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| | <p>Category: UTRGV Division of Health Affairs Policy Number: Effective Date: November 4, 2018 Last Review/Revision Date: New</p> <p>Page 1 of 7</p> |
| <p>Title: Interaction with Industry/Conflict of Interest</p> | |
| <p>Regulatory Compliance:</p> | |

PURPOSE

This policy establishes expectations for interactions between Industry and members of the academic and clinical communities in the UTRGV Division of Health Affairs, including faculty physicians and other health providers employed by the University of Texas Rio Grande Valley School of Medicine (UTRGV SOM) and all activities operated under the branding of UT Health Rio Grande Valley (UT Health RGV).

The goal of this policy is to foster a culture in which faculty, staff, residents, students, and other learners exercise independent and ethical judgment in all their activities and practice evidence-based, cost-effective medical care.

Scope

All faculty, residents, staff, students, other learners, and volunteers of the UTRGV Division of Health Affairs, including the UTRGV SOM.

This policy does not limit or substitute for related institutional policies such as those on conflict of commitment and conflict of interest, continuing medical education (CME), philanthropy, purchasing, etc. However, to the extent this policy is more stringent than related institutional policies, this policy will govern.

Definitions

1. Commercial Interest – any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.
2. Conflict of Interest - a situation in which an individual’s financial, professional, or other personal considerations may directly or indirectly affect, or have the appearance of affecting, the individual’s professional judgment in exercising any UTRGV duty or responsibility.
3. Academic Unit – for the purposes of this policy, any UTRGV academic entity whose organizational structure reports to the President, Executive Vice President for Health Affairs, or Health Affairs Dean (e.g. is a UTRGV School, Program, Institute or Department)
4. Faculty - for the purposes of this policy, any person possessing either a full- or part-time compensated academic appointment in the Division of Health Affairs, including the UTRGV SOM, and to include faculty-level research appointees, faculty librarians, health system clinicians, and contributed service faculty.

5. Gifts - For purposes of this policy, a gift is defined as any item, product, or service of any value. The term includes, but is not limited to, pens, notepads, mouse pads, memory sticks, article reprints, coffee mugs, meals and entertainment, travel, food, cash, equity or other ownership interest.
6. Industry – for the purposes of this policy, industry refers to any for-profit entity that develops, produces, markets or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate illness or improve health.

POLICY

All employees and students within the UTRGV Division of Health Affairs, employees operating through UT Health RGV, including UTRGV School of Medicine, School of Nursing, School of Social Work, and College of Health Professions faculty, staff, residents, students, and other learners will be expected to interact with Industry in an ethical manner to avoid or minimize perceived or actual conflicts of interest allowing for the exercise of independent judgment in all activities and practice of evidence-based, cost-effective medical care independent and free of commercial bias.

When conflicts of interest do arise, they must be minimized to the extent possible and effectively managed. If a situation raising questions of Conflict of Interest arises, faculty, staff, residents, students, trainees, and volunteers must discuss the situation and seek resolution with their supervisor, academic unit director, Dean, Division of Health Affairs Office, the Executive Vice President for Health Affairs, or the UTRGV Office of Institutional Compliance.

The following addresses specific types of interactions with Industry:

1. Gifts to Individuals
 - A. Faculty, staff, employees, residents, students, trainees, and volunteers may not accept from Industry any gifts or entertainment (see below for food and meals), regardless of value. For the purposes of this policy, there is no minimum value to a gift. Items such as pens, sticky notes, coffee mugs, etc., are considered gifts.
 - B. Consulting arrangements involving personal compensation without commensurate associated duties are considered gifts and are prohibited. All such consulting relationships must be approved in advance through the Office of the Executive Vice President for Health Affairs.
 - C. Industry promotional items may not be displayed in any UTRGV or UT Health RGV facility, with the exception of formal exhibit areas during an accredited CME activity under rules currently in effect through the Accreditation Council for Continuing Medical Education (ACCME).
2. Gifts for education
 - A. It is permissible to accept medical or scientific books, anatomical models and posters provided the item does not carry the name or logo of a biomedical, pharmaceutical, or medical device company. Gifts for education must be made directly to the University and distributed by faculty/staff without any industry involvement. Academic units may publicly acknowledge the support of specific

companies as long as the acknowledgement is not directed to or referencing a particular activity or program.

3. Food

- A. With certain exceptions, outlined below, industry-supplied food and meals are considered personal gifts and are not be permitted at UT Health RGV sites or in connection with any activity conducted under the auspices of or using the name of UTRGV, the Division of Health Affairs, or any of the Schools, Colleges, or Departments within these units, UT Health RGV, or in the context of professional activity off-site.
- B. Meals sponsored by industry will not be allowed in any UTRGV campus or remote location, including UTRGV-related residency and fellowship programs.
- C. When invited to a small group meal by an industry representative, UTRGV Health RGV faculty and staff must pay for their own food and drink.
- D. Unrestricted financial gifts to the institution (as specified in Section 4) may be used in part to provide food for UT Health RGV personnel; however, the decision to use gift funds to provide food will be made at the sole discretion of the department or division director. As with any unrestricted gift, departments may publicly acknowledge the unrestricted support of specific companies as long as the acknowledgement is not attributed to a particular activity or program. When a company supports a particular lecture or educational event in accordance with this policy, the support must be disclosed and acknowledged as described herein.

4. Unrestricted Gifts

- A. Through unrestricted gifts, industry may support the educational, research, and patient care missions of UTRGV. All unrestricted gifts must come from the appropriate educational unit at the vendor, not from its divisions of sales or marketing.
 - 1) Gifts may be made only to the University or one of its academic units and deposited in an account directed by the UTRGV Advancement Office.
 - 2) There may be no *quid pro quo*, nor any limitations nor conditions placed on gifts that are inconsistent with UTRGV policies and applicable regulations.
 - 3) In-kind gifts (e.g., equipment, software) to the institution may be accepted if they are provided in accordance with applicable policies (e.g., Research Administration, Division of Institutional Advancement) and are reviewed by UTRGV Office of Legal Affairs.
- B. Unrestricted gifts from industry may be used by an academic unit to support faculty and staff education, research, and/or patient education
 - 1) Distribution of the funds will be at the discretion of the director of the academic unit, who will disseminate the criteria for requesting funds to all faculty members in the department.

- 2) In general, any such solicitation for funds must be done by the appropriate officer in each school and with involvement of the UTRGV Advancement Office.
 - 3) All such gifts will be used without acknowledgement of the vendor in any direct materials developed or used for these educational or research activities.
 - 4) Annually, each department or academic unit will submit to the Dean's Office a list of gifts received from industry in the previous 12 months and specific information as to how the funds were used. The Deans of each Health Affairs college or school will submit an annual report to the Executive Vice President of Health Affairs for review and audit.
 - 5) Academic units may publicly acknowledge the unrestricted educational support of specific companies as long as the acknowledgement is not tied to a particular activity or program.
 - 6) When a company supports a particular lecture or educational event in accordance with this policy, the support must be disclosed and acknowledged in all documents pertaining to the event and in such a manner as not to be perceived as an advertisement for the vendor.
- C. Faculty members may accept prizes and awards for scientific or medical achievements from company-supported foundations if the recipient is selected through an established, independent process of scientific review.
- 1) If awarded to support the individual's research, cash awards may be deposited in the academic unit's recipient's discretionary account. For purposes of this policy, prizes and awards are not considered gifts if received through appropriate not-for-profit mechanisms.
5. Industry Sponsored Scholarships and Other Educational Funds for Residents, Students, and Other Learners
- A. Scholarships and other educational funds from industry or not-for-profit organizations substantially supported by industry must be given directly to a UTRGV academic unit.
 - B. There may be no expressed or implied *quid pro quo* for the funds.
 - C. The evaluation and selection of recipients of such funds is the sole responsibility of UTRGV, with no involvement by the donor organization or company except that the Industry donor may direct the scholarship or other educational funds to a particular academic unit at the time the gift is made.
 - D. When such conditions are met, the donor may be acknowledged in appropriate settings.
6. Attendance at Non-CME Events / Outside Activities Funded by Industry
- A. UTRGV Division of Health Affairs faculty, residents, students and staff may attend industry-sponsored events, such as programs that are not certified for CME credit, at their own discretion.

- 1) Faculty, residents, students or staff may not receive any remuneration or gifts in exchange for attendance, including but not limited to the costs, means of transportation or reimbursement for any expenses to attend the program such as food, travel, accommodations, or registration fees.
- 2) Faculty, residents, students and staff who attend non-CME Industry sponsored events must pay all of their own expenses.

7. Speaking at Non-CME Events Sponsored by Industry

- A. UTRGV Division of Health Affairs faculty, residents, students and staff may NOT participate as speakers in outside activities that are promotional and funded by Industry, such as speaker's bureaus, speaker's training programs, and contracted non-CME educational programs.
- B. Faculty members may speak at an industry-sponsored program ONLY IF the program is an ACCME-accredited continuing medical education (CME) program, the faculty member retains full control and authority over professional material that the faculty member presents and does not allow such communications or presentations to be subject to prior approval by any commercial interest other than approval for the use of proprietary information.
- C. Exceptions to this policy may be granted by the UTRGV Executive Vice President for Health Affairs to allow faculty participation in training such as for a new device or procedure under applicable regulations (e.g., FDA-mandated training).
- D. At any such presentation for which the faculty member has received industry payment or support, the faculty member must fully disclose the name of the company and the nature of the support in accordance with conflict of interest policies.

8. Pharmaceutical Samples

- A. Free pharmaceutical samples and vouchers for free samples may NOT be accepted nor left for use in any UTRGV Division of Health Affairs location nor any location or site operated by or affiliated with UT Health RGV. Faculty, residents, students, and staff will inform patients of affordable options for obtaining medicines such as patient assistance programs.
- B. Specific exceptions may be granted ONLY by a designee of the UTRGV Executive Vice President for Health Affairs, and only when (1) sample medications are necessary for the safe initiation of therapy or when (2) samples are necessary for patient education (e.g., instructing patients in the use of inhalers); they may only be accepted provided they do not carry the name or logo of a company. These exceptions will be rare.

9. Site Access by Industry Representatives.

- A. To protect patients, patient care areas and work schedules, access by pharmaceutical, medical testing, device manufacturing, and other industry representatives to individual UT Health faculty, residents or staff MUST be restricted to non-patient care areas outside of the clinical sites. No representatives will be given access to any UT Health RGV clinical location. These types of visits would general be scheduled in the faculty member's academic offices. Access will be permitted ONLY with advanced scheduling of the visit with the UT Health RGV Senior Director of Clinical Operations or designee.
- B. Industry representatives who are qualified healthcare professionals or scientists, such as a vendor's medical liaison, and who wish to provide information on their products may do so if invited by a UT Health faculty member and ONLY in faculty-supervised, structured group settings outside of UT Health RGV clinical sites and locations that provide the opportunity for interaction and critical evaluation.
 - 1) Involvement of residents, students and trainees in such meetings should occur only with direct and continuous supervision by the faculty member who issued the invitation.
 - 2) Industry promotional material may not be used, exhibited or displayed at any UT Health RGV site.
 - 3) At UT Health RGV CME events and in accordance with ACCME regulations, branded materials may be present and used while on site.
- C. Access by Medical Device Industry Representatives will be permitted ONLY upon invitation from UT Health RGV faculty where the purpose of the visit is to train faculty, residents, or staff or evaluate or repair equipment which has already been procured by UT Health RGV. All requests for access must be approved in advance by UT Health RGV's Senior Director of Clinical Operations or designee.
- D. Device or other industry representatives are permitted to be present during patient care interactions ONLY if all of the following conditions are met:
 - 1) the purpose of the representative's visit is to provide in-service training or assistance to UT Health RGV faculty or staff on devices or equipment;
 - 2) there is a formal written agreement between the appropriate UT Health RGV entity and the representative's employer specifying the terms and conditions of the representative's presence, which may not be less restrictive than the conditions outlined in this policy;
 - 3) the representative is appropriately credentialed in accordance with the UT Health RGV facility's credentialing policies;
 - 4) the request for access has been approved in advance by UT Health RGV's Senior Director Clinical Operations or designee; and
 - 5) there has been prior written disclosure to the patient and family that industry representatives may be present in the procedure area. Device or

other industry representatives may be present under these conditions and remain in the exam or procedure room with residents, students, and other learners present in accordance with CMS regulations and UTRGV Division of Health Affairs policies regarding resident/student supervision.

10. Professional Travel

- A. UTRGV Division of Health Affairs faculty, residents, staff, students, and other learners may only accept travel funds from industry under the auspices of an unrestricted educational grant to the institution, as previously described in Section 4, and in the following circumstances:
- 1) for legitimate reimbursement for travel to provide contractual services, such as approved consulting activity,
 - 2) to view capital equipment in situ if the equipment is being considered for purchase by an entity in the UTRGV Division of Health Affairs; or
 - 3) to participate in meetings directly related to ongoing sponsored research.
 - i. Unrestricted gifts to the institution (as specified in Section 4) may be used in part to support travel for UT Health RGV personnel attending professional meetings; however, the decision to use gift funds for travel expenses will be made at sole discretion of a designee of the UTRGV Executive Vice President for Health Affairs
 - ii. Residents, students and other learners may accept travel funds from scientific societies, whether or not industry is the source of funds, provided the society controls the selection of the recipient of travel support.

11. Consulting for Industry

- A. Faculty may participate in non-promotional outside activities with industry, such as providing expert consultation, serving on advisory boards, or participating in data safety monitoring boards for clinical trials, provided:
- 1) payment is at fair market value;
 - 2) the arrangement is governed by a written agreement specifying the service(s) to be provided;
 - 3) the arrangement is pre-approved in accordance with the Outside Employment Policy and through the Office of the Executive Vice President for Health Affairs; and
 - 4) the faculty member discloses his/her relationship as required under UTRGV policies on Conflict of Interest and Commitment.

12. Ownership and Corporate Board Membership

- A. UT Health RGV Faculty and Staff may own equity interests in or serve in

leadership roles (i.e., serving on a Board of Directors) for Industry companies, provided:

- 1) the activity is pre-approved in accordance with the Outside Employment policy and the Office of the Executive Vice President for Health Affairs;
- 2) the vendor does not have a contractual or sales relationship with UTRGV or UT Health RGV;
- 3) a management plan is in place for interactions with patients;
- 4) the interest is disclosed as required under UTRGV policies on Conflict of Interest and Commitment.

Stocks held in mutual funds are exempt from this policy.

13. Disclosure and Acknowledgement

- A. In addition to the required disclosure of financial interests, faculty and staff must disclose all relevant payments from and interests in industry in related presentations and publications and in lectures to students and trainees.
- B. Disclosures are made in writing to the Office of the Executive Vice President for Health Affairs.

14. Ghost-Writing and Responsible Communication Practices

- A. UT Health RGV faculty and staff shall not allow work credited to them for authorship to be ghostwritten (e.g. to be written by a third party for and in the name of another) by Industry representatives or any other party.
- B. Authorship must always be assigned and acknowledged based on standard academic procedures as described by the International Committee of Medical Journal Editors (ICMJE).
- C. When making oral and poster presentations, all UTRGV Division of Health Affairs faculty, residents, students and staff are responsible for the accuracy of the content of the presentations and any slides prepared by others (this does not extend to material taken from peer-reviewed publication).

Consequences of Violating this Policy

Failure to comply with this policy will be managed in accordance with disciplinary policies and procedures as stipulated in UTRGV's *Faculty Handbook* or *Staff Handbook*, as applicable. This handling may result in disciplinary action, up to and including termination of employment or faculty appointment.

References

1. ACCME. Standards for Commercial Support <http://www.accme.org/accreditation-rules/standards-for-commercial-support>

2. ACGME. 2015. Journal of Graduate Medical Education, Medical Schools' Industry Interaction Policies Not Associated With Trainees' Self-Reported Behavior as Residents: Results of a National Survey <http://jgme.org/doi/full/10.4300/JGME-D-15-00029.1?code=gmed-site>

APPROVAL AUTHORITY:

The UTRGV Division of Health Affairs *ad hoc* Workgroup on Industry Relationships recommends this policy for approval to the UTRGV Division of Health Affairs Executive Management Team, the UTRGV Office of Institutional Compliance, and the UTRGV President.

RESPONSIBILITY AND REVISIONS:

It is the responsibility of the UTRGV Office of the Executive Vice President for Health Affairs to review and initiate necessary revisions based on collaboration and input by and through the *ad hoc* Workgroup on Industry Relationships, and approval by the UTRGV Office of Institutional Compliance, and the UTRGV President.

RIGHT TO CHANGE POLICY:

UTRGV reserves the right to interpret, change, modify, amend or rescind this policy in whole or in part at any time to reflect changes in policy and/or law.

APPROVED BY

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