

Policy Name: Vendor Interaction

Applies to:		
<input checked="" type="checkbox"/> OSU Wexner Medical Center [University Hospital, East Hospital, Brain and Spine Hospital, Richard M. Ross Heart Hospital, Harding Hospital, Dodd Rehabilitation Hospital, Ambulatory Clinics and Services]	<input checked="" type="checkbox"/> Ambulatory Surgical Centers [New Albany, Dublin]	<input checked="" type="checkbox"/> Arthur G. James Cancer Hospital and Richard J. Solove Research Institute and Outreach Sites

Policy Objective

In order to ensure that care is provided in the best interest of the patient, healthcare professionals at The Ohio State University Wexner Medical Center and Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (The James) will maintain trust with their patients by minimizing any conflicts of interest in the delivery of care. This policy outlines a set of acceptable business practices and ethical principles to guide the interactions of all faculty, staff, and trainees of OSUWMC/The James 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 hospital facilities or to interact with individual hospital 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 advancing research, education and patient care.

This policy also applies to all sites operated by or affiliated with OSUWMC/The James, including but not limited to:

- Office of Health Sciences
- College of Medicine including the School of Biomedical Sciences, the School of Allied Medical Professions, and all clinical departments
- Comprehensive Cancer Center, the Davis Heart Lung Research Institute, and all other research labs or other entities under the OSU Medical Center
- 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

Definitions

Term	Definition
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 A1 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.
Medical Center Staff	The use of the term “Medical Center staff” in this policy applies to: <ul style="list-style-type: none"> 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 A1. 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 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.
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.
Vendor Corporation	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 OSUWMC/The James patients are referred for clinical services (e.g., extended care facilities, skilled nursing facilities, etc.).
Vendor Representative	Individuals employed by or who represents any entity defined in section 1.e who is not also an OSUWMC/The James 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.
Continuing Medical Education (CME) or Continuing Education	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.

Policy Details

A. Gifts to Individuals

1. 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, and notepads.
2. 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.
3. Any gifts delivered directly to an individual Medical Center staff member at any site must be either:
Returned directly by the Medical Center staff member to the vendor, or forwarded to the Compliance and Integrity Office for instructions on how to return the gift to the vendor.

B. Gifts to Medical Center Units

1. 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.
2. Any donations or gifts accepted by a Medical Center unit should remain the property of the Medical Center.
3. In the case of a cash donation to a Medical Center unit, those funds may be used by a Medical Center unit to:
 - a) 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
 - b) To compensate individual Medical Center staff members for work done on behalf of the Medical Center unit.
4. 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.
5. 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 receives appropriate recognition from the University

for the gift. When possible, units should contact Medical Center development before the plans for the gift are finalized to ensure that appropriate processes are followed:

- a) If the gift is provided to support a research project or program, OSU Research Foundation (OSURF) must be contacted regarding the policy for accepting funds to support research programs.
 - b) 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.
 - c) 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.
 - d) 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.
6. 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:
- a) The total amount of the gift;
 - b) The timeframe over which the gift will be given (e.g. lump sum, quarterly, annually, etc.); and
 - c) The intended use of the funds or the gift.
7. 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 Office of Legal Affairs to ensure that they are being documented and managed appropriately.

C. Meals

1. Vendors are prohibited from directly supplying meals, food, snacks or other food items to Medical Center staff. The exceptions to this rule are:
 - a) 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 Medical Center sponsored CME/CE events that are officially sponsored by a Medical Center unit but that may have some funding support from a vendor corporation.
 - b) A meal in conjunction with an individual's role as an advisor or consultant to a vendor corporation.
2. 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.

D. Vendor Sponsored Events

1. 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.
2. 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.
3. Individual Medical Center staff members are prohibited from receiving payment or gifts in exchange for attendance as an audience member at any event.
4. 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:
 - a) The item has the name of the conference or sponsoring organization on it
 - b) The item is provided by the educational conference
 - c) The item is provided to all conference attendees
5. 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.
6. Vendor sponsorship

- a) 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.
 - (i) The planning and coordination of the event must remain under control of the Medical Center unit that is sponsoring the event.
 - (ii) The donated funds must remain under the control of the Medical Center unit that is sponsoring the event.
 - (iii) 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.
- b) 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:
 - (i) May attend the event
 - (ii) May be introduced/recognized at the event
 - (iii) 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
 - (iv) May not distribute any gifts or meals, beverages, snacks, candy or other food items
 - (v) May not conduct any marketing or commercial activities within the room where the educational event is occurring
- c) 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 6.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.
- d) 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 requirements:
 - (i) The individual(s) asked to attend the event must be chosen by the director of the educational program or the department chair.
 - (ii) 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.
 - (iii) The Vice Dean for Education or the Associate Dean responsible for the educational program must also endorse the decision of the program director.
 - (iv) 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.

E. Consulting, Speakers' Bureaus and Other Business Arrangements

1. Individual Medical Center staff members may serve as paid consultants or advisors to vendor corporations in accordance with this and other applicable University on outside activities.
2. 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).
3. 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.
4. Paid consulting relationships with vendors require prior approval from the unit and should be disclosed within 30 days of such approval via the University disclosure process.
5. 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:
 - a) Generally commensurate with the amount of compensation provided by the vendor and
 - b) The compensation must approximate fair market value.
6. 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.

- a) If this agreement is between the vendor and the individual, all aspects of [Outside Activities and Conflicts](#) policy and Faculty Senate Rules still apply. *See also the COM Guidance on Faculty Consulting.
 - b) 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.
 - c) The individual must report to the University if any intellectual property will be created as a part of this activity.
 - d) 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 Legal Affairs.
7. 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.
8. Speakers' Bureau and Educational Events
- a) Medical Center staff members are permitted to participate in a vendor-sponsored speakers' bureau or other educational event only:
 - (i) 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
 - (ii) At any event granting CME/CE credit regardless of the location, or
 - (iii) When the presentation is an educational or training activity for a vendor's employees.
 - b) 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.
 - c) 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.
 - (i) 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.
 - (ii) 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.
 - d) 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.
 - e) In accordance with University policies, non-faculty employees should consult the [Outside Activities and Conflicts](#) policy or applicable University policies when receiving an honorarium or compensation for such an event.
 - f) 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.
9. "Token consulting" arrangements are strictly forbidden.
- a) "Token consulting" arrangements are agreements to pay a Medical Center staff member for consulting or advising a vendor corporation when either:
 - (i) No substantive work is done on behalf of the vendor; or
 - (ii) The work done for the vendor is not commensurate with the amount of compensation provided by the vendor; or
 - (iii) When the compensation is not at fair market value as determined by acceptable benchmarks (e.g., AAMC faculty or MGMA practicing physician salary benchmarks)
 - b) If there are any concerns that a consulting arrangement could be considered "token consulting," consult Office of Legal Affairs for further review.
10. 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.

F. 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.

G. Samples

1. 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 G2 below. In an attempt to minimize the need for samples:
 - a) 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.
 - b) 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.
2. If members of a clinical unit believe that their clinical practice requires the continued use of medication samples, they may apply to the Chief Clinical Officer/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 Clinical Officer/Chief Medical Officer:
 - a) The medication samples that are routinely stocked in the clinic;
 - b) The process for ensuring the proper storage, security and distribution for samples;
 - c) The process for monitoring the expiration dates on medication samples; and
 - d) The process for the documentation of distribution to patients.
3. 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.

H. Conflict of Interest in Purchasing Decisions

1. 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, other compensation relationships, or fiduciary relationships between themselves or a member of their family (as defined by applicable University policy) with a vendor under consideration.
2. 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.
 - a) 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.
 - b) If additional assistance is needed to evaluate the conflict of interest, the Office of Legal Affairs and Medical Center Compliance and Integrity may be consulted.

3. 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.
4. 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.
5. 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.

I. Conflict of Interest in Research

1. Individual Medical Center staff members involved in any form of research should be generally familiar with and compliant with any applicable Medical Center, University and IRB policies that govern conflicts of interest in research.
2. Funding or other support for research from vendors may be received in accordance with applicable Medical Center, University and IRB policies that govern industry-funded research.
3. 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 and IRB policies.
4. 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.

J. Non-compliance

1. 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.
2. 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 Compliance and Integrity for further investigation.
3. Reporting of potential non-compliance with this policy may be done through a variety of mechanisms.
 - a) Report entered in the [Ethics Point](#) compliance reporting system or call Toll Free number: 1-866-294-9350
 - b) Report directly to the Compliance and Integrity Office
 - c) Report directly to Medical Center Risk Management
 - d) Report to an appropriate unit, department or Medical Center leader
4. Determination of non-compliance and disciplinary action: Determination of non-compliance by a vendor representative or Medical Center 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 Clinical/Medical Officer, OSUWMC legal counsel, the Dean, or Compliance and Integrity.
5. 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 Medical Center policies. Non-compliance may result in actions including, but not limited to,
 - a) A warning;
 - b) A temporary suspension of access to the Medical Center;
 - c) Permanent revocation of the individual vendor representative's access to the Medical Center; or
 - d) Complete termination of business with the vendor corporation.
6. 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 Medical Center 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,
 - a) A warning;
 - b) Probation;

- c) Suspension;
- d) Removal from a position whose duties include vendor interaction; or
- e) Termination.
- f) 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.).

Resources

- 1) [Vendor Access & Control - 09-14](#)
- 2) [Outside Activities and Conflicts Policy](#)
- 3) *Report of the AAMC Task Force on Industry Funding of Medical Education*, Association of American Medical Colleges, 2008.
- 4) Chapter 2921 of the Ohio Revised Code
- 5) PhRMA Code on Interactions with Healthcare Professionals, PhRMA, August 2021
- 6) American Medical Association Council on Ethical and Judicial Affairs (CEJA) Ethics Opinion E-8.061 – *Gifts to Physicians from Industry*
- 7) American Medical Association Council on Ethical and Judicial Affairs (CEJA) Ethics Opinion E-9.011 – *Continuing Medical Education*
- 8) Relationship of GME to Industry and Other Funding Sources ACGME—October 2011—2

Contacts

Office	Telephone	Email
Compliance and Integrity	614-293-7802	compliance@osumc.edu

History

<i>The Ohio State University Wexner Medical Center</i>		
Approved By (List All Committees): 1. Policy Oversight Committee 2. Health System Operations Team	Approval Date: 1. 11/18/2021 2. 12/2/2021	Issue Date: 03/12/2009 Effective Date: 1/10/2022
Review Cycle: <input type="checkbox"/> 2 years <input checked="" type="checkbox"/> 3 years		Prior Approval Date(s): 10/14/2013

<i>Arthur G. James Cancer Hospital and Richard J. Solove Research Institute</i>		
Approved By (List All Committees): 1. Policy Oversight Committee 2. Health System Operations Team	Approval Date: 1. 11/18/2021 2. 12/2/2021	Issue Date: 03/12/2009 Effective Date: 1/10/2022
Review Cycle: <input type="checkbox"/> 2 years <input checked="" type="checkbox"/> 3 years		Prior Approval Date(s): 10/14/2013