

PROTOCOL FOR: Health Care Industry Sales Representatives (HCIR) in the
Perioperative Setting

- POLICY:
1. The term Health Care Industry Representative (HCIR) refers to all health care industry employees who provide services in the clinical setting (eg, clinical consultants, sales representatives, technicians, and repair / maintenance personnel).
 2. HCIRs may be present during procedures under the conditions prescribed in this protocol and in compliance with accreditation requirements; local, state, and federal regulations; and UCHC infection control, patient privacy, and department- or unit-specific standards.
 3. The role of the HCIR is to provide essential technical training and assistance related to the product, equipment, device or technology for the safe care of the patient. The HCIR is not considered part of the clinical team and should not be requested to perform tasks outside his / her approved role.
 4. The HCIR must obtain specific authorization from the nurse manager (eg, Perioperative Director, Assistant Nurse Manager, Clinical Nurse Specialist, or designee') and the attending physician each time the operative or invasive procedure setting is entered.
 5. Authorization to enter the operative or invasive procedure setting shall be specific to the product, equipment, device or technology that the HCIR will be using, discussing or demonstrating in the clinical setting and will ideally be obtained at least 24 hours prior to scheduled procedures.
 6. The surgeon / must inform the patient or his/her legal agent (conservator, guardian, health care agent or next of kin) about the presence of any HCIR during the operative or invasive procedure, as described in item # 10 of the Authorization for Medical-Surgical Procedure form HCH-127.
 7. If a life-threatening emergency occurs, it will be considered a legitimate exception to the usual consent process. It is "reasonable" that the patient would consent to the presence of an HCIR if it would increase the likelihood of a positive outcome. The attending physician must make a note in the medical record and inform the family of the HCI representative's presence as soon as possible after the procedure.

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8. Materials Management will authorize clearance for all HCIRs in areas where operative and invasive procedures are performed in conjunction with UCHC Public Safety. HCI representatives who have been cleared will be provided with a green UCHC Contractor ID badge through UCHC Public Safety and a temporary day pass for each visit.

Materials Management will maintain documentation electronically that the HCIR has completed instruction in the principles of asepsis, fire and safety protocols, infection control practices, blood borne pathogens and patients' rights. The representative must be aware of and follow federal HIPAA regulations and OSHA Bloodborne Pathogens Standard and any UCHC requirements related to them. It is the responsibility of Materials Management to update the information filed for all HCIRs.

9. HCIRs must check in with Materials Management during regular weekday hours prior to entering the clinical setting until they have received clearance and whenever they have new items. During non-weekday hours, permission will be obtained from the nursing manager or designee' and the HCIR will wear identification.
10. HCIRs cleared for entry into the clinical setting will report to the nurse manager or designee' of the specific unit they will be visiting. If they will be working in a semi-restricted or restricted area, they will don scrub attire provided by the hospital, ideally colored to promote identification of their role, and will wear appropriate personal protective apparel. They will also wear their UCHC ID badge and their temporary day pass badge in the clinical setting or be redirected to Materials Management.
11. Any product, equipment, device or technology used in the perioperative setting must be approved and / or prepared for use prior to the procedure:
 - a. Clinical Engineering (CE) staff will inspect and approve any equipment or device not owned by the hospital prior to use; after hours, the perioperative team either should determine if use of the item can wait until CE can inspect and approve it or they can be responsible for a visual check and permit patient use of the item;
 - b. Instrument Room (JDH), Sterile Processing (FSC), or OR staff will sterilize instrumentation or other items on site prior to use, as necessary. (HCIRs will ensure that any necessary decontamination is performed before / after procedures.)

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12. The nursing staff should be informed before the procedure that an HCIR will be present during a specific procedure as well as the purpose for being in attendance.
13. The RN circulator is responsible for monitoring patient safety, privacy, dignity, and confidentiality in conjunction with other members of the surgical and anesthesia team. HCIRs will not be allowed in the patient care location while prepping and draping are being completed. Monitoring may include restriction of the movement and number of people in the operative or invasive procedure room to prevent airborne contamination.

The RN circulating nurse may ask the HCIR to leave the OR at any time, regardless of cause. If removal of the vendor has potential to disrupt completion of the procedure, the circulating nurse will collaborate with the supervisor regarding any immediate action taken.

13. The RN will document in the medical record the name and role / title of the HCIR present during the procedure.
14. The RN circulator will monitor the HCIR's activities whenever possible and will facilitate their service to the patient and caregivers. Further, the HCIR will only perform activities that facilitate use of the products, equipment, devices, or technology for which s/he has been authorized to enter the clinical setting. Under no circumstances will the HCIR scrub and assist on procedures; the HCIR may assist the circulating RN, but must provide all required information for proper documentation, including but not limited to that required for implant tracking. If an item has an expiration date, the RN circulator must view the date prior to opening any other packaging in the process of presenting the item to the sterile field.

The HCIR with specialized training and facility approval may perform calibration to adjust devices to the attending physician's specification (eg, pacemakers and lasers).

15. Patient education materials will be provided as they are available from the manufacturer and patient care indicates.

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16. HCIRs will provide education and training about products, equipment, devices, or technology prior to bringing them to the clinical setting whenever possible and as requested by the nurse manager (eg, Perioperative Director, Assistant Nurse Manager, Clinical Nurse Specialist, or designee'). If education and training cannot occur prior to the procedure, the sales representative will provide one-on-one training, 24-hour assistance through their employer, and /or operate the item, as appropriate.
17. Experienced HCIRs who are accompanied by persons in training from their own organizations for the purposes of orientation will make arrangements with Materials Management and will comply with any accreditation requirements and local, state, and federal regulations.
18. Trials of products, equipment, devices, or technology that require the presence of an HCIR will comply with established Materials Management and Department of Nursing standards.
19. Any departure from established policy will be addressed immediately:
 - a. the nursing manager or designee' will be notified;
 - b. Materials Management will be notified;
 - c. if patient harm results, the RN will complete a Risk Identification Report;
 - d. non-compliance with any policy statements will result in UCHC assuming no responsibility for payment of products used, lost, or damaged, and may lead to possible vendor restrictions at the facility.

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20. Failure to observe the policy statements contained within this protocol will be considered willful disregard and will result in the following actions:
- a. Nursing or Materials Management Staff:
disciplinary action, as deemed appropriate by management;
 - b. Physicians:
reporting to Chief of Service for disciplinary action;
 - c. HCIRs (nature of offense may affect action taken, but in general:
 - 1st offense: counsel with specific offender, along with formal written warning;
 - 2nd offense: access to UCHC restricted with a letter sent to his / her division manager;
 - 3rd offense: letter sent to the HCIR and his / her division manager, resulting in banning of the representative from business with UCHC. Review of current business between company and UCHC will be evaluated to determine further actions with the company.

APPROVAL: OR Committee
Materials Management
Nursing Standards Committee

EFFECTIVE DATE: 6/00

REVISION DATE: 11/03, 8/06, 10/07, 12/08, 4/09