

 NORTHEAST OHIO MEDICAL UNIVERSITY	Policy No: 3349-20-90
POLICY TITLE: University Personnel Relationships with Industry (Vendor Conflict of Interest)	EFFECTIVE DATE: September 30, 2011
RESPONSIBLE DEPARTMENT: Offices of the Deans of the Colleges of the University	University Personnel, Facilities Owned and Operated by the University

(A) PURPOSE

The purpose of this Policy is to ensure that the University maintains ethical working relationships with vendors in accordance with State of Ohio Ethics Laws, federal regulations and the ethical standards of the health professions of which our faculty, staff, residents and students are a part.

(B) SCOPE

This Policy applies to all sites owned or operated by the University and University Personnel as defined herein. This University strongly encourages all Faculty who are appointed by but not employed by the University or who practice at sites that are not owned or operated by the University, to adhere to the Policy set forth herein.

(C) DEFINITIONS

- (1) “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 or Continuing Medical Education (ACCME) accredited CME provider.
- (2) “University” – as used in this Policy refers to the Northeast Ohio Medical University, established by ORC §3350.10 and/or its successor entity.
- (3) “Department”: The use of the term “Department” in this Policy refers to an academic unit under the control of the University.
- (4) “Off-site and After-Hours Activities”: This Policy applies equally to on-campus activities as well as off-site, out of town, or after-hours (e.g., evening, weekend, etc.) activities.

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- (5) “University Foundation” is used in this Policy refers to the NEOMED Foundation and/or its successor entity.

- (6) “University Personnel”: The use of the term “University Personnel” in this Policy applies to:
 - (a) All tenure and non-tenure track faculty members, who are employed full time by the University or one of its Colleges, and all employees (including clinical, administrative, clerical and other support staff members) working in any facility owned or operated by the University.

 - (b) The term also applies to any student, intern, resident, clinical fellow, postdoctoral fellow, or other trainee enrolled in an educational program through the University or one of its Colleges.

 - (c) 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 owned or operated by the University. However, those individuals are strongly encouraged to abide by this policy in their respective practices, especially when University trainees are rotating in that setting.

- (7) “Vendor Corporations” are those non University owned, operated or affiliated businesses, corporations or other entities that supply or wish to supply equipment, goods, services or other clinically related products to the University or University Personnel. This also includes organizations to which University patients are referred for clinical services (e.g., extended care facilities, skilled nursing facilities, etc.).

- (8) “Vendor Representatives” are those individuals who are employed by or who represent any Vendor Corporation. Vendor Representatives are guests of the University 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 University and to our patients.

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(D) POLICY STATEMENT

(1) Gifts to Individuals

- (a) University Personnel 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) University Personnel may receive marketing, instructional, warning or other educational information from a vendor about the vendor's products.
- (c) Any gifts that are delivered directly to an individual who meets the definition of University Personnel at any site must be either:
 - (i) Returned directly by the individual to the vendor, or
 - (ii) Forwarded to the Office of the General Counsel or the Office of Faculty Affairs which will return the gift to the vendor.
 - (iii) In either case, a standard letter will be sent with the gift that explains that individuals can no longer accept any gifts from vendors.

(2) Gifts to the University, the University Foundation, Individual Colleges or Departments

- (a) The University, University Foundation Individual Colleges or Departments may accept cash donations, gifts or other items of value that support the education, clinical or research missions of the University from a Vendor Corporation in accordance with this Policy.

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- (b) Any donations or gifts accepted by the University, University Foundation should remain the property of the University, University Foundation, or an individual College or Departments.
 - (i) In the case of a cash donation, funds may be used to:
 - (a) Purchase items that may be used by University Personnel in relation to their professional duties or
 - (b) To further the mission of the University an individual College or Department.

- (c) Samples of equipment for non-patient care related activities (e.g., research equipment, teaching laboratory supplies, textbooks for evaluation for use in a course, etc.) may be accepted by the Universities, individual Colleges or Departments in accordance with the Policies of the Purchasing Department. These non-patient care related sample equipment must remain the property of the University, individual College or Department.

- (d) When working with vendors who would like to provide a donation, gift, or other item of value to the University, one of its Colleges or Departments, the vendor must work with the leadership of the University, individual College or Department and with University Institutional Advancement personnel to ensure that the gift is appropriate before finalizing plans for the gift. University Institutional Advancement personnel and leadership personnel are responsible for properly processing the gift.
 - (i) If the gift is provided to support a research project or program, the Office of the Vice President for Research must be consulted concerning Conflict of Interest and other research related policies prior to accepting any research related gift.

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- (ii) If the gift is provided to support a CME education program, the Office of Continuing Professional Education must be consulted prior to accepting any funds to support a CME education program.
- (iii) If the gift is for another purpose beyond those listed above, the Department accepting the gift must work with appropriate University leadership or administrative oversight entities to coordinate the gift based on the gift’s purpose.
- (e) All donations and gifts from vendors to the University an individual College or Department 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 of \$10,000 or more, either in individual or cumulative gifts from one vendor to one Department over the course of a fiscal year must be reviewed by the General Counsel’s Office to ensure that they are being documented and conflicts are being managed appropriately. It is the responsibility of the Department Chair to forward documentation of such gifts to the Office of the General Counsel.
- (3) Meals
 - (a) Vendors are prohibited from directly supplying meals, food, snacks or other food items to University Personnel. The exceptions to this rule are:

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- (i) A modest meal as part of an event that grants CME or other continuing education credit when the event is sponsored by the vendor. This does not include departmental Grand Rounds or other University sponsored CME/CE events that are officially sponsored by a Department but that may have some funding support from a vendor corporation.
 - (ii) A meal in conjunction with an individual’s role as an advisor or consultant to a Vendor Corporation.
- (b) The University, an individual College or Department is allowed to provide meals, food, snacks or other food items to University Personnel at any time in accordance with applicable University policies. The source of funding for such food may be a donation from a vendor or Vendor Representative but the University, College or Department must be responsible for providing and paying for the food.
- (4) Vendor Sponsored Events
- (a) University Personnel 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) University Personnel are prohibited from receiving payment or gifts in exchange for attendance as an audience member at any event.
 - (c) University Personnel are 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, and

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- (iii) The item is provided to all conference attendees.

- (d) 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 University 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 University Department and not by the vendor.

- (e) Vendor Sponsorship
 - (i) If a vendor is interested in providing support to the University and individual College or Department to underwrite an educational event or conference (including the purchase of food), the vendor should make a monetary donation to the University, individual College, or Department to facilitate the event.
 - (a) The planning and coordination of the event must remain under control of the University; individual College or Department that is sponsoring the event.
 - (b) The donated funds must remain under the control of the University, individual College or Department that is sponsoring the event.
 - (c) The University, individual College or Department 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.
 - (d) At the discretion of the leader of the administrative unit responsible for the event, Vendor Representative(s) from the entity providing support for the event may:

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- (i) Attend the event;
 - (ii) Be introduced/recognized at the event;
 - (iii) Set up a table in an area adjacent to but separate from the educational event where he/she may distributed marketing or scientific literature;
- (e) Vendor Representatives from the entity providing support may not:
- (i) Distribute any gifts or meals, beverages, snacks, candy or other food items;
 - (ii) Conduct any marketing or commercial activities within the room where the educational event is occurring.
- (f) Vendors are prohibited from providing funds directly to any University Personnel to attend any CME or other continuing education event (with the exception of section G below). Vendors wishing to provide support for a specific CME or other continuing education event or program should make a donation to the University's individual College or Department that is the sponsor of the event to reduce the cost for all attendees.
- (ii) In the case of students, and other trainees, a vendor may provide support for one or more individual trainees to attend an educational conference with the following stipulations:
- (a) The individual(s) chosen to attend the event must be chosen by the Associate Dean of Academic Affairs or other

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official designated by the University in which the student is enrolled.

- (b) The Associate Dean of Academic Affairs or other official designated by the University in which the student is enrolled must approve the educational conference that is being attended to ensure that the conference is of substantial value to the trainee's education.
 - (c) The student chosen and the program must also be approved by the Chief Student Affairs Officer.
 - (d) The funding support must be directed to the University's Office of Student Affairs which will then either pay for the expenses or reimburse the individual(s) for the expenses related to attending the event.
- (iii) Consulting, Speakers' Bureaus and Other Business Arrangements
- (a) University Personnel may serve as paid consultants or advisors to Vendor Corporations in accordance with this and other applicable University policies, on work outside the University.
 - (i) University Personnel 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).

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- (ii) Any paid advisory or consulting relationships must be disclosed by University Personnel in the course of leading any educational activity for University students, 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 by University Personnel through the annual University research conflict of interest disclosure process and should be discussed directly with the individual's unit leader.
- (iv) Consulting or advisory relationships should be entered into by University Personnel 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.
- (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.

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(A) If this agreement is between the vendor and the individual, all aspects of the University Consultation and Conflict of Interest Policies apply.

(1) The agreement with the vendor must be produced by University Personnel if requested by a Department Chair or University Senior Administrator.

(2) The individual must report to the University Vice President for Research and the University General Counsel if any intellectual property will be created as a part of this activity.

(B) If this agreement is between the vendor and the University, the document should be reviewed and approved in advance by the Office of the University General Counsel.

(C) University Personnel serving as a paid consultant, advisor, etc. for a vendor should comply with University policies regarding the requirement to use appropriate leave time for these activities when required.

(f) Speakers' Bureau and Educational Events

(i) University Personnel are permitted to participate in a vendor-sponsored speakers' bureau or other educational events only:

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- (a) When the presentation is to be made in an academic setting (e.g. grand rounds, visiting professor, guest lecturer etc. at an academic medical center or other teaching hospital), or
 - (b) At any event granting CME/CE credit regardless of the location, or
 - (c) 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 University Personnel must have been prepared by the University Personnel. Use of slides or other vendor-prepared educational materials by the University Personnel is not permitted with the exception of FDA-approved slides that are mandated for use when discussing a specific product.
 - (iii) University Personnel may receive an honorarium or speaker fee for lecturing in a permitted vendor sponsored or supported educational event as defined in this Policy.
 - (a) If the event occurs in an academic setting (i.e., an academic medical center, teaching hospital, etc.), the honorarium or speaker fee must be from the academic institution.
 - (b) If the event occurs as a part of a CME/CE event, the honorarium or speaker fee must be from the organization sponsoring the CME/CE event.

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- (iv) University Personnel 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) University Personnel 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.
- (g) "Token consulting" arrangements are strictly forbidden.
 - (i) "Token consulting" arrangements are agreements to pay University Personnel for consulting or advising a vendor corporation when either:
 - (a) No substantive work is done on behalf of the vendor, or
 - (b) The work done for the vendor is not commensurate with the amount of compensation provided by the vendor, or
 - (c) When the compensation is not at fair market value as determined by acceptable benchmarks (e.g., AAMC faculty or MGMA practicing physician salary benchmarks).
 - (d) If there are any concerns that a consulting arrangement could be considered "token consulting," please consult the Office of the University General Counsel for further review.

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(ii) Ghost-writing of publications, abstracts, case reports or other scholarly work by Vendor Representatives on behalf of University Personnel is strictly prohibited. University Personnel should be aware of published guidelines in the medical literature regarding taking credit for authorship of an article, abstract, or other scholarly work.

(h) Promotional Materials

(i) 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 University owned or operated in patient or outpatient site.

(ii) University Personnel 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.

(iii) Promotional materials that are product-specific or that directly market a vendor's products may be distributed to patients:

(a) Only after they have been reviewed specifically by the University Department to ensure that they are generally complete and accurate regarding the vendor's product, and

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

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- (c) By University Personnel and not directly by Vendor Representatives.

- (iv) 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.

- (i) Samples
 - (i) Industry sales representatives are not permitted in University Facilities without approval from the respective College Deans or designees. If approved, vendor sales representatives are escorted to the proper venue by a member of the University staff.
 - (ii) 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 below.
 - (a) In an attempt to minimize the need for samples:
 - (i) Vendors are encouraged to provide vouchers to clinical units or clinics within the University 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.
 - (ii) Prescribers are encouraged to prescribe generic medications for those patients who cannot easily afford prescription medications and in those

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clinical situations when a generic medication is appropriate for the patient's condition.

- (iii) If members of a clinical Department in a facility owned or operated by the University believe that their clinical practice requires the continued use of medication samples for a specific medication or for a special patient population, they may apply to the Dean of the College in which the Department is located for an exception to this rule. As a part of that approval, the Department will be required to annually report the following to the Dean:
 - (a) All medications will be under the control of a registered pharmacist or medical director of the clinic and dispensed in accordance with State Board of Pharmacy guidelines.
 - (b) The medication samples that are routinely stocked in the clinic,
 - (c) The process for ensuring the proper storage, security and distribution for samples.
 - (d) The process for monitoring the expiration dates on medication samples, and
 - (e) The process for the documentation of distribution to patients.
- (iv) 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.
- (j) Conflict of Interest in Purchasing Decisions

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- (i) Any University Personnel 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.

- (ii) This conflict of interest should be disclosed in writing to the University Personnel’s Immediate Supervisor, and Department Chair as well as to the applicable staff from the purchasing department.
 - (a) The individual’s Immediate Supervisor is required to review the conflict of interest with the Department Chair. If the conflict of interest is significant or cannot be managed appropriately in the opinion of the Immediate Supervisor or the Department Chair or the purchasing department, the individual must remove him/herself from the process.

 - (b) Individuals must report existing conflicts on an annual basis to the Immediate Supervisor, Department Chair and Dean as part of the annual evaluation process.

 - (c) If additional assistance is needed to evaluate the conflict of interest, the University General Counsel, the Vice President for Administration and Finance and the Vice President for Research are additional resources that can be utilized.

- (iii) If University Personnel are in any position to materially benefit from the University relationship with the vendor or if the conflict is deemed too significant by either the Purchasing Department or the individual’s Immediate Supervisor to be managed

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appropriately, the individual must immediately remove him/herself from any further discussions, meetings or negotiations.

- (iv) Any University Personnel who are 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.
 - (v) Communication between University Personnel 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.
 - (vi) All costs related to meals, travel, lodging, etc. for meetings, site visits, or other activities related to a purchasing decision must be covered by University Department and not the vendor unless explicitly approved by a senior administrator at the University.
- (k) Conflict of Interest in Research
- (i) Individual Medical Center staff members involved in any form of research should be generally familiar with and compliant with any applicable University Policies that govern conflicts of interest in research.
 - (ii) Funding or other support for research from vendors may be received in accordance with applicable, University Policies that govern industry-funded research.
 - (iii) As a part of the IRB approval process, University Personnel must disclose to the IRB any financial conflicts regarding the research they are undertaking according to applicable University Policies.

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- (iv) As a part of the IRB approval process, University Personnel 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.

- (l) Non-compliance
 - (i) Department Chairs are charged with ensuring that all University Personnel (e.g., faculty, staff, trainees, etc.) in their Departments are educated about this Policy.

 - (ii) Reporting of potential non-compliance with this Policy may be done through a variety of mechanisms.
 - (a) Report directly to the Vice President for Research;

 - (b) Report directly to the Vice President for Administration and Finance;

 - (c) Report directly to the University General Counsel.

 - (iii) Determination of non-compliance and disciplinary action: Determination of non-compliance will be done with the cooperation of the applicable administrative, academic, research and/or clinical Department 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 Dean, the Vice President for Administration and Finance, Vice President for Research, or University General Counsel.

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- (iv) 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 University policies. Non-compliance may result in actions including, but not limited to,
 - (a) A warning,
 - (b) A temporary suspension of access to the University,
 - (c) Permanent revocation of the individual vendor representative's access to the University, or
 - (d) Complete termination of business with the vendor corporation.

- (v) University Personnel 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 University 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 who duties include vendor interaction, or

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- (e) Termination;
- (f) Any disciplinary action may be appealed in accordance with applicable University HR policies and through a process that is based on the individual’s status within the University (i.e., student, faculty, administrative staff, trainee, etc.).