

## Vendor Visitation and Interaction Policy

<b>Target Group:</b>  <i>Cleveland Clinic United States locations</i>	<b>Original Date of Issue:</b>  02/11/2013	<b>Version</b>  3
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### Purpose

Vendor Representatives can play an important role in a patient's care and may be present in Cleveland Clinic (CC) facilities at the request of the attending physicians, surgeons, anesthesiologists, hospital administrators, or appropriate caregiver. This policy serves to establish uniform guidelines for permitting Vendor Representative access to CC operating rooms (OR) and associated areas, including but not limited to cath labs, hallways, physician offices, etc., so as to ensure reasonable control and identification of Vendor Representatives while ensuring safe patient care.

### Policy Statement

Vendors must follow the requirements established in this document to be allowed access to Cleveland Clinic Personnel and Facilities. Vendor contact is not permitted outside these guidelines.

### Definitions

**Cleveland Clinic Personnel and Facilities** – All personnel, whether employed, contracted or affiliated with CC, including all physicians, health care providers and students of CC. CC facilities are defined as all facilities and respective campuses and regional hospitals, whether owned, leased, rented or controlled by CC.

**cTEKI (COMET)** – Online CC required education modules.

**Vendor** – Manufacturers, suppliers, distributors, or providers of products, equipment or services, whether medical or non-medical.

**Vendor Representative(s)** – Any representative such as, sales person, manager, liaison, account executive, contact, administrator, company technician, clinical support, nurse clinician, home healthcare personnel, manager, medical/scientific liaison of a manufacturer or company who visits CC in any capacity, including but not limited to, soliciting, marketing or distributing information regarding the use of vendor products or services.

**GHX/Vendormate** – Credentialing software utilized by onsite vendor representatives to register to do business with CC.

## **Policy Implementation**

### **Vendor Responsibilities**

#### **Credentialing Process**

Any Vendor Representative who visits Cleveland Clinic Personnel and Facilities:

- **Have a pre-scheduled appointment before any site visits.**
- Complete required cTEKI (COMET) training.
- Register and comply with GHX/Vendormate (see Vendor Handbook for details)
- Adhere to additional criteria outlined by the particular department where he/she has a previously scheduled appointment.

### **General Vendor Requirements**

**Upon completion of the Credentialing Process Vendor Representatives must adhere to the following:**

1. **Required to have an appointment, sign-in and sign-out via GHX/Vendormate for all visits.**
2. **Shall only discuss price, or negotiation of price, and/or contract with Supply Chain Management. Under no circumstances shall the Vendor Representative solicit new products and/or technology improvements, services, or contracts in hospital areas other than Supply Chain Management. CC reserves the right to refuse to pay for any product or service not authorized by Supply Chain Management or the specific department. Contracts must be approved by Supply Chain Management prior to execution. A contract signed by anyone other than an officer, or their delegate, of the respective corporation is not valid.**
3. Shall not provide anything of value to a CC employee that could influence or be perceived as influencing the judgment of the employee in the execution of his/her duties. To this end, no gifts whatsoever, including meals, shall be requested or accepted from vendors.
4. May not use CC's phones, computers or other equipment for vendor's business or personal use.
5. May not distribute or post any type of brochure, advertisements, pens, cups or similar promotional or marketing materials in the OR and/or associated areas or to any personnel.
6. Must disclose any apparent or perceived conflict of interest; specifically, any family, personal, or financial relationships.
7. If CC personnel are employed by vendors as an additional employer, that employee is prohibited from engaging CC on behalf of the vendor. This includes, but is not limited to, activity on vendors' behalf such as sales calls, emails, visits and patient care.
8. **Will not** sell or engage in selling to non-Supply Chain Management personnel (i.e. materials management, OR stock, inventory services tech, etc.), nor will they attempt to increase inventory levels in storerooms and/or clinical areas.

9. Will not counter detail products that are not on contract with CC unless Supply Chain has been advised of the new technology or change in product use as approved by the FDA for the patient care setting, or unless the clinician has expressly requested a discussion regarding new technology. It is not the intent of this policy to limit or be a barrier to true innovation.
10. Will not bring into procedural area, OR, or patient care areas any device that has the capability to record or transmit audio and/or video images, including photography.
11. In the event that CC becomes a vendor showcase, is engaged as a Center of Excellence, or as a training program, Vendor Representatives must be accompanied by CC Staff. Vendor Representatives will notify Supply Chain as to the nature of the visit and date of appointment.
12. Must read, understand and follow all guidelines before conducting business at CC.

### **Access to the OR**

Upon completion of the Credentialing Process, Vendor Representatives will be permitted access to CC's OR and associated areas upon the request of the attending physician, surgeon, anesthesiologist, hospital administrator, or appropriate caregiver.

### **OR Vendor Representatives must adhere to the following:**

1. **Have an appointment, sign-in and sign-out via GHX/Vendormate for every visit.**
2. Obtain permission from the physician, nurse manager, department manager or designee prior to the day of the procedure and before entering any patient care area.
3. Upon signing in, proceed directly to the appropriate OR area and/or designated waiting area until the start of the surgical procedure. ID badge must be visible at all times.
4. The primary role of the Vendor Representative in a patient care area is to provide product consultation, or to answer questions deemed essential for patient care. Under no circumstances will a Vendor Representative be permitted to:
  - a. Participate in hands-on delivery of patient care (e.g. scrub)
  - b. Operate equipment and/or administer supplies; or
  - c. Provide initial training of equipment and/or supplies during a procedure.
5. CC reserves the right to restrict or prevent a contracted vendor's access into the ORs, post-training and education of awarded product or service, unless prior approval through requesting physician is authorized. Non contracted vendors require Physician authorization prior to entering into the OR's.
6. For all participation or observation of a clinical procedure at CC's Main Campus, Vendor Representatives are required to wear orange scrubs. This scrub color is specific to Vendor Representatives and is designed to ensure easy identification. When leaving the surgical or procedure rooms, Vendor Representatives must cover their scrubs with a white, buttoned lab coat while inside the hospital – for example during a lunch break in the cafeteria. However, this attire cannot be worn when traveling to and from work. Vendor Representatives must completely change out of their scrubs with or without a lab coat before leaving the premises. Disposable hats, masks, gowns, gloves and shoe

coverings must be removed and discarded when leaving the OR area. If Vendor Representatives do not comply with these guidelines may risk loss of privileges of the OR area and all other CC facilities.

7. For all other CC facilities, the specific location will provide the Vendor Representative with their scrubs. The Vendor Representative must cover their scrubs with a white, buttoned lab coat while inside the hospitals. This attire cannot be worn when traveling to and from the hospital. Vendor Representatives must completely change out of their scrubs with or without a lab coat before leaving the premises. Disposable hats, masks, gowns, gloves and shoe coverings must be removed when leaving the OR area. Discard these items prior to leaving the OR area. If Vendor Representatives do not comply with these guidelines, they risk loss of privileges of the OR area.
8. **Remain in the designated area pertaining to their visit. Specifically, Vendor Representatives are not permitted to move freely about in areas not pertaining to their specific visit, including but not limited to staff break rooms, other operating suites or physician offices. Under no circumstances may a Vendor Representative wander through the halls of the hospital. Unannounced visits and soliciting of promotional activities by Vendor Representatives are strictly prohibited.**
9. Will not bring into procedural area, OR, or patient care areas any device that has the capability to record or transmit audio and/or video images, including photography.
10. Visitation hours must be consistent with normal hours of operation for CC unless requested by department employee.

### **Equipment/Device/Implant Sets**

1. All equipment/device/implant sets to be used by Vendor Representative must be delivered at least 24 hours before a scheduled procedure to allow for inventory, sterilization, and/or biomedical safety evaluation in accordance with CC's policies. CC will not pay for equipment until the day of its use regardless of when it is brought in.
2. All new products are subject to review by the New Products Committee. A formal process has been established for documentation of product evaluations. Supply Chain Management will provide assistance with the required documents.
  - (1) Vendor will not be paid for product use if prior approval is not obtained.
  - (2) No products should be left in any area of CC without prior approval of the New Products Committee.
  - (3) Vendor Representatives leaving products without permission from Supply Chain Management will be subject to discipline under compliance. Items not previously approved will not be paid for.
  - (4) Supply Chain Management will coordinate with vendors when their products will be needed for evaluation or trial.
3. All equipment/device/implant sets must contain a complete inventory checklist plus written cleaning and sterilization instructions. This includes consigned and loaner instrumentation sets. The inventory list for each kit must be made available in hard copy and electronically in Excel format and be provided to the corresponding department. The inventory list must also be reconciled with the vendor and CC personnel.

4. All equipment and instrument trays must be removed within 48 hours of use.
5. All staff training for new equipment, instrumentation or surgical instruments must be coordinated through CC's OR administrator or Nurse Director at least one week prior to the scheduled surgical procedure.

### **Non-Compliance**

1. Vendor Representatives who fail to comply with CC policies will be subject to disciplinary action up to and including permanent loss of business privileges.
2. Continuous infractions or repeated violations to this policy by Vendor Representatives may result in suspension, a request to replace company representatives, and possible loss of business privileges at CC.
3. Violations committed by any one Vendor Representative of a given company may result in disciplinary action against any or all representatives of that company.
4. Disciplinary action may vary depending upon the nature of the infraction and the circumstances surrounding the offense. Supply Chain Management reserves the right to determine the severity of the infraction and will use its discretion when assessing and determining the proper course of disciplinary action. Consequences may vary depending on the severity of the infraction.
5. Supply Chain Management will notify vendor of the violation, the determined level of infraction, and the planned course of disciplinary action.
6. Duration of restriction of all activity and service calls may be 3 months, 6 months, one year, or permanent depending on extent of the infraction. Certain situations may require deviation from the guidelines outlined in this policy. Vendor Representatives can be banned from CC permanently regardless of Vendor Representative's employer.

### **CC Responsibilities**

1. The departments will be responsible for notifying the vendor of the policy and ensure compliance with identified guidelines.
2. All staff should be observant of others around them. **If a Vendor Representative is in any area without an appointment and badge staff should politely request that the Vendor Representative leave that area.** Repeated instances should be reported to Supply Chain Management and Protective Services.
3. A Vendor Representative may be present in a patient care area when needed for treatment, payment, or health care operation purposes, for example, providing the support necessary for a physician to utilize the product or device safely or education/training. A HIPAA authorization is required when the Vendor Representative's presence in the patient care area is not for treatment, payment, or health care operations purposes. (See [HIPAA Authorization Policy](#) and [HIPAA Privacy Glossary Policy](#) for additional information.) When such an authorization is required, prior to the admission of the Vendor Representative into the patient care area, a clinical caregiver must verify that the patient's authorization concerning the Vendor Representative's presence has been obtained and documented in the patient's medical record. Clinical caregivers will verify

that Vendor Representative's access has been approved by demonstration of the proper hospital-issued identification badge.

4. Upon completion of the surgical procedure, a complete inventory of any equipment, device, implant sets, or any other products brought into or used must be completed by the OR staff.
5. All instruments and related equipment used in the OR area must be properly decontaminated prior to removal from CC in accordance with CC's policies and procedures.
6. If CC personnel are employed by vendors as an additional employer, that employee is prohibited from engaging CC on behalf of the vendor. This includes, but is not limited to, activity on vendors' behalf such as sales calls, emails, visits and patient care.
7. No CC employee is to ask for or receive anything of value from a vendor that could influence or be perceived as influencing the judgment of the employee in the execution of his/her duties. To this end, no gifts whatsoever, including meals, shall be requested or accepted from vendors. Vendors and Cleveland Clinic employees are asked to report any violations of this procedure to the Law Department.
8. Contact Supply Chain Management if Vendor Representative does not adhere to policy, procedures, or guidelines, such as not having an appointment or not signing in or out.

### **Oversight and Responsibility**

*Supply Chain Management sourcing personnel are responsible to review, revise, update, and operationalize this policy to maintain compliance with regulatory or other requirements. It is the responsibility of each hospital, institute, department and discipline to implement the policy and to draft and operationalize related procedures to the policy if applicable.*

### **Appendices**

#### [Vendor Handbook](#)

Link to *Authorization to Disclose Health Information*:

<http://my.clevelandclinic.org/ccf/media/Files/Patients/records-release-form.pdf>

Link to *HIPAA Authorization Policy*: <https://ccf.policytech.com/dotNet/documents/?docid=17193&mode=view>