



# TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

## Operating Policy and Procedure

### **HSCEP OP: 52.16, Vendor Interactions**

**PURPOSE:** The purpose of this Health Sciences Center El Paso Operating Policy and Procedure (HSCEP OP) is to maintain the integrity of Texas Tech University Health Sciences Center El Paso's (TTUHSC El Paso) educational and research programs, and clinical decision making by providing guidance on acceptable interactions between TTUHSC El Paso faculty, residents, staff, students and trainees and vendors (as defined below) to optimize the benefits of such interactions and foster compliance with applicable federal and state laws, while minimizing the risk of actual or perceived conflicts of interest.

**REVIEW:** This HSCEP OP will be reviewed on May 1 of each odd numbered year (ONY) by the TTUHSC El Paso Institutional Compliance Working Committee, with recommendations for revisions submitted to the Institutional Compliance Committee by July 1.

### **DEFINITIONS:**

**Gift** means a tangible item received directly from a vendor. Gifts include any benefit or remuneration, including, but not limited to, cash, meals, checks, coupons, securities, discounts, pre-bates, rebates, subsidies, real property, personal property, referrals, goods, prizes, services, promotional items, tickets, travel, lodging, or anything else that has value to the person receiving it. It does not include items such as product brochures, fact sheets, article reprints, and bibliographies. This list is provided as examples only and is not intended to be comprehensive.

**Educational Conference or Meeting** as defined by the AMA Council on Ethical and Judicial Affairs<sup>1</sup> is any activity held in an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational topic(s) should be the focus of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support of conflict of interest should be made at the beginning of the conference or meeting.

**Financial Interest** includes, but is not limited to equity ownership, compensated positions on advisory boards, paid consultancy or other forms of compensated relationship. It does not include indirect ownership, through mutual funds or other investment vehicles in publically traded companies.

**Vendor** is any individual or company that sells or markets services or items to TTUHSC El Paso and/or its patients, including, but not limited to pharmaceutical companies and their representatives, device or durable medical equipment (DME) manufacturers and their representatives, and equipment and/or service providers, and their representatives, Information Technology/Software Solution companies and their representatives, Office Supply companies and their representatives or any other company or individual that would receive a payment for goods or services provided to TTUHSC El Paso (this excludes employment relationships).

### **GENERAL BACKGROUND:**

Interactions between TTUHSC El Paso faculty, staff, employees and vendors occur in various and unique ways, especially in the academic setting and when properly managed and monitored can benefit public health and education. However, those interactions must be conducted in such a manner as to advance drug discovery, technology development, improving public health and

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<sup>1</sup> See AMA Opinion 8.061

forwarding the mission of TTUHSC El Paso while maintaining the public trust.

As a health care provider and state agency, TTUHSC El Paso, its faculty, residents, staff, and students, are subject to federal and state laws, [Texas Tech University System \(TTU System\) Regents' Rules \(Regents' Rules\)](#) and institutional policies that govern our interactions with vendors.

The American Association of Medical Colleges' (AAMC) Task Force report<sup>2</sup> provides further guidance on policies to manage, and where necessary, prohibit academic-industry interactions that can inherently create conflicts of interests and undermine standards of professionalism.

## **POLICY/PROCEDURE:**

1. **General.** TTUHSC El Paso clinical and academic activities are carried out at multiple campuses and affiliated entities. In all cases where this policy is more restrictive than a TTU System or TTUHSC El Paso conflict of interest policy, this policy shall control. When faculty members, residents or students are in affiliated entities (i.e., hospitals), they should abide by this policy or the affiliated entity's policy, whichever is stricter with respect to a particular action in question.

To the extent that certain interactions with vendors are prohibited in this policy, they are also prohibited when conducted outside the confines of the TTUHSC El Paso campuses, sites and/or facilities and affiliated entities.<sup>3</sup>

2. **Conflicts of Interest and Disclosure**

- a. [Texas Government Code, Section 572, Subchapter A, Section 572.001](#) prohibits any state officer or employee from, having a direct or indirect interest, financial or otherwise, engaging in a business transaction or professional activity, that is in substantial conflict with that individual's duties in the public interest. See also [TTU System Regents' Rule 03.01, Personnel Ethics Policy, TTUHSC El Paso OPs 52.06, Standards of Conduct and Ethics Guide, 73.09, Financial Conflicts of Interest in Research, and 70.18, Dual Reporting and Multiple Employment](#), which may also apply to interactions between vendors and TTUHSC El Paso faculty, residents, and staff.

- b. Any faculty member or employee who recommends or approves the purchase of a vendor's product for TTUHSC El Paso or its affiliated hospitals shall not have a consulting relationship with or serve on the Advisory Board of that vendor for the 12-month period prior to and after the recommendation or approval of the purchase. See also [Regents' Rule 03.01, Personnel Ethics Policy](#).

- c. As required by [73.09, Financial Conflicts of Interest in Research](#), individuals involved in research activities are required to make an annual report of their financial interests as defined in that policy.

3. **Compensation or Gifts from Vendors.** The Federal Anti-Kickback statute makes it a crime to knowingly and willfully solicit, receive, offer or pay, overtly or covertly, directly or indirectly anything of value in cash or in kind in exchange for the referral of patients, items or services payable by a federal health care program. A gift can be improper if it is made to someone in a position to generate referrals (i.e., prescribe drugs or durable medical equipment) or if the payment represents more than fair market value.

- a. No personal gifts shall be sought or accepted by TTUHSC El Paso faculty, residents, staff or students from vendors.

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<sup>2</sup> Industry Funding of Medical Education, Report of an AAMC Task Force, June 2008

<sup>3</sup> See Regents Rule 03.01

- b. Faculty, residents, staff, and students shall **not** seek or accept compensation or gifts from vendors for prescribing, or changing a patient's prescription, using or purchasing a specific device or equipment, or for the referral of patients to a provider of health care services or items (i.e., hospital, hospice, nursing facility, etc.).
  - d. Faculty, residents, staff, students, schools and departments shall **not** seek or accept compensation or gifts, including meals, from vendors for listening to sales presentations or talks about their products (i.e., detailing) by the vendor.
  - e. Compensation or gifts from vendors given as a grant for research or studies of products when the research or studies require little or no actual scientific pursuit shall **not** be sought or accepted. An example of an unacceptable "research grant" is one that only requires minimal record keeping.
  - f. No compensation or gift shall be sought or accepted from a vendor by any TTUHSC El Paso faculty, resident or staff who has or may have a substantive role in the selection of that vendor to provide items or services (including DME) under contract to TTUHSC El Paso or its affiliated hospitals.
  - g. No compensation or gift shall be accepted in exchange for conducting marketing tasks during the course of providing health care, research and/or development services. For example, no one shall accept compensation or gifts from a vendor to complete an evaluation form after using a health care item or product.
  - h. Prescription pads from vendors shall not be accepted.
  - i. No compensation or gift from a vendor raffle, lottery or contest shall be accepted.
4. **Travel, Lodging, Meals and Conference Fees Provided by Vendors**
- a. Faculty, residents, staff, students and/or Departments shall not seek or accept any compensation or reimbursement for travel to and/or attendance at, sporting or entertainment events, all-expense paid trips to vacation resorts, or similar entertainment activities from vendors.
  - b. Conferences.
    - i. Faculty, residents and staff may accept reasonable honoraria and reimbursement for travel, lodging, meals and conference fees for their attendance at educational conferences or meetings, including those related to research activity, only if the individual presents his/her own educational materials, serves as a panel discussion participant, panel moderator, or otherwise actively participates in the conference or meeting. Participation in the event must be more than merely perfunctory and the presenter must determine his/her own lecture content, prepare his/her own materials (including slides and handouts), and present a balanced assessment of the topic being presented. The terms of the arrangement must be in writing and all compensation must represent fair market value. Acceptance of honoraria must be consistent with Texas laws and TTUHSC El Paso policies.
    - ii. Faculty, residents and staff who are only attendees at conferences cannot accept either honoraria or reimbursement for travel, lodging or meal expenses directly or indirectly from any vendor. Token consulting or advisory arrangements cannot be used to justify receipt of honoraria or reimbursement for travel, lodging, meals and/or conference fees.

- iii. Faculty, residents and staff may accept vendor reimbursement for travel, lodging, and meals to attend meetings to act as a “bona-fide” consultant or participate in panels regarding development of new research protocols, to discuss research results or to participate in a conference to understand requirements for future research activities in which the person is involved.
  - iv. No compensation or gift shall be personally sought or accepted by faculty, residents or staff on behalf of such individual from a vendor for attendance at any conferences or meetings where the individual is not lecturing, presenting or otherwise actively participating in the conference or meeting. This policy does not prohibit attendance at conferences or meetings, but only prohibits accepting compensation or benefits from vendors solely to attend a conference or meeting, whether or not it is an educational or research conference or meeting. This policy does not prohibit acceptance of modest meals (comparable to the meal allowance specified by the United States Internal Revenue Service) included as part of the conference fee paid by the individual and/or TTUHSC El Paso or by the vendor as allowed under this policy.
- c. Meals for TTUHSC El Paso Educational Events.
- i. Continuing Education Sponsored Events. Meals for TTUHSC El Paso accredited continuing education (CE) programs shall only be provided through the applicable continuing education office.
  - ii. Non-Continuing Education Sponsored Events. Meals provided by vendors for non-accredited educational meetings shall be modest and must be coordinated with/by TTUHSC El Paso Schools or Departments and only at the request and approval of the designated faculty representative in the School or Department. The vendor shall not select the speaker and shall not be allowed to discuss its product(s) as part of the content of the educational meeting. Content for such events shall be “peer reviewed” and/or publishable material. Any promotional materials to be made available by the vendor at such activities must be reviewed and approved by the designated faculty.
5. **Health Care Vendor Representative Access to TTUHSC El Paso Campuses, Sites and/or Facilities**
- a. TTUHSC El Paso has entered into an agreement with Vendormate, Inc. (“Vendormate”) to provide registration, screening and credentialing of Health Care vendors subject to this policy. Any Health Care vendor seeking access to TTUHSC El Paso facilities, clinics, faculty or residents shall register with Vendormate before their representatives are allowed onto a TTUHSC El Paso campus, site, or facility. As part of this registration process, the Health Care Vendor shall receive information on this policy and other relevant policies based on the Health Care Vendor’s registration tier/level. Health Care Vendors with access to patients (i.e., involved in patient care activities at TTUHSC El Paso) shall be designated at the highest registration tier through the Vendormate service.
  - b. In coordination with the TTUHSC El Paso Institutional Compliance Officer, Vendormate may provide additional Vendor Program awareness/education to TTUHSC El Paso leadership and employees.
  - c. Each TTUHSC El Paso campus shall provide at least one central location for Health Care Vendors to register and receive an access badge to TTUHSC El Paso facilities where patient care activities are conducted.
  - d. Health Care Vendors are required to check-in and receive a Health Care Vendor ID badge each time they enter a TTUHSC El Paso facility, clinic, office and/or department. A

Health Care Vendor who fails or refuses to check-in and/or clearly display their ID badge will be directed to the check-in area or asked to leave.

- e. Health Care Vendors shall only have access to TTUHSC El Paso campuses and facilities during normal business hours or during scheduled on-site educational conferences or meetings.
- f. Health Care Vendors shall not have access if the purpose is to interact with students and/or residents or fellows about their products without a TTUHSC El Paso faculty member present.
- g. To maintain patient confidentiality under HIPAA, Health Care Vendors are limited to administrative areas such as physicians' administrative offices, department offices, conference rooms, public areas and other non-patient care areas. In those cases where it is not possible to directly access administrative areas, the Health Care Vendor shall be escorted through patient areas to access the administrative areas. Health Care Vendors are only allowed in patient care areas for:
  - i. required training on new equipment or devices that have been purchased by TTUHSC El Paso, setting up such equipment, or similar activities associated with the contract as approved by TTUHSC El Paso; or
  - ii. evaluation of new uses for equipment, devices, or related items.

In these cases, the Health Care Vendor shall execute an appropriate Business Associate agreement [See HSC OP 52.13, HIPAA Business Associate Agreement Policy.](#)

- h. Health Care Vendors shall not attend any conferences or meetings at TTUHSC El Paso facilities where patient specific information (i.e., the information is not de-identified) or quality assurance activities are being discussed.
- i. In limited circumstances related to delivery of patient care (i.e., use of new equipment), a Health Care Vendor may be present during treatment, only if the patient has been informed and provided written consent to their presence, and a HIPAA Business Associate Agreement has been signed, and then only to provide in-service training or assistance on devices and/or equipment that has been purchased or is under consideration for purchase by TTUHSC El Paso. The Health Care Vendor shall not provide patient care at TTUHSC El Paso campuses, sites and/or facilities.

## 6. **Drug, Equipment and Medical Device Samples**

- a. No drug, equipment or medical device samples shall be accepted for personal use of faculty, residents or staff employees or their family members. Samples of drugs, equipment or medical devices shall only be accepted if they are used for patient care or education, or student educational purposes. Patients shall only be given sample drugs to determine efficacy to treat the patient's condition.
- b. No drug, equipment or medical device sample shall be billed to any patient or third-party payer, including, but not limited to, government payers or private insurers. Free drug, equipment or medical device samples shall never be sold.
- c. Sample drugs shall be stored in a secure and locked location within the Department or Division or in a central campus location. Expired sample drugs shall be disposed of in accordance with state and federal law. See [Sample Drug Control Policy 4.2.](#)
- d. Sample drugs, equipment and medical devices shall be tracked when given to a patient in a log, indicating the date of it was given to the patient, the patient's name or medical

record number, and the lot number of the sample drug(s), or identifying number of the equipment or medical device(s) given to the patient. The lot number of sample drugs shall be noted in the patient's medical record at the time it is given to the patient.

**7. Funding of Continuing Education Programs at TTUHSC El Paso by Health Care Vendors**

- a. No faculty, resident, staff or employee, School and/or Department shall accept or receive any subsidy from a Health Care Vendor to support the cost of continuing education provided at or through TTUHSC El Paso. All funding from Health Care Vendors in support of continuing education programs at or through TTUHSC El Paso shall be in accordance with applicable accrediting agencies and shall only be made to the appropriate continuing education office at TTUHSC El Paso.
- b. For continuing education activities not using the accreditation of internal TTUHSC El Paso continuing education departments, funding mechanisms and channels must be reviewed and approved by the appropriate school's continuing education department or appropriate individual designated by the Dean of each School, for compliance with accepted accreditation practices.

**8. Consulting Honoraria from Health Care Vendors**

- a. Consulting honoraria shall only be accepted in accordance with [Regents' Rule 03.01.4; HSC OP 70.18, Dual Reporting and Multiple Employment](#) and any applicable practice plan by-laws regarding income-generating activities. (See also TTUHSC El Paso CME policy regarding honoraria for TTUHSC El Paso CME activities) All arrangements must be in writing and represent fair market value for actual work performed by the faculty, resident or employee and approved by the faculty member's immediate supervisor.
- b. Payment or compensation from Health Care Vendors for token consulting or advisory arrangements shall not be accepted.
- c. Faculty, staff, residents and students shall not accept honoraria or any other type of payment for presenting at events where the content and/or materials, including slides (in whole or in part) have been prepared by or on behalf of a Health Care Vendor.

**9. Health Care Vendor Support for Scholarships, Fellowships or other Trainees**

- Scholarships or subsidies from Health Care Vendors to permit students, residents and fellows to attend carefully selected educational conferences or meetings (i.e., major educational, scientific or policy-making meetings of national, regional, or specialty medical, nursing, pharmacy or allied health associations) may be permissible as long as:
- the funds are provided to the School, Department, Program or Division and not directly to the student, resident or fellow;
- Nothing is given in return for the scholarships or subsidies;
- the selection of students, residents or fellows who receive the funds is made by the Dean or Department;
- the educational conference or meeting does not solely address the Health Care Vendor's products; and
- it is otherwise consistent with any continuing education requirements.

**10. Ghostwriting and Speakers Bureaus**

- a. Faculty, staff, residents and students shall not publish articles under their own names that are written in whole or in part by Health Care Vendor employees, contractors or representatives (i.e., "ghost-written"). The International Committee of Medical Journal Editors guidelines should be followed in determining the criteria for being listed as an author on any publication.

- b. Faculty, staff, residents and students may participate in, or receive compensation for, speaking engagements, provided **ALL OF THE** following exist:
- The event meets the criteria of Section 2 above;
  - The lecture content or presentation materials (including slides and handouts) are prepared by the speaker and is not subject to prior approval by either the Health Care Vendor or its representatives, including, but not limited to event planners contracted by the Health Care Vendor;
  - The lecture content, including slides and handouts, is based on the best available scientific evidence;
  - The Health Care Vendor does not directly or indirectly select the attendees or provide any honorarium to attendees; and
  - The speaking arrangement is not long term (more than 12 months).

11. **Response to Non-Compliance**

- a. Non-compliance with this policy should be reported to the appropriate Dean or the Institutional Compliance Officer. Alternatively, reports can be made through the TTU System Compliance Hotline at 1-866-294-9352 (toll-free) or the web at [www.ethicspoint.com](http://www.ethicspoint.com),
- b. Alleged violations of this policy by TTUHSC El Paso faculty, residents, staff, or students shall be investigated by the Institutional Compliance Office. Suspected violations involving faculty, residents, or staff shall be referred to the individual's Dean or Department Chair, who shall determine what actions, if any, shall be taken in accordance with TTUHSC El Paso policies. Suspected violations involving students shall be reported to the Dean of Students for the School in which the student is enrolled. Violations of this policy may result in one or more of the following, depending on the seriousness of the violation, whether the violation is a first or repeat offense, whether the individual(s) knowingly violated the policy or attempted to hide the violation:
- Counseling;
  - Additional education/training regarding this policy;
  - Written reprimand;
  - Suspension of future relationships between the individual(s) involved in the violation and vendors for a set period of time;
  - Return of any gifts or compensation received in violation of this policy or related TTU System and TTUHSC El Paso policies;
  - Termination for cause.

Any disciplinary action taken under this policy shall follow established TTUHSC El Paso procedures.

- c. Violations of this policy by vendors or their representatives shall result in one or more of the following actions by the Institutional Compliance Officer:
- Verbal warning to the representative;
  - Written warning to the representative and vendor;
  - Written notice to the Health Care Vendor that badge access is terminated and its representatives are no longer allowed on TTUHSC El Paso campuses, sites or facilities for purposes of selling or marketing their services or items.

12. **Right to Change Policy.** TTUHSC El Paso reserves the right to interpret, change, modify, amend or rescind any policy in whole or in part at any time without the consent of workforce, but may seek input, where appropriate.