Vendor Interaction Policy

Approved OSUMC Executive Cabinet, March 12, 2009
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Purpose
All healthcare professionals and institutions have an ethical obligation to provide safe, effective, patient-centered, timely, efficient, and high-quality care for their patients. In order to ensure that the care provided is always in the best interest of the patient, healthcare professionals and institutions should always strive to maintain the trust of their patients and to minimize any conflicts of interest in the delivery of care. The fiduciary nature of the relationship between patients and the healthcare professionals who treat them is based on an inequality of information about medicine and an imbalance of control between the parties. However, it is also based on an implicit understanding that a healthcare professional will make decisions that are in the best interest of the patient as opposed to the best interest of the professional.

Over the past twenty years, healthcare professionals have continued to redefine the appropriate ethical boundaries for relationships with vendor corporations and their representatives that have an interest in marketing products or services to professionals, institutions and patients. Since the early 1990’s, a variety of professional and vendor organizations have developed broad statements of ethical principles related to this issue. In the last few years, a number of medical centers and medical schools have developed detailed policies that operationalize those ethical statements. These policies tend to include (but are often not limited to) a focus on the issues of gifts to healthcare professionals, payment to healthcare professionals for consulting or other advisory work, and payment to healthcare professionals who participate in speakers’ bureaus or other educational programs.

The purpose of this policy is to outline a set of acceptable business practices and ethical principles that will guide the interactions of all faculty, staff, and trainees of The Ohio State University Medical Center with vendor corporations and vendor representatives. The goal of this policy is not to completely or even materially limit the ability of vendor representatives to enter Medical Center facilities or to interact with individual Medical Center staff members. A separate policy entitled “Vendor Access and Control” covers the physical access of our facilities for vendor representatives. Ethical relationships between healthcare professionals, institutions, and vendor representatives can often be beneficial for all parties involved – including patients – in
that these relationships may be the basis of advances in research, education and patient care. The goal of this policy is simply to place ethical boundaries on the actions of both parties.

**Policy**

1) **Definitions:**

a) Scope: This policy applies to all sites operated by or affiliated with the OSU Medical Center including but not limited to:

   i) the OSU Health System, including all hospital business units, the Primary Care Network and the Specialty Care Network.

   ii) the James Cancer Hospital and Solove Research Institute.

   iii) the Office of Health Sciences.

   iv) the College of Medicine including the School of Biomedical Sciences, the School of Allied Medical Professions, and all clinical departments.

   v) the Comprehensive Cancer Center, the Davis Heart Lung Research Institute, and all other research labs or other entities under the OSU Medical Center.

   vi) the sites operated by Ohio State University Physicians (OSUP) and Nationwide Children’s Hospital will operate under a vendor interaction policy with similar principles that will be adopted by their respective organizations.

b) Medical Center Unit: The use of the term “Medical Center unit” in this policy refers to an identifiable administrative unit within those areas outlined in section 1.a of this policy. For example, this could include an academic department, a division, a training program, a research center, a diagnostic department, a patient care unit, etc.

c) Medical Center Staff: The use of the term “Medical Center staff” in this policy applies to:

   i) All regular faculty members, auxiliary faculty members employed full-time by the University, and all employees (including clinical, administrative, clerical and other support staff members) working within any entity within or affiliated with the OSU Medical Center as noted in section 1.a.

   ii) The term also applies to any student, intern, resident, clinical fellow, postdoctoral fellow, or other trainee enrolled in an educational program through the OSU College of Medicine or one of its departments.
iii) The term also applies to all members of the medical staff of University Hospital and/or the James Cancer Hospital who may or may not be directly employed by the University.

iv) This policy does not apply to auxiliary or volunteer faculty (e.g., those with a “no salary” appointment) who are not working at a site noted in Section 1.a. However, those individuals are strongly encouraged to adopt this policy in their respective practices, especially when OSU trainees are rotating in that setting.

d) “Off-site and After-Hours Activities”: For those individuals to whom this policy applies as defined in this section, this policy should be considered to apply equally to both on-campus activities as well as off-site, out of town, or after-hours (e.g., evening, weekend, etc.) activities.

e) Vendor Corporation: This policy applies to those businesses, corporations or other entities that supply or wish to supply equipment, goods, services or other clinically related products to physicians, nurses, administrators or hospitals. This also includes organizations to which OSUMC patients are referred for clinical services (e.g., extended care facilities, skilled nursing facilities, etc.).

f) Vendor Representative: This policy applies to any individual who is employed by or who represents any entity defined in section 1.e who is not also an OSUMC faculty member, staff or student. Vendor representatives are guests of the Medical Center and, as such, must provide their services in accordance with acceptable rules of conduct as determined by this policy and in a manner that provides the greatest benefit to the Medical Center and to our patients.

g) Continuing Medical Education (CME) or Continuing Education: In this policy, the use of the terms “continuing medical education” and “continuing education” relate to a certified or accredited continuing professional education activity that provides credit toward maintenance of licensure for a healthcare professional. For example, CME in this document means a program that has been certified to provide Category 1 CME credit by an Accreditation Council for Continuing Medical Education (ACCME) accredited CME provider.

2) Gifts to Individuals

a) Individual Medical Center staff members are prohibited from accepting any gifts from vendor representatives or vendor corporations regardless of the value of the gift. This includes items of minimal value like pens, mugs, notepads, etc. that have been commonly distributed by vendors in the past.

b) Individual Medical Center staff members may receive marketing, instructional, warning or other educational information from a vendor about the vendor’s products at any time.
c) Any gifts that are delivered directly to an individual Medical Center staff member at any site must be either:

   i) Returned directly by the Medical Center staff member to the vendor, or
   
   Forwarded to the Medical Center Corporate Compliance Office which will return the gift to the vendor.

3) **Gifts to Medical Center Units**

   a) Any Medical Center unit may accept cash donations, gifts or other items of value that support the education, clinical or research missions of the unit from a vendor corporation in accordance with this policy.

   b) Any donations or gifts accepted by a Medical Center unit should remain the property of the Medical Center.

   i) In the case of a cash donation to a Medical Center unit, those funds may be used by a Medical Center unit to:

      (1) purchase items that may be given to individual Medical Center staff members to use in relation to their professional duties (e.g., textbooks for trainees) or

      (2) to compensate individual Medical Center staff members for work done on behalf of the Medical Center unit.

   c) Samples of equipment for non-patient care related activities (e.g., sample research equipment, a sample textbook for evaluation for use in a course, etc.) may be accepted by Medical Center units in accordance with the policies of the respective purchasing department assigned to work that Medical Center unit. These non-patient care related sample equipment must remain the property of the Medical Center unit.

   d) When working with vendors who would like to provide a donation, gift, or other item of value to a Medical Center unit, the unit leadership must work with Medical Center development to ensure that the gift is appropriately processed and that the vendor gets appropriate recognition with the University for the gift. When possible, Medical Center development should be contacted before the plans for the gift are finalized to ensure that appropriate processes are followed.

   i) If the gift is provided to support a research project or program, OSURF must be contacted regarding the policy for accepting funds to support research programs.
ii) If the gift is provided to support a CME education program, the Center for CME must be consulted regarding the policy for accepting funds to support a CME education program.

iii) If the gift is provided to support a GME training program, the GME Office must be consulted regarding the policy for accepting funds to support a GME training program.

iv) If the gift is for another purpose beyond those listed above, the unit accepting the gift must work with the appropriate University or Medical Center administrative oversight entities to coordinate the gift based on the gift’s purpose.

e) All donations and gifts from vendors to Medical Center units should be documented in writing. Although no specific form is required, at a minimum, this documentation should include:

i) the total amount of the gift,

ii) the timeframe over which the gift will be given (e.g., lump sum, quarterly, annually, etc.), and

iii) the intended use of the funds or the gift.

f) All gifts to a Medical Center unit of greater than $10,000 (either in individual or cumulative gifts from one vendor to one unit over the course of a fiscal year) must be reviewed by the Medical Center Associate General Counsel’s Office to ensure that they are being documented and managed appropriately.

4) Meals

a) Vendors are prohibited from directly supplying meals, food, snacks or other food items to Medical Center staff. The exceptions to this rule are:

i) a modest meal as part of an event that grants CME or other continuing education credit. This does not include departmental Grand Rounds or other OSUMC sponsored CME/CE events that are officially sponsored by a Medical Center unit but that may have some funding support from a vendor corporation.

ii) a meal in conjunction with an individuals role as an advisor or consultant to a vendor corporation.

b) Medical Center units are allowed to provide meals, food, snacks or other food items to staff members at any time in accordance with applicable Medical Center and University policies. The source of funding for the unit to provide such food
may be a donation from a vendor or vendor representative but the Medical Center unit must be responsible for providing and paying for the food.

5) **Vendor Sponsored Events**

a) Medical Center staff members are permitted to attend, participate in and/or lead any off-site event that offers CME or other continuing education credit regardless of the sponsor of the event.

b) Individual Medical Center staff members may attend any non-CME/CE dinners or other events sponsored by a vendor only if the staff member pays for their own meal, beverages, etc. Documentation of payment by the individual should be maintained and must be produced upon request by a supervisor.

c) Individual Medical Center staff members are prohibited from receiving payment or gifts in exchange for attendance as an audience member at any event.

d) An individual Medical Center staff member is permitted to accept an item with a vendor logo on it in conjunction with an educational conference (e.g., a tote bag, a water bottle, etc.) if:

i) the item has the name of the conference or sponsoring organization on it,

ii) the item is provided by the educational conference

iii) the item is provided to all conference attendees

e) Meetings with vendors regarding the potential purchase, lease or rental of equipment or services from the vendor and any meals provided at such a meeting must be in accordance with the policies of the respective purchasing department working with that Medical Center unit and the laws of the State of Ohio. In general, all costs for meals, travel, lodging, etc. for these meetings should be covered by a Medical Center unit and not by the vendor unless explicitly approved by a member of the purchasing department or other senior administrator.

f) Vendor sponsorship

i) If a vendor is interested in providing support to a Medical Center unit to underwrite an educational event or conference (including for the purchase of food by the Medical Center unit), the vendor should make a monetary donation to the Medical Center unit to facilitate the event.

(1) The planning and coordination of the event must remain under control of the Medical Center unit that is sponsoring the event.
(2) The donated funds must remain under the control of the Medical Center unit that is sponsoring the event.

(3) The Medical Center unit is required to provide appropriate recognition of the vendor support for the event especially when the activity is granting CME or other continuing education credit.

(4) At the discretion of the Medical Center unit leader responsible for the event, the vendor representative(s) from the corporation providing support for the event:

(a) May attend the event
(b) May be introduced/recognized at the event
(c) May set up a table in an area adjacent to but separate from the educational event where he/she may distribute marketing or scientific literature
(d) May not distribute any gifts or meals, beverages, snacks, candy or other food items
(e) May not conduct any marketing or commercial activities within the room where the educational event is occurring

(5) Vendors are prohibited from providing funds directly to any Medical Center staff member to attend any CME or other continuing education event (with the exception of section 5.e.ii below). Vendors wishing to provide support for a specific CME or other continuing education event or program should make a donation to the sponsor of the event to reduce the cost for all attendees.

ii) In the case of students, housestaff, and other trainees, a vendor may provide support for one or more individual trainees to attend an educational conference with the following stipulations:

(1) The individual(s) chosen to attend the event must be chosen by the director of the educational program or the department chair.

(2) The director of the educational program must approve the educational conference that is being attended to ensure that the conference is of substantial value to the trainee’s education.

(3) The Vice Dean for Education or the Associate Dean responsible for the educational program must also endorse the decision of the program director.

(4) The funding support must be given to the Medical Center unit which will then either pay for the expenses or reimburse the individual(s) for the expenses related to attending the event.
6) **Consulting, Speakers’ Bureaus and Other Business Arrangements**

a) Individual Medical Center staff members may serve as paid consultants or advisors to vendor corporations in accordance with this and other applicable University policies on work outside the University (please see University HR Policy 1.30 and applicable Faculty Senate Policies).

i) Medical Center staff members may receive complimentary meals from a vendor only in direct relation to their work for the vendor as a paid consultant or advisor (e.g., a lunch or dinner at an advisory committee meeting). This does not include meals or gifts from a vendor not in conjunction with their work as an advisor or consultant (e.g., one-on-one lunch with a vendor representative unrelated to their paid position).

ii) Any paid advisory or consulting relationships must be disclosed by a Medical Center staff member in the course of leading any educational activity for Medical Center students, housestaff, faculty, or other employees if the topic being discussed relates to products or services that they provide consultation on to the vendor. This includes both CME/CE and non-CME/CE educational activities.

iii) Any paid consulting relationship with a vendor corporation must be disclosed through the annual University disclosure process and should be discussed directly with the individual’s unit leader.

iv) Consulting or advisory relationships should be entered into by Medical Center staff members carefully. The work that will be done for the vendor corporation must be:

   (1) generally commensurate with the amount of compensation provided by the vendor and

   (2) the compensation must approximate fair market value.

v) There should be a signed agreement that outlines, at a minimum, the work to be done for the vendor corporation and the compensation to be provided by the vendor.

   (1) If this agreement is between the vendor and the individual, all aspects of University HR policy 1.30 and Faculty Senate Rules still apply.

   (a) The agreement with the vendor must be produced by the individual staff member if requested by a Medical Center unit leader or by the University.
(b) The individual must report to the University if any intellectual property will be created as a part of this activity.

(2) If this agreement is between the vendor and the University, the Medical Center, or a Medical Center unit, the document should be reviewed and approved in advance by the office of the Medical Center Associate General Counsel.

vi) Faculty and staff serving as a paid consultant, advisor, etc. for a vendor should comply with University HR and faculty policies regarding the requirement to use appropriate leave time for these activities when required.

b) Speakers’ Bureau and Educational Events

i) Medical Center staff members are permitted to participate in a vendor-sponsored speakers’ bureau or other educational event only:

   (1) when the presentation is to be made in an academic setting (e.g., grand rounds, visiting professor, guest lecture etc.), at an office practice educating trainees, at an academic medical center or at a teaching hospital, or

   (2) at any event granting CME/CE credit regardless of the location, or

   (3) when the presentation is an educational or training activity for a vendor’s employees

ii) When presenting at a vendor-sponsored speakers’ bureau or other educational event, any slides and other information presented by the Medical Center staff member must have been prepared by the Medical Center staff member. Use of slides or other vendor-prepared educational materials by the Medical Center staff member is not permitted with the exception of FDA-approved slides regarding a specific product.

iii) Medical Center faculty members may receive an honorarium or speaker fee for lecturing in a permitted vendor sponsored or supported educational event as defined in this policy.

   (1) If the event occurs in an academic setting (i.e., an academic medical center, teaching hospital, etc.), the honorarium or speaker fee should be from the academic institution when possible.

   (2) If the event occurs as a part of a CME/CE event, the honorarium or speaker fee should be from the organization sponsoring the CME/CE event when possible.
iv) Medical Center faculty members are prohibited from receiving a retainer or other similar payments simply for being a member of a speakers’ bureau. Any payments for involvement with a speakers’ bureau must be in relation to actually performing a service as a speaker, lecturer, etc.

v) In accordance with University policies, non-faculty employees are never permitted to receive an honorarium for such an event.

vi) Medical Center faculty members are prohibited from participating in and receiving an honorarium for a vendor sponsored “speakers’ bureau” event when the goal of the activity is marketing of the vendor’s products.

c) “Token consulting” arrangements are strictly forbidden.

i) “Token consulting” arrangements are agreements to pay a Medical Center staff member for consulting or advising a vendor corporation when either:

(1) No substantive work is done on behalf of the vendor, or

(2) The work done for the vendor is not commensurate with the amount of compensation provided by the vendor, or

(3) When the compensation is not at fair market value as determined by acceptable benchmarks (e.g., AAMC faculty or MGMA practicing physician salary benchmarks).

(4) If there are any concerns that a consulting arrangement could be considered “token consulting,” please consult the office of the Medical Center Associate General Counsel for further review.

d) Ghost-writing of publications, abstracts, case reports or other scholarly work by vendor representatives on behalf of a Medical Center staff member is strictly prohibited. Faculty and staff should be aware of published guidelines in the medical literature regarding taking credit for authorship of an article, abstract, or other scholarly work.

7) Promotional materials

a) Vendor corporations and vendor representatives are prohibited from directly placing any promotional materials or educational materials in any patient care area or waiting area of any Medical Center inpatient or outpatient site.

b) Medical Center units and individual staff members are permitted to distribute or display high-quality patient education materials produced by a vendor corporation in patient care areas or waiting rooms of any inpatient or outpatient site provided that the materials are unbiased and are not product-specific.
c) Promotional materials that are product-specific or that directly market a vendor’s products may be distributed to patients:

i) only after they have been reviewed specifically by the Medical Center unit to ensure that they are generally complete and accurate regarding the vendor’s product, and

ii) only after it is determined that the patient needs or potentially needs to use the product or medication covered in the promotional material, and

iii) preferably by the unit’s faculty or staff and not directly by a vendor representative.

d) This policy should not be construed in any way to limit the distribution of accurate and complete instructions for use or safety warnings for any product or medication regardless of the source of the information after an item has been ordered or prescribed for use by a patient.

8) Samples

a) In order to ensure patient safety and the appropriate storage and distribution of medication samples, the distribution of medication samples will be prohibited except as noted under Section 8.b below.

i) In an attempt to minimize the need for samples:

   (1) vendors are encouraged to provide vouchers to clinical units or clinics within the Medical Center that may be distributed to patients. These vouchers, in addition to a valid prescription, will allow a patient to receive free or discounted medications at a retail pharmacy.

   (2) prescribers are encouraged to prescribe generic medications for those patients who cannot easily afford prescription medications and in those clinical situations when a generic medication is appropriate for the patient’s condition.

b) If members of a clinical unit believe that their clinical practice requires the continued use of medication samples, they may apply to the Chief Medical Officer for an exception to this rule. As a part of that approval, the unit or clinic will be required to annually report the following to the Chief Medical Officer:

   i) The medication samples that are routinely stocked in the clinic,

   ii) The process for ensuring the proper storage, security and distribution for samples,
iii) The process for monitoring the expiration dates on medication samples, and

iv) The process for the documentation of distribution to patients.

c) For non-medication product samples, the unit or clinic should ensure that any samples provided to patients are appropriately packaged, in good condition and have not expired.

9) **Conflict of Interest in Purchasing Decisions**

a) Any Medical Center staff member who is involved in the evaluation of a product, selection of a vendor, negotiation with a vendor, or the decision to purchase a product must fully disclose any equity positions, consulting agreements, or other compensation relationships between him/herself or a member of his/her family (as defined by applicable University policy) with a vendor under consideration.

b) This conflict of interest should be disclosed in writing to the Medical Center staff member’s direct supervisor as well as to the applicable staff from the respective purchasing department assigned to the purchase.

i) Both the individual's supervisor as well as the respective purchasing department staff member are required to review the conflict of interest with the Medical Center staff member. If the conflict of interest is significant or cannot be managed appropriately in the opinion of the supervisor or the purchasing department representative, the individual must remove themselves from the process.

ii) If additional assistance is needed to evaluate the conflict of interest, the Medical Center Associate General Counsel, the Professionalism Council and the Office of the Senior Vice President are additional resources that can be utilized.

c) If an individual Medical Center staff member is in any position to materially benefit from the Medical Center relationship with the vendor or if the conflict is deemed too significant by either the Purchasing Department or the individual's supervisor to be managed appropriately, the individual must immediately remove him/herself from any further discussions, meetings or negotiations.

d) Any Medical Center staff member who is involved in the evaluation of a product, selection of a vendor, negotiation with a vendor, or the decision to purchase a product should be generally familiar with all Purchasing Department policies regarding their role in the process.

e) Communication between Medical Center staff members and vendor representatives related to selection of a vendor, negotiation with a vendor or a
decision to purchase a product should occur only in accordance with Purchasing Department policies.

f) All costs related to meals, travel, lodging, etc. for meetings, site visits, or other activities related to a purchasing decision must be covered by a Medical Center unit and not the vendor unless explicitly approved by a member of the Purchasing Department or other senior administrator.

10) Conflict of Interest in Research

a) Individual Medical Center staff members involved in any form of research should be generally familiar with and compliant with any applicable Medical Center, University, OSURF and IRB policies that govern conflicts of interest in research.

b) Funding or other support for research from vendors may be received in accordance with applicable Medical Center, University, OSURF and IRB policies that govern industry-funded research.

c) As a part of the IRB approval process, individual Medical Center staff members must disclose to the IRB any financial conflicts regarding the research they are undertaking according to applicable Medical Center, University, OSURF and IRB policies.

d) As a part of the informed consent process, individual Medical Center staff members must disclose to prospective research subjects any substantial conflicts of interest regarding the research they are undertaking when required to do so by the IRB.

11) Non-compliance

a) Medical Center unit leaders are charged with ensuring that all Medical Center staff members (e.g., faculty, staff, trainees, etc.) in their unit are educated about this policy.

b) If a potentially non-compliant act or event is brought to the attention of any Medical Center unit leader, that leader must either directly investigate the issue or refer the issue to their supervisor or to the Professionalism Council for further investigation.

c) Reporting of potential non-compliance with this policy may be done through a variety of mechanisms.

   i) Report entered in the Ethics Point compliance reporting system
      (1) Web URL: https://secure.ethicspoint.com then select Ohio State University as the organization.
      (2) Toll Free number: 1-866-294-9350
ii) Report directly to the Medical Center Compliance Office
iii) Report directly to Medical Center Risk Management
iv) Report to an appropriate unit, department or Medical Center leader

d) Determination of non-compliance and disciplinary action: Determination of non-compliance by a vendor representative or OSUMC staff member and the determination of any disciplinary action will be done with the cooperation of the applicable administrative, academic, research and/or clinical unit leadership where the alleged issue(s) occurred. For faculty members, this should also include the Department Chair for the individual involved. Additional assistance in any investigation, determination of non-compliance with this policy, or determination of disciplinary action can also be provided by the Chief Medical Officer, OSUMC legal counsel, the Dean, the Office of the Senior Vice President, or the Professionalism Council.

e) Vendor non-compliance: Each issue of non-compliance with this policy will be dealt with on an individualized basis taking into account the actual events that occurred and any previous non-compliance with OSUMC policies. Non-compliance may result in actions including, but not limited to,

i) a warning,

ii) a temporary suspension of access to the Medical Center,

iii) permanent revocation of the individual vendor representative’s access to the Medical Center, or

iv) complete termination of business with the vendor corporation.

f) Staff non-compliance: Each issue of non-compliance with this policy will be dealt with on an individualized basis taking into account the actual events that occur, any previous non-compliance with OSUMC policies, and the individual's overall applicable work or academic record. Any disciplinary action will be consistent with regard to existing disciplinary policies that apply to the individual in question. Non-compliance may result in disciplinary action, including but not limited to,

i) a warning,

ii) probation,

iii) suspension,

iv) removal from a position whose duties include vendor interaction, or

v) termination.
vi) Any disciplinary action may be appealed in accordance with applicable Medical Center and University HR policies and through a process that is based on the individual's status within the University (i.e., student, faculty, A&P staff, trainee, union member, etc.).

12) References

1) OSU Health System Policy 09-14, “Vendor Access and Control”
4) Chapter 2921 of the Ohio Revised Code
5) PhRMA Code on Interactions with Healthcare Professionals, PhRMA, April 2002
6) OIG Compliance Program Guidance for Pharmaceuticals Manufacturers, April, 2003
7) American Medical Association Council on Ethical and Judicial Affairs (CEJA) Ethics Opinion E-8.061 – Gifts to Physicians from Industry
8) American Medical Association Council on Ethical and Judicial Affairs (CEJA) Ethics Opinion E-9.011 – Continuing Medical Education
11) Ohio State University HR Policy 1.30 – “Conflict of Interest and Work Outside the University”
12) Ohio State University Faculty Senate Policy – “Paid External Consulting Policy”
13) Ohio State University Faculty Senate Policy – “Financial Conflict of Interest Policy for Faculty”

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