Section 9	Clinical Policies	10/01/00 -Originated
Subject 9.7	Visitor Information	04/05/12 -Reviewed w/ changes -Reviewed w/o changes
Policy 9.7.2	**Vendor Visitation: UTMB Clinical Enterprise**	05/05/12 - Effective Logistics -Author

Vendor Visitation: UTMB Clinical Enterprise

Definitions

Industry Vendor: Any sales representative or account executive, including but not limited to pharmaceutical representatives and equipment- or device-manufacturer representatives.

Clinicians and Staff: Faculty members and trainees at all levels (e.g., students, interns, residents, fellows, postdoctoral trainees) in any patient care discipline, including specialties of medicine, dentistry, nursing, and other health professions. This term also includes volunteers and persons hired by UTMB to perform work at or on UTMB's behalf.

Continuum of Care: The provision of comprehensive care from the hospital to the home which advocates the pooling together of medical and social services within the community and the creation of linkages between community care initiatives at all levels of the health care system.

Contractor: Any representative of a company contracted with to perform long term service-related work requiring frequent and routine visits to the UTMB campus.

Hospital and Clinical Enterprise Sites and/or Clinical Enterprise: The buildings used by UTMB for inpatient or outpatient care, including physician and administrative offices.

Shadowing: Following physicians or other clinical personnel.

Tailgating or Piggybacking: The accompaniment of an industry Vendor who has a verifiable appointment with a specific department or area by an individual who does not officially have an appointment.

Policy

This policy establishes regulations for Industry Vendors doing business within the Clinical Enterprise at UTMB, and ensures appropriate identification of all vendors and consistency with UTMB's patient care, academic, and research missions. It also provides a mechanism for enforcement.

Policy, continued

To the extent this policy conflicts with IHOP Policy 6.1.1 Clinical Conflicts of Interest, that policy shall prevail.

UTMB Clinicians and Staff shall interact with Industry Vendors in a manner that meets ethical standards, protects patient confidentiality, does not interfere with the process of patient care, and encourages the appropriate, efficient and cost-effective use of equipment, supplies, and pharmaceuticals at UTMB.

Industry Vendors who conduct business at or with UTMB must do so in accordance with this policy, UTMB Vendor Representative Procedures, and the UTMB Healthcare Vendor Code of Conduct Industry Vendors found in violation of UTMB policies or procedures may be denied access to the UTMB campus for a period of time determined by the Executive Vice President and Chief Executive Officer of the UTMB Health System, with notice provided to appropriate officials.

All UTMB personnel must monitor Industry Vendors to ensure compliance with these guidelines. UTMB personnel must immediately report non-compliant Industry Vendors to Purchasing.

Any pricing or contract terms discussed before review and approval by Purchasing are considered “preliminary”. Final pricing and contract terms may be negotiated by Purchasing only, with input from the requesting department.

Under IHOP Policy 4.5.6 Procurement Policy, only staff members with signature authority delegated to them by the President may sign contracts or enter into agreements on behalf of UTMB.
Therefore, all UTMB employees must route all procurement related contracts and other signature documents to Purchasing for review and proper execution, or further routing to the appropriate UTMB authority.

Violation of this policy may result in disciplinary action up to and including termination for employees; a termination of employment relationship in the case of Contractors; or suspension or expulsion in the case of a student.

Vendor Access

Industry Vendors may not be on campus without prior permission from authorized personnel. In addition, Industry Vendors must:

- have an appointment with authorized personnel before arriving on campus;
- have obtained approval from the authorizing department;
- have obtained and wear a UTMB vendor/visitor ID badge; and
- be accompanied by authorized UTMB staff when in clinical secured areas.

Industry Vendors representing Continuum of Care services or facilities (e.g., nursing homes, rehab facilities) may receive information about the patient they are scheduled to visit only.

Industry Vendors may not have access to Protected Health Information (PHI) unless a business associate contract specifically permits such access or patient authorization has been obtained.

UTMB reserves the right to limit the number of Industry Vendors that any single company may have visiting UTMB facilities.

Shadowing, Tailgating, and Piggybacking are prohibited.

Industry Vendors are prohibited from entering patient care areas for promotional purposes.

Industry Vendors are not permitted to touch or treat patients or undertake any activity that could be construed as patient care unless the Industry Vendor has been credentialed by the Medical Staff Office. Clinicians involved in such evaluations or testing are advised to seek clarification from the UTMB Institutional Review Board (IRB) regarding whether the activity qualifies as human subject research.

Products, Devices, and Equipment Approval Process

Only products, devices, and equipment that have been approved by the Value Analysis/Cost Management Team may be purchased with Clinical Enterprise Funds.

Before any patient-related or laboratory equipment is purchased, leased, loaned or accepted as a donation for use or trial involving patients, it must be evaluated by Clinical Equipment Services (CES) or other authorized service department(s) to determine whether it meets UTMB's guidelines as outlined in the equipment management plan.

Criteria for Trial/Evaluation of Products, Devices, and Equipment

- Products, devices, and equipment that have related consumables must go through the Value Analysis Program prior to evaluation and must be presented to the appropriate cost management team.

- Products, devices, and equipment brought in for loan or assessment must have approval from the appropriate approval agency (e.g., Food and Drug Administration, Underwriters Laboratory, etc). If this approval has not been obtained, the IRB must be contacted before proceeding.

- Product samples may not be left by Industry Vendors in any inpatient or outpatient clinical area, and may not be evaluated for patient use without first going through the Value Analysis Program and being presented to the appropriate cost management team.

- Industry Vendors must complete and sign a Vendor Release Form before delivering any loaned equipment or products to UTMB.

- All medical electronic devices and equipment brought in by Industry Vendors for loan or evaluation must be tested for electrical safety and approved by CES or other UTMB-authorized service providers before evaluation.

- Appropriate training must be provided to personnel in the area where the evaluation will take place, as well as personnel in any other impacted areas before using the equipment brought in by Industry Vendors for loan or evaluation. Training must be documented in accordance with the applicable departmental policy.

- Department-specific guidelines regarding interacting with Industry Vendors must be followed. If research is intended to be published, the IRB must be contacted for possible review (as used here, "research" means a systematic evaluation including development testing designed to develop or contribute to generalizable knowledge).

- Products and equipment may not be evaluated for an "off-label" use. If deemed absolutely necessary, requests to evaluate products or

Criteria for Trial/Evaluation of Products, Devices, and Equipment, continued

- equipment for an "off-label" use must follow the guidelines contained in the UTMB Vendor Representative Procedures.

Industry Support for Educational Programs at UTMB

Industry Vendors must adhere to IHOP Policy 6.1.1 Clinical Conflicts of Interest for all industry supported/sponsored educational programs at UTMB.

Industry Vendors shall not attend programs in which specific patients are identified or quality assurance or risk management issues are presented.

References

IHOP Policy 2.6.5 Acceptance and/or Solicitation of Gifts or Benefits from Vendors

IHOP Policy 6.1.1 Clinical Conflicts of Interest

IHOP Policy 4.5.6 Procurement Policy

Logistics Purchasing Policies and Procedures

UTMB Security Clearance Requirements

Value Analysis Program