

LOMA LINDA UNIVERSITY MEDICAL CENTER

OPERATING POLICY

CATEGORY: HUMAN RESOURCE MANAGEMENT CODE: I-96

EFFECTIVE: 05/2015

SUBJECT: INTERACTIONS WITH VENDORS REPLACES: 07/2012

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Related Policies:

Conflict/Duality of Interest (A-6)

Distributing Literature, Selling, and Soliciting (A-15)

Vendor Endorsements (A-56)

Vendor Representatives Visits to LLUMC (G-18)

Gifts/Sponsorships (I-18)

PURPOSE

The purpose of this policy is to establish guidelines for interactions of Loma Linda University Medical Center (LLUMC) personnel with vendor representatives. Interactions with these representatives occur In a variety of contexts, including marketing of new products, on-site training of newly purchased devices, educational support of medical students and trainees, and continuing medical education. Many aspects of these interactions are positive and important for promoting the educational, clinical and research missions of LLUMC. However, these interactions must be ethical and cannot create conflicts of interest that could endanger patient safety, data integrity, the integrity of our education and training programs, or the reputation of either the faculty member or the institution. This policy affirms that healthcare professionals should use objective and evidence-based sources of information to make clinical decisions, rather than information obtained through marketing efforts of pharmaceutical, biotech or medical device manufacturers.

SCOPE

This policy applies to all LLUMC personnel, with the exception of resident physicians. Resident physicians are covered separately by the LLUSM "Guidelines for the Interactions Between Faculty at LLUSM and the BioPharmaceutical/Device Industry," the same policy governing attending physicians. Whenever practicable, this policy and the LLUSM policy are complimentary.

DEFINITIONS

LLUMC Personnel – All trustees, officers and employees of LLUMC (except resident physicians).

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Vendor – An entity doing or seeking to do business with LLUMC or its related entities.

Educational events – Those events for which the attendees may receive certification toward their professional CME or CEU requirements, as well as any other activities provided for general educational purposes.

Industry – Pharmaceutical, biotech, medical device, hospital and research equipment, software and medical supply companies.

A. GENERAL PRINCIPLES

- 1. LLUMC's selection of and conduct of business with vendors shall be based solely on transparent and appropriate business, medical, clinical and/or research criteria, as applicable. The selection of and conduct of business with vendors shall not be based on, or be influenced by, past, present or future gifts to or for the benefit of LLUMC personnel, donations to LLUMC, support to LLUMC or LLUMC personnel such as clinical, research or educational support, or factors other than arm's length and transparent interactions based on appropriate business, medical, clinical and/or research criteria.
- 2. LLUMC personnel who are involved in decision making with respect to the use or purchase of equipment, products, supplies or services shall avoid conflicts of interest, whether real or perceived, including the appearance that decisions with respect to vendors. Certain LLUMC personnel, such as employees involved in LLUMC's purchasing/supply chain, have such significant vendor interactions that they shall be held to a higher standard in terms of avoiding the appearance of a conflict of interest with respect to vendors.
 - 2.1 LLUMC personnel serving on the Medical Device Committee and pertinent subcommittees, e.g., Pharmacy and Therapeutics Sub-committee, shall disclose any relationship they have with respect to a vendor (or competitor of the vendor with respect to the product and/or service under consideration) whose product and/or service is being considered that constitutes an actual, potential or perceived conflict of interest under the provisions of Policy Conflict/Duality of Interest (A-6). Such LLUMC personnel shall recuse themselves from involvement in the purchasing decisions.
 - a If such LLUMC personnel expertise is necessary in evaluating the product and/or service, e.g., the person uniquely understands certain scientific or clinical information about the product that is important for the committee to know, the LLUMC personnel may be allowed to make a presentation before the committee, provided they leave the committee meeting while the matter is being discussed and/or voted upon.

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b The minutes should reflect the fact that the conflicted person was not present for the discussion or vote.

- 2.2 LLUMC personnel who provide input, but are not involved in decision-making with respect to the use or purchase of equipment, products, supplies or services, shall, prior to providing input, disclose any relationship they have with respect to the vendor (or competitor of the vendor with respect to the equipment, product, supply or services under consideration) whose equipment, product, supply, or service is being considered that constitutes an actual, potential or perceived conflict of interest under the provisions of Policy Conflict/Duality of Interest (A-6) to their department head or applicable supervisor, and to the person(s) or committee(s) to whom the conflicted person expects to provide input.
 - a Disclosure to the department head or applicable supervisor shall be made at least annually if the provision of input is ongoing and the disclosure to the person(s) or committee(s) to whom the conflicted person expects to provide input should be made at each instance prior to the conflicted person providing such input.
- 3. Although this policy is intended to address a broad range of situations that may arise from interactions between vendors and LLUMC personnel, questions may arise about certain situations that do not appear to be covered by this policy or any other relevant LLUMC policy. In those circumstances, LLUMC personnel shall seek advice from their department head or applicable supervisor, the Office of the General Counsel, or the Compliance Department.

B. ACCESS TO CLINICAL AND NON-CLINICAL AREAS BY SALES AND MARKETING REPRESENTATIVES

1. Site access by Pharmaceutical and Medical Device Representatives shall be governed by Policy Vendor Representatives Visits to LLUMC (G-18).

C. DISCLOSURE OF RELATIONSHIP WITH INDUSTRY

1. LLUMC personnel shall be prohibited from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, Industry or otherwise.

NOTE: Ghostwriting is the provision of written material that is officially credited to someone other than the writer(s) of the material. It includes unacknowledged, undisclosed provision of content. Transparent writing collaboration with attribution between academic and Industry investigators, medical writers, and/or technical experts is not ghostwriting.

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2. All speaking relationships and contracts shall be fully disclosed to LLUMC administration in accordance with Policy Conflict/Duality of Interest (A-6). Speaking relations are subject to review and approval by the participant's administrator or department head.

D. PROMOTIONAL MATERIALS

- 1. Vendor corporations and vendor representatives shall be prohibited from directly placing any promotional materials or educational materials in any LLUMC patient care or waiting area (reference Policy <u>Distributing Literature, Selling, and Soliciting (A-15)</u>, and Operational Guidelines <u>Media in Public Settings (OG V-7)</u>).
- 2. The distribution and/or display of patient education materials produced by a vendor shall be centralized through the Patient Education Team. Individual employees shall not be permitted to distribute or display patient education materials produced by a vendor.

E. LLUMC ENFORCEMENT

- 1. Vendors who fail to comply with the provisions of this policy shall be subject to appropriate action, up to and including having their access to LLUMC Facilities restricted and losing their business privileges at LLUMC.
- 2. Any LLUMC personnel who violate any provision of this policy may face sanctions up to and including termination, depending on the seriousness of the violation.

APPROVED: Hospital Executive Leadership, LLUMC Chief Executive Officer