



## Chief Executive Officer of the Medical Center

### MEDICAL CENTER POLICY NO. 0013

A. SUBJECT: Vendors, Sales and Service Representatives at the Medical Center

B. EFFECTIVE DATE: January 1, 2020 (R)

C. POLICY:

1. This policy applies to all persons providing patient care or other services, receiving training, or involved in health care education and research within, or for the benefit of, the University of Virginia Medical Center, regardless of employer (“Covered Persons”). By definition, “Covered Persons” includes all Members of the Clinical Staff and all persons holding clinical privileges at the Medical Center.

This policy also applies to vendors, sales and service representatives (whether individuals or legal entities; hereinafter collectively referred to as “Representatives”) and their relationships and interactions with Covered Persons while on Medical Center premises (“Visits”). Visits include, but are not limited to, sales activities, product demonstrations, observation of surgical/interventional procedures, and educational events.

All Representatives’ activities conducted within the University of Virginia Medical Center shall be conducted in accordance with University of Virginia, University of Virginia Health System, and Medical Center policies and shall not interfere with the provision of patient care or Medical Center operations.

Employees of the Medical Center and the University are subject to the State and Local Governmental Conflict of Interests Act and the Ethics in Public Contracting Section of the Virginia Public Procurement Act of the Code of Virginia. This policy incorporates the requirements of these Acts, and in some instances imposes more stringent requirements. To the extent that this policy exceeds the requirements of state or federal law or other codes of conduct, this policy shall control. (See University of Virginia [Health System Policy BEH-002 “Conflicts of Interest and Conflicts of Commitment”](#))

Covered Persons are also expected to adhere to the National Association of Educational Buyers Code of Ethics available at:

<http://www.naepnet.org/?page=CodeOfEthics&hhSearchTerms=%22code+and+ethics%22>

Failure by Representatives to comply with the requirements set forth in this policy shall be sufficient grounds for restriction from the Medical Center and its facilities in accordance with state law and Medical Center Procurement Guidelines as set forth in [Medical Center Policy No. 0189 “Medical Center Procurement Guidelines”](#) as well as additional penalties up to and including debarment.

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All Covered Persons are required to assist in monitoring adherence to this policy.

**2. General Standards applicable to Covered Persons during Visits:**

Unless otherwise permitted under this policy, Covered Persons shall not:

- i. Meet with a Representative who does not have an approved, scheduled appointment and is not wearing an official identification badge.
- ii. Meet with Representatives in patient care areas.
  - a) Patient care areas exclude physician offices, but include patient units, nursing stations, conference rooms located in patient care units, physician lounges, patient care areas of outpatient offices (including clinics located off-grounds), surgical areas or the Emergency Department.
  - b) Exceptions may be made for in-service training (i.e., when a Representative is on site to conduct instruction on the use of specific devices or equipment) or technical consultations (i.e., Representatives' presence during procedures or for equipment repair or maintenance) conducted in accordance with other relevant Medical Center policies.
- iii. Permit Representatives to see patients, review records, or attend rounds or surgical procedures unless otherwise permitted under this policy, or in accordance with [Medical Center Policy No. 0092 "Release of Patients' Protected Health Information"](#), and other relevant Medical Center policies.

**3. General Standards applicable to Representative Visits:**

- a. Unless otherwise permitted under this policy, **Representatives shall not offer or provide to Covered Persons, directly or indirectly**, any of the following items<sup>1</sup>:
  - i. gifts or compensation, of any kind and regardless of value;
  - ii. promotional items of any kind and regardless of value, (i.e., pens, note pads, cups or similar items). Covered Persons may accept items of nominal value having a legitimate educational purpose (i.e., brochures, pamphlets, training videos or similar items) for use by Covered Persons or patients;
  - iii. food or beverage of any kind, and regardless of value on the grounds of the Medical Center or on University grounds. Funds given to the University or Medical Center without restrictions on their use ("unrestricted gifts") may be applied to provide food or beverage at an educational event or function. Representatives seeking to make an unrestricted gift should follow the guidance provided in Section D.6 of this Policy.
  - iv. gifts or compensation, of any kind and regardless of value, for listening to a presentation;

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<sup>1</sup> Covered Persons shall follow [Health System Policy BEH-002 "Conflict of Interest and Conflict of Commitment"](#) for Health System policy on the acceptance of food and beverages from Representatives off site.

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- v. any product samples, for personal or family use, including but not limited to medication samples or ancillary product samples such as infant formula, lotions, etc.;  
or
  - vi. gifts or compensation, of any kind and regardless of value, for prescribing or changing a patient's prescription or for prescribing or using a particular medical device.
- b. Generally, all Representatives must be enrolled in the Medical Center's Reprax system (a vendor tracking service), before their first Visits. In those instances where Reprax has no record of a Representative's compliance with Reprax or Procurement requirements (for example, where the Representative's presence has been requested by the physician on an emergency basis and the Representative has not yet been approved in Reprax or notified Procurement of the intended visit, or the Representative is substituting for another approved Representative and the substitute Representative has not completed the Reprax approval process), the procedures in Section D.2 shall apply.
  - c. A Representative may not visit with any Covered Person unless the Representative is invited for a particular purpose, and that particular appointment and its purpose are documented in Reprax. Once that appointment has concluded, the Representative is expected to promptly leave Medical Center premises.
  - d. Representatives must display valid Medical Center identification badges at all times. (See [Health System Policy ACC-001 "Health System Identification"](#)).
  - e. The presence of Representatives during a clinical procedure at the Medical Center shall require approval by the Attending Physician requesting the Representative's presence and shall require the consent of the patient who may be observed by the Representative.
  - f. Representatives are not allowed to bring "trial" equipment or supplies into patient care areas without approval from Clinical Engineering or Medical Center Contracts & Procurement (MCC&P).
  - g. Representatives must comply with all requirements regarding attire, patient privacy, and infection control.
  - h. Representatives in patient care areas must at all times be accompanied by Medical Center personnel.
  - i. Representatives cannot have a role in the diagnosis and/or treatment of patients.
  - j. Representatives shall not be permitted to see patients, patient records, or attend rounds or surgical procedures without appropriate authorizations in accordance with this policy and other relevant Medical Center and University policies.
  - k. Pharmaceutical Representatives shall not promote any product that has been excluded from the Medical Center Drug Formulary.

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- l. Medication and other product samples (whether provided to patients, Covered Persons, or their families) are prohibited.
- m. Detailing of restricted medications is limited to the restrictions or guidelines for use approved by the Pharmacy and Therapeutics Committee.

#### **4. Representatives' Presence for Informational and Educational Purposes**

- a. Representatives may only meet with Covered Persons to provide information and education about products in the following venues, unless permission has been granted in advance by MCC & P for use of another space: academic conferences, office appointments, and public areas (e.g. cafeteria).
- b. Meetings with Representatives may not occur in patient care settings except as described in this Policy.
  - i. Patient care settings exclude physician offices but include inpatient units, nursing stations, conference rooms located in patient care units, physician lounges, patient care areas of outpatient offices (including clinics located off-grounds), surgical areas, or the Emergency Department.
  - ii. Exceptions may be made for in-service training (i.e., when a Representative is providing instruction on the use of specific devices or equipment) or technical consultations (i.e., where a Representative is present during procedures or for equipment repair or maintenance) conducted in accordance with this Policy and other relevant Medical Center policies.
- c. In-service training for Covered Persons on specific devices or equipment or technical consultations must be arranged by appointment in accordance with this Policy.

#### **5. Representatives' Presence During Clinical Procedures**

- a. A Representative may be present during a clinical procedure only when deemed necessary by an attending physician; such attending physician shall be defined as the Representative's Sponsor, for purposes of this policy.
- b. A Representative's presence shall be limited to clinical procedures in which the Representative's presence is requested by the Sponsor to provide information for coordination of treatment, such as advice or education on medical device specifications and selection for proper sizing during the procedure, or to provide technical expertise on the implant, use, and operation of their companies' equipment, by operating programmers, analyzers, and other support equipment under the supervision of the physician, while also providing education and training to Medical Center healthcare professionals.
- c. A Representative may participate in a procedure as described in paragraph C.3.e. above, but may not enter the sterile field.
  - i. If a Sponsor anticipates that a Representative will be required to enter the sterile field in order to support a surgeon as necessary to develop competency with equipment, that Sponsor must make a written request to the oversight committee for the

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procedure area in question. For the OR, the oversight committee is the Operating Room Committee. For procedure areas, the oversight committee is the Patient Care Committee.

- ii. That oversight committee must have both physician and non-physician membership, and be able to evaluate the credentials of the Representative, evaluate the clinical justification presented by the Sponsor, and validate training required of the Representative to be within the sterile field.
- iii. Representative shall not provide any patient care.
- iv. Any/all instruments brought into the Medical Center from an outside facility must be processed and sterilized by Medical Center Sterile Processing. Representatives providing implants and/or loaner instrumentation to the Main OR or Outpatient Surgery shall contact Sterile Processing at those locations for specific policies regarding proper handling.
- v. When obtaining patient consent for a clinical procedure, the patient's physician or designee shall inform the patient of the presence and role of the representative during performance of the procedure and document this discussion on the procedure consent form. (See also [Medical Center Policy No. 0024 "Informed Decision-making".](#))

#### **6. Representatives' Presence for Other Purposes**

Representatives occasionally request access to Medical Center facilities so that they or their customers or other non-Medical Center personnel might receive training or education from Covered Persons in the use of a technology or a diagnostic or therapeutic application or technique which is sold or promoted by the Representative. Access to Medical Center facilities for such purposes is expressly prohibited under this policy, unless written permission, in advance, has been obtained from the Chief Executive Officer or designee, or the Chief Operating Officer, or designee, in consultation with the University of Virginia Office of Sponsored Programs. Suspected violations of this Section should be reported as indicated in Section D.8 of this Policy.

#### **7. Access to medical education conferences including Graduate Medical Education Events:**

- a. Representatives may sponsor speakers for medical education conferences conducted at the Medical Center.
- b. Topic(s) to be addressed at GME events must be approved in advance by the DIO, or designee.
- c. The date, topic, and time of any drug-related presentation must be communicated to the Administrator of Pharmacy, or designee.
- d. Representatives may not provide meals, gifts or other compensation.
- e. Representatives shall not attend programs/meetings in which specific patients are identified or when quality assurance or risk management issues are presented. This does not apply to Representatives who have been specifically requested to consult with Attending Physicians regarding a specific patient or group of patients.

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- f. All clinical educational conferences, programs and events conducted by or for Clinical Staff and Graduate Medical Trainees and/or Allied Health Professionals must conform to the Accreditation Council for Continuing Medical Education (“ACCME”) guidelines, the Accreditation Council for Graduate Medical Education (“ACGME”) guidelines, or other applicable guidelines, whether or not credit is awarded, and must otherwise comply with all relevant Medical Center, University of Virginia and University of Virginia Health System, School of Medicine policies and guidelines relating to educational and professional activities.

#### D. PROCEDURE

1. All Representatives calling on Covered Persons on Medical Center grounds for any reason, including education purposes, shall register as follows:
  - a. Representatives shall register at a Reprax kiosk each day they conduct business with UVA staff or faculty; a current listing of all Departments or areas with Reprax kiosks can be found on the [MCC & P website](#);
  - b. At the time of sign-in, an official temporary identification badge shall be issued to the Representative in accordance with [Health System Policy ACC-001 “Health System Identification”](#).
  - c. At the time of sign-in, Representatives shall be asked to supply their name, company's name, company's phone number, and their contact at the department or clinic they are visiting.
  - d. University Security may ask unauthorized Representatives to leave the premises.
2. In those instances where Reprax has no record of a Representative’s compliance with Reprax or Procurement requirements (for example, where the Representative’s presence has been requested by the physician on an emergency basis and the Representative has not yet been approved in Reprax or notified Procurement of the intended visit, or the Representative is substituting for another approved Representative and he/she has not completed the Reprax approval process):
  - a. The Representative shall complete Section 3 of the University of Virginia Medical Center Vendor Presence Agreement and forward it to the Patient Care Services Manager of the area the Representative intends to visit.
  - b. The Representative shall supply to the department or area manager a copy of thier job description, statement of competency from their employer, copies of any licenses or certifications required by the employer and proof of insurance coverage for liability.
  - c. The manager, at thier discretion, may then permit or deny the Representative access to the area.
3. Representatives who call upon Covered Persons at Medical Center facilities located at outpatient clinics and other facilities not located on Medical Center grounds for any reason, including education purposes, shall, additionally, sign-in and obtain authorization from the Manager of the off-site location in advance of their visit. Representatives shall be asked to supply their name, company's name, company's phone number, and their contact at the department or clinic they are visiting.

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4. When a Representative is to be present for a procedure, the Sponsor or designee shall document the Representative's presence and the physician's sponsorship of that Representative by either:
  - a. documenting in the EMR the presence and role of the Representative during the procedure; or
  - b. completing Sections 1 & 2 of the University of Virginia Medical Center Representative Presence Agreement ([see attachment to this policy](#)) and forwarding to the Patient Care Services Manager for that area.
5. All documentation of a Representative's presence during a clinical procedure shall be maintained in accordance with relevant law and Medical Center policy regarding record retention.
6. Proposals from Representatives for any interactions described in this policy at the Medical Center shall be referred to the appropriate office for review, evaluation and approval, with documentation as required. The following may be used as a referral guide:
  - a. Research grants, and contracts in which University personnel provide consulting and other services to a Vendor – School of Medicine Grants and Contracts Office.
  - b. Representative's offer of a service or product – Medical Center Contracts & Procurement (Medical Center); University Procurement Services (Schools of Medicine and Nursing, Health Sciences Library).
  - c. Gifts to the Medical Center and/or University – Health System Development Office.
  - d. Sponsorships of educational conferences, programs and events – Medical Center Contracts & Procurement (Medical Center); University Procurement Services (Schools of Medicine and Nursing, Health Sciences Library); Continuing Medical Education Office; Graduate Medical Education Office.
  - e. Representatives' grants to support the stipend and benefits of post-graduate fellows – Graduate Medical Education Office.
  - f. Unrestricted gifts in association with a specific educational activity or other purpose as permitted – Medical Center Contracts & Procurement Office; University Procurement Services; Continuing Medical Education Office; Graduate Medical Education Office.
7. Covered Persons shall be familiar with other relevant policies, including:
  - a. Conflict of Interests; <https://uvapolicy.virginia.edu/policy/FIN-054> and <http://provost.virginia.edu/conflict-interest-faculty>
  - b. Objectivity in Research, Income from Professional Activities, Faculty Interactions with Industry, Solicitation or Accepting of Gifts and Bequests; <http://provost.virginia.edu/faculty-resources/faculty-handbook>
  - c. The Policy on Conflict of Interest and Conflict of Commitment issued by the Office of the Dean of the School of Medicine of the University of Virginia:

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<https://med.virginia.edu/school-administration/wp-content/uploads/sites/304/2015/11/Conflictsinterest.pdf>

- d. [BEH-002 Conflicts of Interest and Conflicts of Commitment \(University of Virginia Health System\)](#)
8. Suspected violations of this policy shall be reported as follows:
- a. By Representatives: reported to the Chief of Supply Chain Management;
  - b. By Members of the Clinical Staff: reported to the Chief Medical Officer;
  - c. By Medical Center employees: reported to the CEO or COO;
  - d. By GME Trainees: reported to the Designated Institutional Officer.

Medical Center Policy No. 0013 (R)

Approved July 1983

Revised May 1986, March 1988, August 1990, September 1993, July 1994, November 1994, May 1996, May 1999, March 2001, November 2002, February 2004, October 2007, February 2008, June 2008, September 2008, June 2009, September 2011, June 2013, September 2014, March 2015, September 2016, December 2019

Approved by Chief of Finance



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**University of Virginia Medical Center Representative Presence Agreement**

**Physician Sponsor: Complete Sections 1 and 2 and forward form to vendor.  
Vendor: Complete Section 3 and forward form to the Patient Care Services Manager prior to the start of the procedure.  
Patient Care Services Manager: Retain completed form on file in department for two years.**

**Section 1 (please print):**

**Name of Representative:** \_\_\_\_\_

**Name of Representative’s Employer:** \_\_\_\_\_

**Name of Attending Physician Sponsor:** \_\_\_\_\_

**Date of Presence:** \_\_\_\_\_

**Purpose of Presence:**  
\_\_\_\_\_

**Location(s) :** \_\_\_\_\_

**Signature of Manager in area:** \_\_\_\_\_

**Manager Name:** \_\_\_\_\_

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**Section 2:**

In consideration of being given the opportunity to sponsor a vendor’s presence during a clinical procedure at the University of Virginia Medical Center, I agree to the following:

1. I shall review Exhibit 1 – Patient Confidentiality at UVA Medical Center-Information for Vendors and Exhibit 2 – UVA Medical Center Infection Control Information for Vendors (attached to this agreement) with the Representative and shall answer any questions the Representative may have about this information.
2. I understand that the Representative is permitted to be present during a procedure only after I have secured the patient’s informed consent to the vendor’s presence and role in the procedure. I agree to follow the requirements of the “Industry Employed Allied Professionals” (IEAP) or equivalent guidelines that apply to the procedure location (e.g., OR, EP lab).

The Representative shall wear his/her identification badge at all times while in the Medical Center or its satellite locations. Identification badges are available in the Clinical Engineering Office (Room G-421, Zero Level, University Hospital) and other designated locations as identified in Medical Center Policy N0.0013 – D1.

3. The Representative shall follow good hand washing practices while at the Medical Center, specifically after using the bathroom, and upon entering or leaving a patient care area. The Representative shall not enter isolation rooms and shall not be present when he/she is ill, has a fever, or has been exposed to a contagious disease.

**Physician Sponsor Signature:** \_\_\_\_\_

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**Date:** \_\_\_\_\_

**Section 3:**

I agree to the following regarding my presence at a clinical procedure at the University of Virginia Medical Center:

1. I agree to follow the directives of my sponsor or their designee. I understand that I must remain with him or her while in patient care areas – I am not permitted to move freely around the hospital. I understand that I am on Medical Center Property at my own risk and insurance coverage.
2. I have read, understand, and agree to abide by Exhibit 1 – Patient Confidentiality at UVA Medical Center-Information for Vendors and Exhibit 2 – UVA Medical Center Infection Control Information for Vendors.
3. I agree to abide by the hospital’s dress code and to dress neatly.
4. I have attached copies of the following documents:
  - My current job description
  - A statement of competency from my employer
  - Copies of any licenses or certifications required by my employer
5. A Fire Alarm is announced by a series of four gongs followed by “Call to Station,” and the location of the alarm. I agree to follow directions of my sponsor in the event of a fire alarm in an area where I am present.
6. With my signature below, I agree to uphold The UVA Medical Center policies regarding patient confidentiality, and will not divulge any medical, financial, or other personal information about a patient or their family.
7. I understand that failure to comply with the rules and policies above shall result in termination of my ability to be present at clinical procedures.

Representative Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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**Exhibit 1:**

**Patient Confidentiality at UVA Medical Center**  
**Information for Vendors**

When a patient comes to the University of Virginia Medical Center, the Medical Center assumes an obligation to keep in confidence all that pertains to that patient. Information regarding the patient's admission, diagnosis and treatment, as well as personal and financial affairs is confidential and must be respected. Every person employed or providing services in any capacity in the University of Virginia Medical Center shares this responsibility.

**The Basics:**

1. Information learned at the hospital stays at the hospital. Information in all possible forms is confidential, whether verbal, written, overheard, on the computer screen, told to you by the patient.
2. Access to patient information is on a need to know basis only. If you need information to do your job for the patient, you are allowed to know it, and keep it confidential. Vendors may not read a patient's medical records.
3. Information about a patient is shared only with that patient or his/her caregiver, and with patient permission, with his/her family. If you have questions or concerns about a patient, ask your sponsor, not the patient.
4. In conversation, do not breach confidentiality by speaking about patients in corridors, elevators, and the cafeteria. Seek privacy as much as possible.

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**Exhibit 2:**

**UVA MEDICAL CENTER**  
**INFECTION CONTROL INFORMATION FOR VENDORS**

This infection control information is designed to help you understand how you can help protect yourself from a bloodborne pathogen exposure while visiting at the Medical Center. Bloodborne pathogens are passed from person to person by blood, body fluids, or other potentially infectious materials. Bloodborne pathogens include viruses like hepatitis B, hepatitis C, and HIV, the virus that causes AIDS. Healthcare workers can become infected with these viruses if they are exposed to a patient's blood or body fluids in a way that can transmit disease, such as a needlestick. While you are visiting at the Medical Center, you will not be allowed to perform tasks that will bring you in contact with blood or body fluids so you are at extremely low risk for having an exposure to a bloodborne pathogen.

**What is an exposure?**

Although you are not allowed to perform tasks that bring you in contact with blood or body fluids, accidental exposures can occur. If you are exposed to blood or body fluids in any of the following ways, you may be at risk for getting a bloodborne pathogen:

1. Stick with a sharp object that has blood or body fluids on it (needles, scalpel, broken glass);
2. Getting blood or body fluids on nonintact skin (cuts, abrasions, hangnails, rash);
3. Getting blood or body fluids into your eyes, nose or mouth;
4. Getting blood over a large area of intact skin; or
5. Getting a stick with an unidentified object

During your presence at the Medical Center, you should not be exposed to risk for these kinds of incidents. However, if you do accidentally have one of the above exposures or get blood or body fluids on your clothes, immediately ask for assistance from the nursing staff. Remove any contaminated clothing without contaminating the rest of your body. Such clothing must be laundered or disinfected before it can be taken home. Wash any exposed area of your body immediately with soap and running water followed by rubbing alcohol. If your eyes, nose or mouth are splashed with blood or body fluids, flush them with large amounts of running water. **Report your exposure immediately to the Nursing Supervisor. She can be reached by having the unit staff or hospital operator page her at beeper #1523.**

**Standard Precautions**

Standard Precautions are used to **prevent** health care workers, hospital staff, volunteers, vendors, and any other persons providing services from coming in contact with blood or body fluids. Because no one can tell who may have a bloodborne pathogen, using Standard Precautions means you must consider all patients' blood, body fluids, mucous membranes and tissue to be infected. Following these precautions will help keep you safe while you observe.

- Do NOT eat, drink, apply cosmetics, lip balm or handle contact lenses in patient care areas.
- Do NOT handle sharp instruments or glass containers that may be contaminated with blood, body fluids, or human tissue.
- Do NOT handle contaminated materials containers (CMC's) that are in use.
- Do NOT handle patient specimens.
- Do NOT touch surfaces or objects that may be contaminated with blood or body fluids.
- Do NOT get close to a procedure in which splash or spray of blood or body fluids may occur.

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- Do NOT clean up blood or body fluid spills, or handle linen that is visibly soiled with blood or body fluids.