the department.
- Guest speakers must sign a standard Disclosure Statement (See Attachment D) indicating compliance with institutional conflicts of interest policies.
- The Marketing and HIPAA Compliance Offices should be consulted regarding potential issues with patient privacy, media consents, etc.
- 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 all events.
- 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 event room(s) before, during, or after the activity.
- Vendors may apply for exhibit space outside the room(s) in which the educational event is held. The conference organizers have discretion to grant the requests and fees may be imposed. In the event that exhibit space is approved, exhibitors are subject to gift restrictions as described in Section II of this policy, as well as to the PhRMA Code.
- If a vendor wants to distribute marketing materials at an event, the vendor is required to follow Mount Sinai Branding Guidelines, e.g. content must be free of product, service, and company endorsements; questions should be addressed to the Marketing Office and Compliance Department.
- Refreshments, study materials, etc. should be appropriate to the event.
- Chairs are responsible for ensuring that all events adhere to ACCME Standards.

E. Acknowledgment of Vendor Support

Commercial support may be acknowledged verbally or in printed materials, but specific products and services may not be mentioned.

F. Vendor Support for MSHS Individuals

Vendor support can never be made directly to or earmarked specifically for an identified individual. Vendor support for staff education, including salary support, must be in the form of educational grants to Mount Sinai. (For further information, contact the Development Office.)

G. Education and Training on Vendor's Own Products

Vendor representatives from pharmaceutical, biotechnology, and other industries may visit health care providers or researchers to talk about and demonstrate their new products. While these visits are generally acceptable as straightforward sales visits, an appointment is always required and the protocol set forth in Section VI, Subsection D of this policy must be followed.

IV. Vendor Supported Educational Events That Occur Off Premises

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, vice president, or equivalent have overall responsibility to monitor the frequency and nature of participation in these paid and unpaid activities. In all cases, speakers must be aware of and abide by MSHS policies, including the Policy on Use of Mount Sinai Name.

Staff are encouraged to participate in industry-sponsored events that occur off the MSHS premises only when CME credit is offered. For events that fall outside the realm of CME, the following are guidelines for participation.

A. Educational Value of Event

Discretion must be employed in determining whether to attend based on whether the event has a legitimate educational value. Industry sponsors often organize their own conferences and invite health care staff to attend; it is incumbent upon the invitee and his/her department Chair, vice president, or equivalent to determine whether it is truly a learning event or if it is designed primarily to influence participants to favor the vendor's products or services. The setting for and cost of the event should be appropriate to its purpose and of a reasonable and modest standard. The invitee and his/her department Chair, vice president, or equivalent must ensure adherence to the standards for a legitimate educational program, as set forth in Section IV, Subsection B of this policy.

Continuing Medical Education events are subject to strict guidelines issued by the ACCME, 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.

Although educational events may also offer recreational or entertainment experiences, the latter must not occur at the same time or in conjunction with the educational proceedings. Funding for recreation or entertainment must be refused.

B. 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 health care staff 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 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.

If offered an opportunity to participate in a speaking engagement, whether paid of unpaid, staff must follow the protocol below.

- 1. First submit a Staff Relationships with Outside Entities, Attestation of Compliance with Institutional Policies (Staff Attestation) (See Attachment E) for signed approval to the staff member's department Chair, vice president, or equivalent along with any associated documentation, e.g. proposed contracts, email threads, terms and conditions, etc.
- 2. Subsequent to department approval, the Staff Attestation and documentation must be submitted to the Staff COI Office, which will analyze the proposed relationship and

- identify areas of risk it may pose for Mount Sinai. The staff member may not move forward with the proposed agreement until he/she receives a response from the Staff COI Office, which will include guidance to enable the staff member to mitigate risks and manage the outside relationship in harmony with MSHS policies.
- 3. If the outside entity does not provide a written agreement or the contract proposed by the outside entity conflicts with MSHS policy, the Staff COI Office will provide a document to be executed in tandem with the outside relationship. In part, the document makes clear that: the staff member's MSHS obligations take precedence over any outside agreement; no MSHS branding may be used in relation to the outside agreement; and no MSHS resources, including but not limited to use of the MSHS premises, hardware, software, etc., may be used in connection with an outside agreement.
- **4.** In all instances where a staff member partakes in an outside agreement, that relationship must be disclosed on the staff member's online Annual Report of Outside Relationships in Sinai Central.

If the proposed event does not offer CME credits, then you are expected to provide alternative evidence to your department Chair, vice president, or equivalent and the Staff COI Office 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 the following.

- 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. MSHS staff are prohibited from performing product, service, 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. Event marketing materials require review and approval from the Mount Sinai Health System Marketing and Communications Department and must be shared with the Staff COI Office to ensure presentations are fair and balanced.
- 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 control over the content, use of materials that are not your own, and use of ghostwritten materials are strictly prohibited.
- Is the proposed payment to you fair and reasonable? Staff may only accept compensation 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 similar work effort. Your department Chair, vice president, or equivalent or the Staff COI Office can help to assess whether the proposed payment is 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 primarily 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 (1) your department Chair, vice president, or equivalent, (2) the Staff COI Office, and (3) 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.

C. Paid Engagements

Staff who are offered compensation to participate in non-MSHS events outside the scope of CME are subject to the MSHS Policy on Financial Arrangements With Extramural Entities and must submit written agreements for approval by the department Chair, vice president, or equivalent and thereafter submit the documentation to the Staff COI Office prior to participation, as per Section IV, Subsection B of this policy. Staff must also adhere to CME guidelines concerning disclosure. For engagements involving expert training, the individual must also abide by the guidelines of relevant professional organizations.

D. Vendor Support to Participate in Events

Mount Sinai staff may not accept scholarships or other special funding directly or indirectly from a vendor. Commercial educational support requires the approval of an unrestricted grant (See Section III of this policy). All grants or financial contributions from vendors must be approved by the Development Office and documented in a written agreement. Vendors may make donations to a general departmental education fund, in which instance the department will use its own criteria to select the person to receive support for participation in educational events. Under no circumstances may staff be paid by a commercial sponsor to attend an educational event.

V. Authorship

Authorship on articles and scientific presentations must be in accordance with Mount Sinai's Responsibilities of Authors and the Journal of the American Medical Association (JAMA) 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 other is unacceptable, e.g. an article prepared by industry for publication under a staff member's name is not permitted.

VI. Purchasing Decisions

All purchasing decisions must be made in a manner consistent with Mount Sinai's Purchasing Policy in order to promote the best interest of Mount Sinai. Staff involved in decision making with respect to the use or purchase of equipment, products, supplies, or services must safeguard against actual or perceived conflicts of interest with respect to current and/or potential vendors.

A. Disclosure of Financial Interests

Mount Sinai staff involved in decisions regarding the purchase of equipment, supplies, product, or services—including but not limited to individuals who submit recommendations to

the Pharmacy and Therapeutics Committee or Value Analysis Committee—must submit an Annual Report of Outside Relationships in Sinai Central identifying any financial interests that they or a related party have with vendors or potential vendors. The Report should be amended immediately following any change to your outside relationship(s). No one with a conflict of interest may participate in discussions or decisions on:

- Purchases from a company in which they or a related party have a financial interest; and/or
- Purchase of products or services from a competitor of the company in which they or a related party has a financial interest.

B. 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 II of this policy and cannot be accepted under any circumstances.

C. Departmental Incentives

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

D. Visits by Vendor Representatives

Access to MSHS by Medical Vendor Representatives (MVRs) is a privilege provided to allow mutually beneficial interactions. As invited guests, MVRs are expected to adhere strictly to the Business Relationship Between Mount Sinai Health System and Medical Vendor Representatives Policy as well as guidelines outlined by the Food and Drug Administration (FDA), the American Medical Association (AMA), and the PhRMA. It is MSHS policy that MVRs may only have controlled access to medical care facilities and staff.

Sales representatives may not access any patient-specific information. They are not permitted in patient care areas unless they have: 1) completed all badging requirements as a Patient Care Area Vendor in the Mount Sinai Health System Vendor Portal, including immunization requirements; and 2) been specifically requested by the department to assist with a particular case, or have been issued a written appointment by the department.

Refreshments and gifts from vendors, however modest, are prohibited during MVR visits, as per 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.

E. Placement of Vendor Equipment at Mount Sinai

Vendors may offer to place a new device or piece of equipment on the MSHS premises on a trial basis. Such arrangements require Finance Department and Purchasing Department approval of a no-charge Purchase Order that describes the item and the timeframe for evaluation. The vendor is expected to deliver and retrieve the item within the designated time period, which may not exceed 90 days.

F. Site Visits to View Vendor Products and/or Services

Staff 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 Chair, vice president, or equivalent. 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 must be paid with departmental funds.

G. Pharmacy and Therapeutics Committee

The Pharmacy and Therapeutics Committee Policy 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 an Annual Report of Outside Relationships in Sinai Central. See Formulary Change–New Drug Request Policy (PH–402-A), Formulary–Additions or Deletions (PH–609-A), and Procedure for the Request of a Non-Formulary and Restricted Drug (PH–403-A).

H. Value Analysis Committee

The Value Analysis Committee identifies cost reduction opportunities for the Mount Sinai. The Committee performs systematic analysis (e.g. product demonstration, trial and evaluations, implementation, and data/products monitoring) related to materials and/or processes to identify and approve the best value alternatives. All requests to the committee regarding sourcing and value analysis of new products and services require the requestor to contact the Corporate Office of Supply Chain to obtain specific information about the new product request process.

VII. Pharmaceutical Samples

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

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

- If a physician or staff member with authority to prescribe determines there is compelling medical necessity to treat an urgent condition, where immediate treatment prior to leaving the physician's office will alter the clinical outcome; or
- If a physician or staff member with authority to prescribe determines there is a need to demonstrate appropriate use of a product to the patient.

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.

VIII. Patient Referrals

Mount Sinai does not pay for referrals. MSHS accepts referrals and admissions based solely on patients' clinical needs and MSHS's ability to render the needed services. No individual acting on behalf of Mount Sinai is permitted to solicit or receive anything of value, directly or indirectly, in exchange for the referral of patients.

Mount Sinai providers may be permitted to refer patients to external health care related entities 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 providers. However, they depend on Mount Sinai for their business through patient referrals, for which they bill the patients or carriers directly. Neither Mount Sinai nor any individual provider may accept gifts, e.g. equipment, research grants, salary support, etc., from these vendors in exchange for 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 or Staff COI Office for review to ensure compliance with all regulatory requirements and MSHS policies. (See Section II of this policy)

Mount Sinai is committed to ensuring that providers make appropriate referrals in accordance with applicable federal Stark Laws and relevant state laws.

IX. Consulting/Relationships with Outside Entities

There is a potential for a conflict of interest in any business relationship between a staff member and an outside company or organization. Relationships can take many forms, including but not limited to: membership on boards of directors or scientific advisory boards; review/evaluation of efficacy of new products or devices for vendors; consultation with institutions on behalf of a vendor; and/ or expert witness testimony.

Staff with decision-making authority to procure specific products or services for Mount Sinai need to recuse themselves if they have an outside business relationship with a company that provides those products or services to the institution.

Individuals with decision-making authority and staff who submit product/ service suggestions to the Pharmacy and Therapeutics Committee and/or Value Analysis Committee must have all of their outside relationships reviewed and approved in accordance with Sections IV and VI of this policy and the Policy on Financial Relationships with Outside Entities, which includes disclosure on the staff member's online Annual Report of Outside Relationships in Sinai Central.

X. Role of Development Office

As a non-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.

XI. Corporate Compliance Governance

Staff Conflicts of Interest Office, Assurance and Compliance Services

- Vivian Dillion, Senior Director, Corporate Compliance vivian.dillion@mountsinai.org
- Alma Azua-Cassady, Manager, Corporate Compliance alma.azua-cassady@mountsinai.org
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The following attachments relate to this policy:

- Attachment A Gift Refusal Letter Template
- Attachment B Vendor Support Proposal for Health System Educational Events Form (Vendor Support Form)
- Attachment C Written Agreement for Commercial Support of Mount Sinai Educational Activities Outside the Scope of CME
- Attachment D Disclosure Statement
- Attachment E Staff Relationships with Outside Entities, Attestation of Compliance with Institutional Policies (Staff Attestation)