

Thomas Jefferson University
Industry Relationships Policy

Statement of Policy

Topic	TJU Policy
Application to Off-Site Activities	Standards described in this Policy apply to off-site, as well as on-site, activities of Personnel. Application of TJU policies to institutional affiliates to be addressed in the future.
Gifts	All Personnel are prohibited from accepting Gifts funded by Industry, regardless of nature, value or location.
Food	All food or meals furnished directly by Industry are prohibited, regardless of nature, value or location. This prohibition does not apply to food or meals provided as part of a CE Accredited Program or in connection with a properly documented and disclosed Consulting Relationship.
Consulting Relationships (excluding Scientific Research and Speaking)	All Consulting Relationships must be disclosed to the COI Committee (per its annual disclosure process) and are subject to all applicable TJU policies, including the level of review described below. Consulting Relationships must be documented in writing and payment for services must be commensurate to the task. Duration and frequency of Consulting Relationships subject to Conflict of Commitment Policy (draft under review). <u>Value Below \$10,000:</u> Summary of COI disclosure to Chair/Director. <u>Value Between \$10,000 and \$50,000:</u> Summary of COI disclosure to Chair/Director and Dean; COI Committee approval. <u>Value Above \$50,000 or Relationship Implicates Significant Institutional Interest:</u> Summary of COI disclosure to Chair/Director; Dean and University Counsel review; COI Committee approval.
Speaking Relationships	Personnel are prohibited from participating, either as a speaker or organizer, in Promotional Speaking Relationships, except as part of a CE Accredited Program. All speaking relationships engaged in by Personnel are subject to applicable governmental (<i>e.g.</i> , FDA), professional and, where applicable, CE Accreditation Standards. All paid speaking relationships must be disclosed to the COI Committee (per its annual disclosure process) and are subject to all applicable TJU policies, including the level of review described below. The duration and frequency of speaking relationships is subject to the TJU Conflict of Commitment Policy (draft under review). <u>Value Below \$10,000:</u> Summary of COI disclosure to Chair/Director. <u>Value Between \$10,000 and \$50,000:</u> Summary of COI disclosure to Chair/Director and Dean; COI Committee approval. <u>Value Above \$50,000 or Relationship Implicates Significant Institutional Interest:</u> Summary of COI disclosure to Chair/Director; Dean and University Counsel review; COI Committee approval.
Disclosure of Relationships	Personnel are required to disclose financial arrangements with Industry (<i>e.g.</i> , consulting relationships, speaking relationships, research grants) through the COI Committee's internal annual disclosure process and to disclose such relationships to patients, students and trainees and in other contexts when the relationship might

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	represent an apparent or perceived conflict of interest.
Pharmaceutical Samples	Industry samples are permitted in JUP physician practices in accordance with JUP Detailing and Sample Management Policies. These policies address site access and permit industry representatives to furnish samples to individual practices through designated practice personnel (<i>i.e.</i> , centralized management of samples at practice level).
Purchasing & Formularies	Formulary committees and committees overseeing purchases of equipment or devices should exclude those who have a financial relationship with an Industry member whose product is under consideration. This exclusion may be specific to participation in particular decisions for which the committee member has a conflict of interest. There is no prohibition on expert clinicians advising a committee, provided that potential conflicts are disclosed, nor is there a prohibition on indirect financial interests in manufacturers, such as mutual fund investments.
Site Access by Pharmaceutical Representatives	<p>Pharmaceutical representative access to JUP physician practice sites is permitted in accordance with JUP Detailing and Sample Management Policies. These policies permit representative access to JUP sites by appointment only and only in designated areas.</p> <p>[Note: TJUH Policy No. 114.10 (eff 1/1/2005) governs pharmaceutical representative access to TJUH property. Pharmaceutical representatives are required to register and sign-in with the TJUH Pharmacy. Detailing is prohibited in patient care areas and is permitted in private physician offices, outpatient service areas, Atrium, Health Science Center and 1st floor Gibbon.]</p>
Site Access by Device Representatives	<p>Training for physicians or other healthcare professionals by device representatives is permitted, upon demonstration of appropriate rationale and written approval by the Chair/Director. Representatives must be qualified and sign a confidentiality agreement. No compensation may be provided to the physician or other healthcare professional in connection with the training.</p> <p>[Note: TJUH Policy No. 102.51 (eff. 1/2/2007) governs device industry representative access to procedural areas.]</p>
On-Site Education Activities	<p><u>CE Activity:</u> All on-site CE activity must comply with CE Accreditation Standards and be overseen through Jefferson Medical College Office of Continuing Medical Education (OCME) or such other Jefferson office as may be designated to provide CE credit for the applicable professional discipline. Requests for Industry support of CE activity must follow guidelines established by the applicable Jefferson CE office. Industry support for CE activity is permitted through unrestricted grants. The applicable Jefferson CE office must be the provider of CE credits for any Industry-supported CE program where the “Jefferson” name is used to promote the program, other than in the title of a program faculty member.</p> <p><u>Non-CE Activity:</u> Industry may contribute unrestricted funds to a central fund managed in the applicable Dean’s Office or by the Jefferson Foundation, which pools and disburses funds for programs that are independent of Industry input or control. Industry may also provide support for specific educational programs that are conducted under the oversight of TJU ORA and consistent with CE Accreditation Standards, even if CE credit is not issued.</p> <p>All other direct Industry support to School or College Departments (including for departmental meetings, grand rounds and other educational and professional activities) is prohibited. No TJU or JUP facilities may be used to house Industry-sponsored educational activities involving presentations by Jefferson or non-Jefferson faculty functioning as part of a Promotional Speaking Relationship.</p>

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Industry Support for Scholarships & Educational Funds for Trainees	<p>See above re unrestricted Industry support for educational activities.</p> <p>See below re trainee scholarships. This Policy does not apply to Industry support for scholarships covering TJU tuition or for fellowships, provided that such support is furnished under the auspices of the Jefferson Foundation.</p>
Compensation for Travel or Attendance at Off-Site Lectures & Meetings	<p>Except as provided below, Personnel may not accept payment, Gifts or other financial support from Industry to travel to or attend lectures and meetings. The following exceptions to this prohibition apply:</p> <ul style="list-style-type: none"> • Reasonable reimbursement for faculty of a CE Accredited Program or of a non-CE accredited educational program that isn't a Promotional Speaking Relationship; • Reasonable reimbursement of travel in connection with a Consulting Relationship (e.g., service on scientific advisory board) rendered by a faculty member; • Modest meals provided to attendees as part of a CE Accredited Program; and • Trainee scholarships if TJU, not Industry, determines who receives assistance and if funds are provided to School or Department not individual trainees.
Ghostwriting	<p>Faculty and trainees are prohibited from permitting their professional presentations of any kind, whether oral or written, to be produced by Ghostwriting of Industry or any other party.</p>
Industry Relationships in Curriculum	<p>Policy standards will be addressed in School curricula.</p>
Enforcement	<p>Matters addressed by this Policy are subject to systematic reporting to the TJU COI Committee and TJU Enterprise Risk Program. Responsibility for interpretation and enforcement of this Policy rests with the JMC Dean and TJU Senior Vice President for Academic Affairs. Violations are subject to discipline, up to and including termination.</p>



Policy No: **107.25**
 Revision No: **1**
 Effective Date: 9/21/2010

UNIVERSITY POLICIES & PROCEDURES

Category:	Compliance Administration
Title:	INDUSTRY RELATIONSHIPS POLICY
Applicability:	Thomas Jefferson University
Contributors/Contributing Departments:	

INTRODUCTION

Thomas Jefferson University recognizes that relationships with Industry, when properly structured according to the principles listed below, foster health sciences and enhance patient care. Conversely, failure to structure these relationships appropriately may subject TJU and its Personnel to potential liability and public scrutiny. In order to achieve an appropriate balance between these competing considerations, this Policy provides guidance on variety of potential relationships between TJU Personnel and Industry and, in all cases, is intended to minimize the likelihood of biased decisions by academic health care providers, promote an influence-free environment for health care trainees and optimize the benefits inherent in principled relationships between TJU Personnel and Industry. This Policy does not address research relationships between Industry and TJU Personnel.

The attached Statement of Policy describes TJU's expectations and requirements with respect to certain types of interactions between TJU Personnel and Industry. The attached Glossary defines key terms mentioned in the Statement of Policy.

Beginning on October 1, 2009, questions about the Policy can be submitted by clicking [here](#). Questions will be retrieved on a weekly basis and responses will be provided in approximately 2-4 weeks.

Attachment 1: [Statement of Policy \(PDF\)](#)

Attachment 2: [Glossary of Defined Terms \(PDF\)](#)

Revision Date(s): 09/21/2010

Review Date(s):

Responsibility for maintenance of policy: JMC Dean and TJU Senior Vice President for Academic Affairs

(Signature on File)

Approved by:

Mark L. Tykocinski, M.D.

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 Dean, JMC and Senior Vice President, TJU

(Signature on File)

Approved by:

Michael J. Vergare, M. D.

Senior Vice President for Academic Affairs, TJU

Thomas Jefferson University

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Glossary of Defined Terms

- CE Accreditation Standards:** Published, nationally-recognized standards for the promotion of quality and independence of continuing education in the applicable professional discipline (e.g., medical, nursing, pharmacy). In the absence of nationally-recognized accreditation standards for continuing education in a particular professional discipline, the relevant standards for continuing *medical* education will pertain.
- CE Accredited Program:** An educational program that satisfies applicable CE Accreditation Standards and for which qualified attendees receive continuing education credits recognized by their professional discipline.
- COI Committee:** The Thomas Jefferson University's Standing Committee on Conflicts of Interest and Commitment (see TJU Policy No. 107.03)
- Consulting Relationship:** Any arrangement pursuant to which Personnel provide services based upon clinical or scientific expertise (other than speaking or the conduct of research) at the request of an Industry member. This term includes, but is not limited to, service on a scientific advisory board, delivery of expert testimony or commentary, participation in clinical trial planning and participation in investigator workgroups or meetings. In addition, this term applies to services rendered by Personnel directly or through a privately-held business entity.
- Ghostwriting:** A process through which Industry (or any third-party) funds and/or participates materially in the preparation of articles or other written works intended for publication in professional or scientific journals. In order to avoid characterization as Ghostwriting, authorship credit must be based on (1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content and (3) final approval of the version to be published.
- Gifts:** Anything of value provided by or on behalf of Industry other than as a fair market value in exchange for the performance of a commercially-reasonable service by the recipient. This term includes, but is not limited to, food, beverages, office supplies, personal benefit items, travel expenses and drug samples (other than drug samples provided in accordance with applicable TJU, JUP or TJUH policies).

Industry: Firms or vendors engaged in the manufacture or sale of diagnostic or therapeutic drugs, devices, supplies, or services for research, education or clinical care, as well as advertising agencies, medical education companies and market research firms providing services on behalf of (or funded by) such firms or vendors. This term does not include publishing companies or manufacturers of equipment or supplies used solely in the conduct of basic scientific research.

Personnel: All faculty, staff and trainees of TJU.

Promotional Speaking Relationship: A paid speaking engagement or relationship with any of the following characteristics:

- An Industry member or program sponsor has a contractual right to dictate or control content;
- An Industry member or program sponsor creates slides or presentation materials and has final approval of content or edits; *or*
- A speaker is expected to act as an agent or spokesperson of an Industry member or program sponsor for the purpose of disseminating information about the Industry member or its products.

This term does not include (1) a speaking engagement that is labeled as a “speakers’ bureau” but that does not possess any of the above characteristics, or (2) a speaking engagement that involves a product or process for which the speaker is a named inventor.