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# UHealth Vendor Program

**Purpose:**

This policy is intended to provide guidance and instructions as to the appropriate activities and ethical principles of conduct for interactions between vendors and the UHealth staff. Products and services include medical and surgical supplies, devices, implants, nutritional products and pharmaceuticals.

Vendor Representatives are defined as agents of manufacturers and suppliers who promote products and/or services and provide information to UHealth staff. We recognize the value of having Vendor Representatives interact with our staff, we also have expectations that all Vendor Representatives will comply with the UHealth Vendor Representatives Program Policy. The promoting of products and services at UHealth by Vendor Representatives is a granted privilege, not a right.

# Definitions:

UHealth: Refers to University of Miami Hospital, Sylvester Comprehensive Cancer Center (SCCC), Anne Bates Leach Eye Hospital (ABLEH) and the University of Miami Medical Group Clinical sites (UMMG).

Vendor Representatives: Individuals, who promote, sell; provide training and advice on medical systems, devices, procedures and drugs.

Operating Room: All references to the Operating Room (OR) include by definition all Surgical Services areas.

Patient Care Setting: Any area where patient care is delivered directly or indirectly. Non Clinical Areas: Relates to medical areas in the facility with no patients.

* All Vendor Representatives currently serving UHealth must complete an online registration process, managed by Vendormate in order to continue their business relationship with UHealth.
* Vendor Representatives with scheduled appointments will be required to check in upon arrival and obtain a badge. Vendor Representatives must complete a check-out process upon the completion of their visit.

# Overview of the Registration Process

To access the registration website directly, visit the following website: www.Vendormate.com

* Registration of each Vendor Representative and/or other staff members who visit UHealth for business purposes.

The company and each representative will be required to provide contact information and upload documentation as specifically required to become a registered “Vendor Representatives company” or registered “Vendor Representative”.

# Note: The registration process requires entry of the Vendor Representatives Company’s federal tax identification number. This number must be available to avoid delays in completing the registration process.

The company/Vendor Representatives registration process entails the following steps:

* 1. Business Identification:
     + Legal business
     + Type of business
     + Federal Tax Identification Number (FEIN)
  2. Basic Business Information:
     + Business address and telephone
     + Catalog of products sold (identified using UNSPSC codes)
     + Vendor Representative Information
  3. Acknowledgment of UHealth policies
  4. Confirmation: You will receive an email and click link to confirm your email address and login information.

# Registration/Certification Requirements for Vendor Representatives

Based on the scope of products and services marketed to UHealth, a Vendor Representative will be classified into one of the two categories, based on the representative’s product offerings, access to patient areas, and other qualifying criteria. There are certification requirements specific to each category; these requirements are consistent with standards set forth by the following:

1. Health Insurance Portability & Accountability Act of 1996 (HIPAA)
2. Association of Peri-Operative Registered Nurses’ (AORN) Standards for Health Care Industry Representatives in Operating Rooms
3. ACS-American College of Surgeons
4. The Joint Commission
5. UHealth Policies and Procedures

Regardless of classification, all Vendor Representatives must acknowledge and abide by the following principles to conduct business with UHealth:

* 1. **Conflict of Interest**. Vendor Representatives must provide a full disclosure about any conflicts of interest that exist.
  2. **Corporate Compliance Program, Deficit Reduction Act (DRA) of 2005, and False Claims Act**. Vendor Representative acknowledges and abides by UHealth Compliance Program and agrees to disseminate to its employees information about UHealth Compliance Program.
  3. **Smoke-Free Policy**. Vendor Representatives should abide to the no-smoking policy of the University.
  4. **HIPAA and Patient Confidentiality**. The discussion, release, or use of any patient-related information viewed or overheard may not be used for any purpose other than that which is related to job assignments and in compliance with patient privacy laws.
  5. **Confidentiality of Business and Other Proprietary Information**. Any type of information generated in connection with UHealth operations must not be accessed, downloaded, discussed, used, or disclosed for any purpose other than to conduct business with, or on behalf of, UHealth. Agreement to not improperly disclose confidential information continues after termination of the Vendor Representatives business partnership.
  6. **Scheduling of Appointments**. Vendor Representatives must schedule appointments in advance of visits, display a UHealth-issued badge while on the premises and complete the required check-in and check-out process.
  7. **Accompanying Guests.** Vendor Representatives agrees to accompany, at all times while visiting UHealth facilities, any guests accompanying the Vendor Representatives who are not registered with the UHealth Vendor Program.
  8. **Conduct & Interactions with UHealth Employees & Medical Staff**. When in UHealth facilities and interacting with employees and Medical Staff, Vendor Representatives understands and agrees that:
     + Conversations with staff in patient care areas should be minimal, must be professional and case related only. No socializing.
     + All patient education materials must be evaluated by the appropriate Patient Education staff prior to their use.
     + Procedure rooms are to be entered only at the request of, and as directed by, the physician(s). The Vendor Representatives cannot change or touch any equipment, carts, or sterile equipment. The Vendor Representatives must follow the instructions of the Circulating Nurse at all times.
     + Standards governing introduction of new products and the removal of expired or recalled products are abided by as a condition of doing business with UHealth.
     + Policy for providing gifts, meals, and education to UHealth employees and Medical Staff must be followed.
     + Items and services provided to and accepted from UHealth will not exceed those that are reasonable and necessary for ethical business purposes and that the amount paid to or payable by, UHealth will be at a fair market value amount.

Compliance with the above standards, as well as those set forth in this policy shall extend to the Vendor Representatives Representative’s Company, Co-workers, agents, and subcontractors.

# Conducting Business with UHealth

**Gener****al Facility Access Standards**

Vendor Representatives may enter UHealth facilities for the purpose of conducting business only when the following conditions are met:

# Vendor Representatives New to UHealth

A new Vendor Representatives is required to make an initial appointment with the Supply Chain Department to become acquainted with the Purchasing Staff and to address any questions that the new Vendor Representatives may have. The Vendor Representatives and its company must complete the Vendormate registration process and new vendor packet before doing business with the University. Once this is complete, the vendor will be notified of the approval and can then make an appointment with UHealth personnel.

# Scheduled Appointments

The Vendor Representatives must have a scheduled appointment – a meeting or clinical case, for example – and must limit his/her business-related activities at UHealth to the scheduled appointment(s). Under **no circumstances** will cold calls (visits without previously-scheduled appointments) be allowed after November 2009**.** Drop-in visits to other departments are **not** permitted.

Scheduling of department appointments must be arranged by the department and the Vendor Representatives. Supply Chain is not responsible for scheduling Vendor Representatives appointments for other departments.

# Vendor Representatives who will have access to procedural areas: (OR, GI, Cath Lab, Interventional Radiology, etc.) are required to wear disposable scrubs provided through the RepScrubs vending machine. (Reference: Vendor Peri-Op Surgical Attire Policy)

* **Badge and Check-In Process at Facilities Other Than UHealth**

The Vendor Representatives must check in, obtain a badge, and sign out at the conclusion of the scheduled appointment(s). This process is to be completed with assistance from Front Desk staff at the location where the appointment is occurring. With the exception of the introduction meeting that a new Vendor Representatives must complete, it is **not** necessary for a Vendor Representatives to report to Supply Chain prior to attending a scheduled appointment.

# Vendor Certification Requirements Clinical Areas:

Documentation of minimum criteria for requesting approval to be present in any patient care area must include:

* Vaccination & Medical-Chicken Pox, Hepatitis B, MMR, Proof of Drug Screen, TB & Influenza Vaccine
* Insurance & Legal-Proof of Employer General Liability Coverage
* Certification & Training: Aseptic Techniques Training, Blood borne Pathogens Training, Evidence of Employer Product/Service Competency, HIPPA Training and O.R. Protocol Training.
* Other Requirements-Background check: OIG check and Excluded Parties List System.
* Basic Education: Baccalaureate degree and/or education requirements per vendor representative company policy, which included such basic science courses as biology, chemistry and physics as well as credits in human anatomy and physiology.
* Infection control practices
* Blood borne pathogens
* Fire, electrical and other safety protocols
* Patients’ right and confidentiality, including HIPAA compliance strategies
* Informed patient consent regarding the presence and role of Vendor Representatives in the patient care area
* Certificate that attests to training in the medical system, device, treatment or procedure for which they are seeking approval for their presence in the patient care area, including experience for that medical system, device, treatment or procedure in a mentorship program supervised by an experienced vendor.

Documentation of sponsorship and attestation of responsibility from an active member of the medical staff with privileges compatible to the privileges being requested by the vendor representative.

The Vendor Representative must sign an agreement to comply with facility policies. Additionally, the Vendor Representative must sign the facility Confidentiality agreement. Failure to comply shall result in termination of privileges without right to appeal. All privileges are granted by the board and may be rescinded by the chief executive office on behalf of the governing body, at any time based on advancement of patient care and facility policy with no appellate process to the Vendor Representative.

Obtain letters of reference from the director of the applicant’s training program.

Alternatively, a letter of reference regarding competence should be obtained from the medical director of chief of surgery at the institution where the applicant has most recently provided technical support for their presence and involvement in patient care.

Vendor Representative company to provide results of criminal background check.

Vendor Representative must complete the Hospital Orientation Packet prior to first assignment at facility. All applications and responses will be maintained at the Vendormate database and will remain confidential.

The physician will be notified and approve of the vendor representative presence in the patience care area prior to the treatment/procedure if the physician did not initiate the request.

The Vendor Representative’s presence and purpose should be prescheduled with the designated Department Director and communicated to the registered nurse/charge nurse/manager in the patient care setting.

Medical equipment and other complex devices must be reviewed and approved prior to their use by the Biomedical department per facility policy.

The applicant and/or employer will provide the hospital with a list of representatives designated for coverage of the Vendor Representative. The additional representative(s) will also submit all necessary information to Vendormate.

In the “event of an emergency”, where coverage is provided by a Vendor Representative not previously submitted as a designated Vendor Representative, a “one time privilege” will be submitted to the Administrative Hospital designee for approval. Upon approval, the privilege is valid for a one time occurrence during a (30) day period. The application process will apply to the representative providing coverage to the hospital Vendor Representative.

# Criteria for Non Clinical area:

* Certificate that attests to training in the medical system, device, treatment, drug for which they are seeking approval for their presence in the facility.
* Fire, electrical and other safety protocols
* Proof of professional liability insurance coverage.
* The Vendor Representative must sign an agreement to comply with facility policies. Additionally, the vendor representative must sign the facility Confidentiality agreement. Failure to comply shall result in termination of privileges without right to appeal. All privileges are granted by the board and may be rescinded by the chief executive office on behalf of the governing body, at any time based on advancement of patient care and facility policy with no appellate process to the vendor.
* Vendor representative company to provide results of criminal background check.
* Vendor representative must complete the Hospital Orientation Packet prior to first assignment at facility.
* All applications and responses will be maintained at the Vendormate database and will remain confidential.

# IT IS THE VENDOR REPRESENTATIVES RESPONSIBILITIES TO REVIEW ALL POLICIES AND DOCUMENTS PROVIDED ONLINE VIA VENDORMATE ON AN ANNUAL BASIS.

**Fire Safety**

In the event you hear the fire alarm while conducting an appointment at UHealth, you should listen for an overhead paging announcement of “Code Red”, UHealth “code” for fire – along with an announcement about the location of the alarm. If the alarm is not near your location, you may continue what you were doing. However, **do not use the elevators,** use the stairs instead.

For your safety, and that of others, remember the word **“RACE”** as a reminder about the appropriate action to take – at UHealth, your home, or elsewhere.

RACE is an acronym for Rescue, Alarm, Confine, and Extinguish/Evacuate.

**Rescue:** Rescue individuals who are in immediate danger

**Alarm:** Pull the nearest fire alarm box by grabbing the center handle and pulling down until it stops. Release the handle and notify the closest [UHealth] employee.

**Confine:** Confine the heat and smoke by closing all doors and windows in the area of the fire, plus adjacent areas.

**Extinguish/Evacuate:** Use a fire extinguisher to put out the fire, if you feel comfortable doing

so and if use of an extinguisher would be effective in eliminating or greatly reducing the fire. Otherwise, evacuate the area immediately, closing the door behind you.

To use a fire extinguisher, remember the word “PASS” to correctly use the device:

**P** Pull the pin

**A** Aim the nozzle at the base of the fire

**S** Squeeze the handles to release the extinguishing agent

**S** Move the extinguisher in a back and forth sweeping motion, as though you were operating a broom, to extinguish the fire.

# Infection Control: Important Facts

To reduce the risk of transmitting pathogens, there are a few precautionary practices to employ:

# Wellness:

Stay home if you are sick with something infectious. If you are not feeling well, for your own health and for consideration of others, we prefer that you cancel your appointment and reschedule when you are feeling better.

# Bloodborne Pathogens:

Bloodborne pathogens are microorganisms present in human blood and other potentially infectious materials. Examples of common illnesses spread by blood borne pathogens include Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV), and Malaria. Any body fluid with visible blood may be infectious.

These microorganisms can cause disease or death when transmitted from an infected person to another person. The transmission may occur when blood or body fluid from an infected person enters another person’s body. For healthcare workers, this transmission may occur:

* through accidental puncture from contaminated needles, other sharps, or broken glass
* contact between mucous membranes and infected body fluids

# Standard Precautions:

In 1996, the Centers for Disease Control issued “Standard Precautions” as recommendations for the protection against the transmission of blood borne diseases and other diseases when treating all patients. To protect yourself and others, always treat all blood, body fluids, secretions and excretions, non-intact skin and mucous membranes as if they are infected with bloodborne or other pathogens.

# Handwashing

Handwashing is one of the most important precautions for preventing the transmission of infections. A standard handwashing technique consists of: soap, a vigorous rubbing together of all surfaces of lathered hands for 10 – 15 seconds, thorough rinsing under a stream of water, thorough drying hands with a clean, disposable paper towel, turning off faucets with the paper towel, and disposing of the paper towel in a garbage receptacle.

Handwashing must occur:

* Before and after treatment with each patient
* Before donning gloves and after gloves are removed
* Immediately when accidental bare-handed contact with blood, body fluids, secretions and excretions, non-intact skin, mucous membranes, or infected equipment occurs.

# When Blood Spills Occur:

To clean up blood spills, wear gloves, blot the blood with absorbent materials, use a disinfectant to clean the area of the spill, and discard the blood-soaked materials in a biohazard bag.

# Contaminated Sharps and Linens:

Sharps: When handling sharps, always wear gloves. Do not recap the needles. Dispose of the used sharp in a needle box immediately after use.

Linens: When handling contaminated linens, always wear gloves, and handle the linens as little as possible. Place the soiled linens in a leak-proof bag if soaking is likely.

# HIPAA and Patient Confidentiality

UHealth respects the privacy of its patients and requires that all who conduct business with UHealth share this commitment. HIPAA, the Health Insurance Portability and Accountability Act of 1996, enhanced the protection of a patient’s privacy. HIPAA prohibits a Vendor Representatives Rep from reviewing the medical records of patients for the purpose of determining which patients may benefit from the Vendor Representatives Rep’s products or services.

All information regarding patients of Hospital and Affiliates and their treatment, will be held in strict confidence. This information will not be discussed with third parties or in public places. HIPAA privacy standards require Hospitals to regulate business associates.

Therefore, any person or company performing an activity or service for UHealth that involves the use or disclosure of individually identifiable health information must agree to enter into a business associate contract to ensure that each business associate protects protected health information (PHI). The business associate contract must contain provisions that establish the permitted and required uses and disclosures for PHI. Furthermore, the business associate contract must provide that the business associate may not use or further disclose the information other than as permitted by the contract or as required by law.

All contracts proposed by Vendor Representatives should include appropriate HIPAA compliance provisions. In any event, the Vendor Representatives must agree that any and all actions taken or authorized by the Vendor Representatives regarding the transaction, goods, or services involving or relating to UHealth shall comply with all applicable laws pertaining to standards for electronic transactions, including those set forth in the Health Insurance Portability and Accountability Act of 1996, and all rules promulgated there under. The Vendor Representatives is also responsible for requiring all agents or subcontractors to comply with such applicable law. Upon the request of UHealth, the Vendor Representatives will provide appropriate documentation of its agents or subcontractors compliance with such requirements.

# Confidentiality of Information

In the course of interacting with UHealth you may receive information about UHealth patients, employees, donors, and its financial or business operations. Some of this information may be considered “confidential” by law or by UHealth policies. Confidential information may exist in any form – e.g., written, oral, overheard, observed, or electronics. It is your responsibility to comply with UHealth policies by accessing only such information that you need to perform your job and in accordance with the law.

Individuals receiving confidential information are prohibited from disclosing such information to friends, relatives, co-workers, patients, and others unless permitted by UHealth policies, applicable law, or as required to perform your assigned job duties. Confidential information must be protected while doing business with UHealth and after your business relationship with UHealth ends. Violation of UHealth confidentiality policy may subject you to adverse action, up to and including termination of your business relationship with UHealth, as well as civil or criminal penalties as applicable by law.

# Non-Disclosure and Confidentiality of University of Miami Proprietary Information

Vendor agrees not to divulge to any third party or parties, or use any of University of Miami’s proprietary and confidential Information including, but not limited to any and all information, know-how and data, technical or non-technical, trade secrets, and specifications (hereinafter referred to as “Information”) for any purpose other than for the purpose of Vendor’s business relationship with the University of Miami.

Vendor further agrees to limit disclosure to only those of its officers and employees as Vendor considers necessary to complete its business with the University of Miami, and shall make such disclosures only after such officers and employees have undertaken to comply with the obligations of Vendor under this

policy. Vendor shall take all appropriate and reasonable steps to prevent the disclosure of the Information as provided herein. This obligation shall be binding upon Vendor for a period of ten years.

# Corporate Compliance Program

UHealth is committed to providing quality health care services in an ethical and legal manner. The business partnerships that we have with your organization, and our other Vendor Representatives, are an important aspect of our ability to fulfill of our commitment of providing quality health care to the community we serve. Therefore, we must work together to ensure that we maintain a partnership that is compliant with the multitude of government regulations, accreditation standards, and industry codes of ethics – for hospitals, physicians, and manufacturers – that impact our business interactions and thereby minimize the probability for noncompliance to occur.

Our Corporate Compliance Program is based on the following key elements:

# Policies and Procedures

A series of policies and procedures, including a Code of Ethics, have been developed to address components of UHealth Corporate Compliance Program. Our Code of Ethics states that all UHEALTH personnel must conduct themselves according to the highest ethical standards in accordance with all applicable laws, rules and regulations. Vendor Representatives, contractors, and agents conducting business with us, or on our behalf, are expected to comply with our Code of Ethics as business is carried out.

# Compliance Office

The Compliance Officer for UHealth provides oversight to the day-to-day operations of the compliance program and can be reached at 305-243-4357.

# Communication (Incoming)

Employees, Vendor Representatives, contractors, and agents have an obligation to report suspected fraud, false claims, or other issues of potential non-compliance to us so that we may properly address the allegation. Anyone reporting an issue in good faith is protected from retaliation, as set forth in federal and state laws.

* **Hotline.** UHealth has a confidential Hotline that is available 24 hours a day, 7 days a week to receive questions and concerns of potential compliance issues. An individual can choose to remain anonymous when using this voice-mail reporting system unless a response is expected. However, sufficient detail must be provided in order for the issue to be investigated. The Hotline can be reached at 305-243-4357 and is available for use by UHealth contractors and Vendor Representatives, as well as by employees and medical staff members.
* **Other Options.** Other options for reporting a suspected violation include: department supervisors and senior management.

# Response to Compliance Issues

The Office of Corporate Compliance ensures that potential issues are thoroughly and promptly investigated and that corrective actions are taken as necessary. Corrective action may include policy development, reporting to a government agency, or disciplinary action for an individual committing a violation.

# Compliance Issues to Report

From a Vendor Representatives’ perspective, the types of general compliance issues that you should report to the Corporate Compliance Officer, or other person of authority, include, but are not limited to, the following categories:

* Conflict of interest issues
* Non-compliance with UHealth policies or procedures
* Confidentiality and patient privacy violations (including review of medical records unrelated to job responsibilities)
* Safety and security issues
* Harassment by a UHealth employee or medical staff member
* A request for a gift or other item of value in exchange for referring or using your company’s products

– or a gift whose magnitude is prohibited by UHealth policy

* Receipt of kickbacks, rebates, or special discounts from another Vendor Representatives in exchange for purchasing and/or referring the other Vendor Representatives’ products

# Conflicts of Interest

UHealth expects its employees, contractors, and Vendor Representatives to conduct business in an honest and objective manner. Vendor Representatives Reps, and their Vendor Representatives companies, have an obligation to avoid and disclose any relationships and/or ethical, financial, or legal interests involving UHealth and its associates that could potentially impair their ability to make objective decisions involving UHealth.

Examples of situations involving a Vendor Representatives and a UHealth associate (defined as employee or medical staff member) that could impose potential conflicts of interest include, but are not limited to, the following:

* A personal relationship existing between the Vendor Representatives and the UHealth associate who makes purchasing decisions about the Vendor Representatives’ products and services
* A UHealth staff who has a substantial financial interest in the Vendor Representatives’ company or serves as on a Board connected to the Vendor Representatives’ company
* A Vendor Representatives who is also a part-time employee of UHealth – or vice versa
* Knowledge of confidential business information, gained about the business partner through the business relationship, which could be improperly used for personal gain.

# Conducting Business a UHealth Facility Parking

Vendor Representatives Reps may park in any of the designated visitor parking garages on the campus.

# Badge and Sign-In Process at UHealth

The Hospital’s Main Entrance and serves as the primary entrance for Vendor Representatives and other visitors. For appointments at a specific facility the Vendor Representatives Rep must complete the check- in and badge process at the sign-in station located in each main lobby.

# Check-Out Process at UHealth

The check-out process must occur at Supply Chain, at the department where the appointment occurred, or via the self-service kiosk. The badge should be discarded after the check-out process.

# Appointments after 5 PM and Before 6 AM

When appointments at the Hospital occur after the regular business hours, vendor representatives may need to contact Security at the respective Main Lobby to gain access to the facility.

Vendor Representatives are not allowed to enter the Facility using an employee’s badge; during off- hours, Vendor Representatives are still required to complete the check in and check out process and obtain a badge.

The Manager of the department being visited by the Vendor Representatives is responsible for ensuring that the Vendor Representatives gains access to UHealth when the facility is closed. It may be necessary for the Vendor Representatives to present some form of photo identification to the Security Officer in order to gain access. Therefore, it is recommended that the Vendor Representatives Rep has in his/her possession a photo ID issued by his/her employer – bearing the company’s name and the Vendor Representatives rep’s name.

The department being visited is responsible for ensuring that the Vendor Representatives arrival time and departure times are correctly reflected in the online Vendor Representatives Registration Program.

# Access to Patient Care Areas:

Vendor Representatives are not allowed to enter patient care areas of the Hospital without specific permission from a director or manager of that department or the staff responsible for in-service education. While in patient care areas, the Vendor Representatives should be accompanied by a UHealth employee at all times and must follow any internal policies of the respective department.

# Access to Common Areas of Hospital:

Excluding appointments, a Vendor may spend **up to one hour** in the Hospital’s cafeteria, or lobby. However, the Vendor Representatives Rep is **prohibited** from approaching physicians or UHealth employees in these areas, as well as in elevators or patient care areas, for the purpose of conducting business discussions.

# Supply Chain Policies

The Supply Chain Department for UHealth is located hospital facility. The Departments may vary in daily operation times but are generally open from 7:00 AM to 5:00 PM, Monday through Friday and can be reached at individually to schedule appointments. After **launch date** all visits to Supply Chain must be scheduled in advance; cold calls are no longer accepted.

# Use of Purchase Order

All purchasing-related transactions require a purchase order. Any equipment or devices brought into a facility for evaluation will require a no-charge purchase order and Biomedical clearance before the item can be demonstrated for patient use. Prior Value Analysis Committee approval is required.

# Group Purchasing Membership

UHealth is a member of Health Trust. Additional information is available by contacting the Purchasing Department.

# Standard Payment Terms

Standard non-contracted payment terms are Net 60 and shipments are FOB destination.

# Non-Pharmaceutical Samples & Products for Trial Use

It is the policy of UHealth that all new patient care products or substitute products (with the exception of pharmaceutical products) to be used at a UHealth facility will be evaluated for cost and quality by the Value Analysis Committee. This Committee will conduct a patient safety and product efficacy evaluation to ensure that there is a standardized review process before patient care products are, evaluated, appropriate recommended and purchased.

# New Product Introductions

Vendor Representatives are responsible for scheduling an appointment with Value Analysis to introduce new products **before** these products can be discussed with physicians or UHealth Medical Staff. The product must be left with Value Analysis for review and evaluation by Value Analysis Committee whenever possible. Equipment/supplies furnished by the Vendor Representatives must be in usable and unopened condition at the time it is brought into the hospital. UHealth assumes no responsibility for supplies or equipment left by Vendor Representatives in the organization for the purpose of evaluation. It is the responsibility of the Vendor Representatives, unless agreed to by the requesting department, to deliver, install, and remove the equipment or supplies upon completion of the evaluation.

The Department wishing to use a new or substitute product is responsible for completing a “Value Analysis New Product Request Form” and forwarding it to the Value Analysis Department for introducing items to the Value Analysis Committee. (Email: ValueAnalysis@miami.edu)

The Value Analysis Committee will be responsible for conducting product trials and for reporting the trial’s results back to the requesting department. If a product is accepted, the product will be assigned an item number to be entered into the Materials Management System.

Vendor Representatives performing maintenance service on medical equipment must deliver a customer- signed service report to the Purchasing or Biomed Department upon completion.

# Clinical Equipment

Clinical equipment can only be brought into a facility with a no charge purchase order (PO) and must go directly to Biomedical Engineering prior to the trial.

# Removal of Product

A Vendor Representative cannot remove any supply, product, and equipment without authorization by Supply Chain during business hours and by charge personnel after business hours. A product return document will be issued when returning equipment – for tracking purposes.

# Product Recalls

Vendor Representatives are required to notify the appropriate Department Manager about product recalls, with such notification to include identification of the product (including lot numbers affected and quantities removed from UHealth), the reason for the recall, and a copy of the recall or FDA information. Similar information about product substitutions must be provided to the Department Manager.

# Vendor Representatives Interactions with UHealth Employees & Departments

UHealth is committed to conducting business on the principles of honesty, fairness, and the merits of a Vendor Representatives’ products or services. Neither the Vendor Representatives nor anyone working on behalf of the Vendor Representatives may offer or give money, gifts, gratuities, favors, entertainment, the opportunity to earn money, or other items of value to any person associated with UHealth or its Affiliates for the purpose of inducing such person to use, prescribe, or refer the Vendor Representatives Rep’s products or services. Additionally, under no circumstances may a UHealth employee solicit a gift from a Vendor Representatives whose products are billed to a federal healthcare program.

Vendor Representatives are encouraged to follow the principles set forth by their own companies regarding interactions with health care providers.

# Gifts and Meals From Vendors

1. **Gifts to Individuals**. UHealth prohibits employees from receiving gifts which may improperly influence employees in the conduct of their Hospital responsibilities. Notwithstanding the $50.00 limit provided in the UM policy, this policy too prohibits **all** gifts from vendors to departments and employees.

This includes meals, food, gifts and entertainment.

* + Individual vendors are not allowed to bring food into the organization.
  + Staff is not allowed to have meals paid for by vendors.
  + Staff is not allowed to receive gifts, including pens, books, note pads, trinkets and any other items.

1. **Gifts to Departments.** Vendors are prohibited from providing gifts (including but not limited to meals, gifts and entertainment) to individual departments because they may be perceived as incentives to influence transactions between departments and the HCRI.
2. **Sit****e Visits.** Vendors may fund necessary site visits by Hospital staff for the purpose of demonstrating vendor products and equipment. However, vendors may only pay for the reasonable and actual cost of travel, food and lodging for essential Hospital staff. Site visits must be approved in advance by Administration.

# In-Service Training Sessions

All in-service must be on formulary items and **must** be approved by the Department Manager in advance of the training being conducted. Meals may be provided during these training sessions; refer to the paragraphs about meals.

# Training Programs

Programs requiring “hands on” training about medical procedures, medical devices, or medical equipment must be held at training facilities, laboratories, hospitals, or other appropriate facilities conducive to learning. The training staff must possess the proper knowledge, skills, and certifications (if applicable) to conduct such training. UHealth employees may attend meals and receptions provided with product training programs, as long as the meals and receptions are modest in nature and subordinate in time and focus to the educational session. Reasonable travel and lodging costs may be paid for UHealth employees, provided that the training is necessary to correctly employ the procedure, device, or equipment and is applicable to the employees’ current job responsibilities. It is not acceptable to pay for guests of UHealth employees. Travel expenses to be absorbed by the Vendor Representatives must be approved in advance by the appropriate administrative staff.

Vendor Representatives may not detail in any patient care area at any time. In addition, hallways leading to patient care areas are also prohibited areas for detailing. Under NO circumstances may a Vendor wander through the halls of the hospital. Vendor Representatives shall proceed directly to the place of their appointment and shall also leave directly thereafter.

# Hospital and Non-Hospital Physician based Clinical Care Setting

1. Approval to be present in any patient care area of the facility is a privilege which will be extended only to professionally competent Vendor Representatives who continuously meet the qualifications, standards, and requirements as described in this policy.
2. Written informed consent will be obtained from patients for the presence of vendor in any facility setting. The patient will be informed of the Vendor Representative’s permitted level of involvement and role. The patient has the right to refuse the presence of the Vendor Representative. Documentation of the presence of the Vendor Representative during the procedure will be included in the permanent medical record.
3. Vendor Representatives will wear disposable scrubs and facility issued identification badges during their visit to any procedural patient care areas as provided for via RepScrubs.
4. Under the guidelines established by the UHealth System, the Vendor Representative may provide training, education, and technical assistance for medical systems, devices, procedures, and drugs to the healthcare team under direct supervision of the physician (when applicable) requesting the presence of the Vendor Representative. The Vendor Representative will instruct employed staff on how to operate the equipment and the staff will be responsible for the operation of the equipment. Medical equipment and other complex devices must be reviewed and approved prior to their use by the Biomedical Department as appropriate.
5. The Vendor Representative shall NOT deliver patient care, scrub in for any procedure or otherwise provide hands-on assistance, open sterile supplies, or have access to any patient information outside of the single care to which patient consent was obtained and this access shall be limited to a clinical, patient specific need to know level.

# General Standards

UHealth recognizes the need for education and introduction of new technology, procedures, and techniques to health care professionals in the perioperative setting. At the same time, a patient’s right to privacy and safety must be protected – particularly when a Vendor Representative is present during a surgical procedure. All Vendor Representatives present in procedural areas must abide by the following general standards:

* A Vendor Representative may observe a procedure **only** at the request of a physician performing the procedure.
* If a new medical product is being used, the product **must** be approved by Value Analysis **before** the product can be introduced to the physician and/or other clinical staff and before the product can be used with a patient.
* Vendor Representatives are **not** permitted to:
* scrub in
* assist with procedures (other than technical assistance in the form of verbal consultation)
* open sterile products, or
* have patient contact
* Vendor Representatives or Technical Support Reps with specialized training may perform remote calibration of their company’s products – e.g., pacemakers and pain management devices – to the physician’s specifications.
* A Vendor Representative’s presence during a surgical procedure is to be recorded in documentation of a patient’s surgical procedure.
* Sales calls with physicians must be conducted in non-patient care areas only.

1. Vendor Representatives may be present in the Operating Room **only** with the advance approval/request of the physician performing the procedure. **No walk-ins will be accepted.**
2. Vendor Representatives must **first** check-in with at the self-service kiosk prior to arriving in the Operating Room area.
3. When entering the Operating Room Vendor Representatives will:
   1. Approach the O.R. front desk.
   2. Leave a business card that is to be given to the appropriate Circulating Nurse.
   3. Have their UHealth-issued badge displayed prominently at all times.
   4. Be suitably attired, according to UHealth’s Operating Room policies.
   5. Leave brief cases/bags in the designated area. They are not to be taken into the Center Core or Operating Rooms.
   6. Adhere to the UHealth standards of confidentiality and Infection Control.
   7. Not be allowed to participate in the actual procedure or make any adjustments to equipment used during the cases.
   8. Not be allowed to open sterile supplies and implants.
   9. Enter the Operating Rooms through the scrub area.
   10. Enter the Operating Room only after induction of anesthesia or unless invited by the Surgeon prior to induction of anesthesia.
   11. As an invited guest they will function under the direction of the Circulating Nurse and the Director of Surgical Services. Noncompliance to directions from either of the nurses could result in removal from the OR.

# Required Documentation & Competencies

A Vendor Representative that is present in the **Operating Room, Catheterization lab, or other procedural patient care areas** during a procedure are REQUIRED to maintain documentation of certain competencies, health status, and background checks on file with UHealth through Vendormate.

The Vendor Representatives must provide the following documentation in advance of being granted access to a procedure:

* Educational training and/or certification of the products/services the Vendor Representatives is authorized to perform
* Competency assessments for the products/services provided: Evidence of the Vendor Representatives comprehension and retention of the training received
* Pre-employment background checks, including criminal background checks and drug testing
* Liability (or Malpractice) Insurance Certificates
* Documentation of Education/Training for the following areas:
* Aseptic Principles and Infection Control
* Bloodborne Pathogens
* Sterile Techniques
* Product Complaints and Medical Device Reporting (MDR) requirements
* Product Recall Processes
* Patient Rights, Confidentiality, and HIPAA
* Documentation of Vendor Representatives Rep’s Current Status for the following:
* MMR (Measles, Mumps and Rubella) Vaccination
* Hepatitis B Vaccination
* History of Varicella (Chickenpox)
* TB Testing (if positive, documentation of chest x-ray
* Influenza Vaccine

# NON-CLINICAL

**Pharmaceutical Manufacturer Representatives**

Vendor Representatives detailing pharmaceuticals, intravenous solutions, tubing or any item marked “Federal law prohibits dispensing without a prescription” shall deal directly with the UHealth Departments of Pharmaceutical Services.

1. Pharmaceutical Vendor Representatives must schedule appointments by contacting the Pharmacy Departments directly.
2. Pharmaceutical Vendor Representatives must use the Vendormate Badge system located in each facility’s designated area.
3. Pharmaceutical Vendor Representatives MAY **NOT** enter patient care areas, e.g.: Emergency Room, Operating Room, Nursing Stations, and Anesthesia.
4. **No drug samples, legend or over-the-counter product may be left in any facility**. Any educational or promotional programs for prescribing medications must be registered in the Pharmacy prior to discussing with UHealth Staff.
5. As new products become available, objective information shall be provided to the Pharmacy for further evaluation.
6. Only Formulary approved medications may be “Detailed” on UHealth Medical property. The Formulary status of a medication may be determined by contacting the Pharmacy Department.
7. Displays are not permitted in public areas. Speaker programs may be arranged through the Pharmacy or Medical Education Departments.
8. UHealth has a “closed” formulary system. Non-Formulary medications are not available for use on patients. Requests for addition of items to the formulary must be initiated by a physician with privileges at the institution and reviewed by the Pharmacy and Therapeutics Committee. The requesting physician must contact the Pharmacy directly and provide appropriate documentation for P&T Committee consideration.
9. Violation of these policies by the Pharmaceutical Vendor Representatives will result in expulsion from the institution and suspension of visiting privileges.

# CLINICAL LABORATORY

All sales activities for laboratory tests or devices, whether for testing in the Clinical Laboratory or in a clinic/nursing unit (i.e. Point of Care testing) must be conducted with Clinical Laboratory staff.

Vendor Representatives may not contact physicians, clinics, or nursing units for the sale of or to provide information on laboratory test or devices.

# INFORMATION SERVICES

Under specific circumstances, software and/or hardware vendors must be on the UHealth system premises to perform services. Examples would be: installation of products, go-live support, and user or IS team training. In these instances, the Vendor Representative may be required to be in the patient care areas without direct UHealth system staff supervision. The following criteria should be met:

* + UHealth Project Manager or Management staff must be aware that vendor is on-site.
  + Physical Plant Manager and/or Supply Chain Manager will notify the Manager of the area the contractor is going to be working.
  + Company assigned identification must be worn at all times.

# NEW PRODUCTS

* + All new product/equipment are subject to review by the designated Value Analysis Committee. A formal process has been established for documentation of product evaluations. The Value Analysis Department staff will provide assistance with the required documents.
  + A Value Analysis New Product Request form must be submitted for each new product to be evaluated. (email: ValueAnalysis@miami.edu)

# Vendors will not be paid for product use if prior approval is not obtained.

* + No products should be left in any area of UHealth without prior approval of the Committee.
  + Vendor Representative leaving products without permission from Material Management will be subject to discipline. **Items not previously approved will not be paid for.**
  + Supply Chain will help make arrangements with vendors when their products will be needed for evaluation or trial.
  + We require that Vendor Representative not pressure UHealth staff during a negotiation or request for quotation process. The best way to expedite the process is to be prompt in returning calls and providing proposals & information as needed.
  + If the medical/surgical product merits further investigation or evaluation, it will be referred to the appropriate Department Director. In the event of a trial where product is required to determine its merit, the supplier or manufacturer will, at no charge, provide an adequate supply to make a fair determination, unless the product qualifies as an implant. All implants will be paid for and pricing will be negotiated PRIOR to trial.
  + All medical/surgical products that are to be evaluated in an actual clinical setting are to be delivered in a properly sealed package that assures the integrity of sterile products.

# SALES OR SERVICE CALLS

* + Meetings with UHealth staff will only occur at the request of the staff member by appointment only. Verification of the scheduled appointment will be confirmed to insure compliance with hospital policy.
  + Meeting places are restricted to staff offices & conference rooms in non-patient care areas.
  + Vendor Representative must leave the area immediately upon completion of an appointment. Loitering in UHealth corridors, cafeterias, and other areas in an attempt to facilitate a nonscheduled meeting with a UHealth staff member is prohibited.

# Disciplinary Action

Vendor Representatives who do not adhere to UHealth policies will be subject to remedial actions ranging from suspension to permanent dismissal of rights to conduct business with UHealth on behalf of their companies. Because UHealth does not want to hinder the delivery of patient care, the Vendor Representatives company may assign another Representative to service UHealth during the suspension or permanent dismissal of the Vendor Representatives violating UHealth policies. All UHealth staff will assist in monitoring the level of compliance and will report violations to the Material Management Department.

* First Violation: Written notification of a 60-day suspension of facility visits and selling for the Vendor Representatives committing the violation.
* Second Violation: Written notification of a one (1) year suspension of business interactions with UHealth for the Vendor Representatives.
* Third Violation: Written notification of a permanent ban of business interactions at UHealth by the Vendor Representatives committing the offense.

In the event that a Vendor Representative is found in a patient care area without authorization or requests or attempts to gain access to confidential information concerning patients or product use, privileges will be immediately and permanently revoked.

# It is the responsibility of the Vendor Representative to renew their credentials on an annual basis.

**Required Documentation Checklist for Vendor Representatives**

The following table represents a summary of documentation and competencies that are required for specific groups of Vendor Representatives. You may find it helpful to refer to this page in preparing your registration package.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Pharmaceutical Reps** | **Reps in Procedural Areas (OR, Cath Labs, Etc.)** | **Medical Equipment Service Personnel or Clinical Service Techs** | **General Maintenance or Repair Personnel** |
| **Health Status or Immunizations** |  |  |  |  |
| MMR (Mumps, Rubella, Rubeola) |  | X |  |  |
| History of Chickenpox (Varicella) |  | X |  |  |
| TB Skin Test (Chest X- Ray if positive) |  | X |  |  |
| Influenza Vaccine |  | X |  |  |
|  |  |  |  |  |
| **Education/Training** |  |  |  |  |
| Products/Services being provided | X | X | X | X |
| Competency Assessment on Product Knowledge | X | X | X | X |
| Pre-Employment Screening of Criminal Background Check | X | X | X | X |
| Pre-Employment Drug Testing | X | X | X | X |
| Bloodborne Pathogens |  | X |  |  |
| Compliance/Ethics | X | X | X | X |
| HIPAA, Patient Privacy, Patient Rights | X | X | X | X |
|  |  |  |  |  |
| **Liability Insurance** | X | X | X | X |
|  |  |  |  |  |
| **Photograph (Recent Head Shot) for Badge** | X | X | X | X |