

**STORMONT-VAIL REGIONAL HEALTH CENTER
MEDICAL STAFF POLICY AND PROCEDURE**

Policy Name	Policy for Health Care Industry Representatives (HCIR) in the Operating Room, and Other Invasive and Special Procedure Sites
Initial Approval Date	8/19/08
Revision Dates	4/19/11; 2/21/12
Approved by	Board of Directors

Policy: Health Care Industry Representatives (HCIRs) within the hospital premises, including the operating room, are defined as individuals who promote or sell equipment or products and/or who provide training and advise on medical systems, devices and procedures. HCIRs must obtain approval by the Medical Staff prior to being allowed in patient care areas of the hospital. HCIRs shall not be permitted to scrub in or participate directly in any procedures on the patient.

Procedure: 1. Application Process: The HCIR is required to complete the application form and to provide the following documentation:

- Documented proof of a 2 or more negative Tuberculin Skin Test
- A. Documented proof of a current two-step tuberculin skin test (TST) can be fulfilled by one of the following:
 - One negative TST performed within the past 12 months and 2 or more previous negative TSTs performed greater than 12 months ago; or;
 - Two negative TSTs performed within the past 12 months. The TSTs must be performed a minimum of seven days apart.
- B. A two-step TST is not required if documentation of a negative interferon-gamma release assays (IGRA) completed within the last 12 months is provided.
- Current influenza vaccination (typically October through March).
- Current professional liability insurance, general liability insurance and products liability insurance in the minimum amount of \$ 1,000,000 per occurrence and \$ 3,000,000 in the aggregate, or an acceptable alternative, as specified in Appendix A.
- Letter documenting training (letter must be on company letterhead and include date, name of representative, signature of personnel authoring letter before the document will be accepted. HCIR must provide evidence of training for all of the following:
 - Completion of Operating Room protocols course (e.g. AORN course)
 - Infection control practice and blood borne pathogens
 - Occupational Safety: biohazardous waste, fire, electrical, radiation and other safety protocols
 - HIPAA compliance and all matters related to patients rights and confidentiality

- Informed patient consent regarding the presence and role of the HCIR in the OR
- Training specific to the medical system, device, or procedure for which the HCIR is providing technical support.
- Sponsorship by a member of the Active Medical Staff at SVRHC, with privileges compatible to the area of technical support provided by the HCIR. It is the responsibility of the applicant to obtain the signature of the supervising Medical Staff member.
- Coordination of the HCIR's presence and purpose with the designated procedural area management authority.
- Documented specialized training for HCIRs who will be performing remote calibration to adjust devices to the physician's specification (e.g. pacemakers).

2. Authorization Process: The application should be submitted **a minimum of 3 days** prior to the HCIR's scheduled presence in the hospital. Medical Staff Services will assist in obtaining the signatures of the Hospital Department Director, and the Anesthesia Director or designee (if necessary) based on the schedules of the above named individuals.

The HCIR will be notified in writing that he or she has been authorized to come into the hospital's procedural areas and provide the technical expertise requested. The period of authorization may be limited to a specific procedure or to a specified period of time, not to exceed 1 year.

3. Responsibilities of the HCIR: The HCIR within the hospital premises must adhere to the following:

- The HCIR must strictly adhere to all department policies and procedures.
- The HCIR must wear a hospital issued identification badge at all times while in the hospital.
- The HCIR is responsible for maintaining compliance with this policy at all times during the approved authorization period. This includes providing documentation of ongoing TB screening (when required by the organization), current general, products and professional liability insurance coverage, and notification of change(s) in employer or the type of technical support provided.
- All HCIRs are required to sign the confidentiality clause on the application.

4. Responsibilities of Hospital: The Hospital must document the following:

- Verification of identity of HCIR by obtaining a government issued ID.
- Verify that application and supporting documents are complete.

- Query the Office of Inspector General (OIG) and General Services Administration (GSA), and state licensing agency
- Obtain and document informed consent from the patient(s) concerning the HCIR's permitted level of involvement and role.
- Ensure the patient information provided to the HCIR is limited to the clinical patient specific level on a need to know basis for which patient consent was obtained.
- If the physician did not initiate the request for the HCIR's presence, the physician must be notified and approve prior to the procedure.
- The roles, responsibilities, and restrictions in the procedural area will be clearly defined in written policy specific to that area.
- The HCIR's presence during the procedure should be documented in the medical record.

5. Renewal of authorization: HCIR may be approved for technical support for a specific system, device, or procedure, not to exceed a period of over 1 year.

- The approval period for HCIRs will run from January 1 to December 31. HCIRs will be required to reapply annually for continued authorized status. Annual screening of OIG and EPLS databases will be performed as part of the renewal process.

Please send completed application to: Stormont-Vail HealthCare
Medical Staff Services
1500 S.W. 10th Ave.
Topeka, KS 66604-1353
Phone: (785) 354-6241
Fax: (785) 354-6159

**STORMONT-VAIL HEALTH CARE INDUSTRY REPRESENTATIVE
APPLICATION FOR AUTHORIZED STATUS**

Name _____ Company _____
Address _____ Address _____
City, State, Zip _____ City, State, Zip _____
Telephone _____ Company Contact _____
E-Mail _____ Employee Independent Contractor
Date of Birth _____ State of Licensure (if applicable) _____
TB Skin Test Results _____ (Attach copy)
(Attach Copy of Documentation d) Professional Liability _____
Insurance Company: _____

Requested Area for Authorized Status: _____

Reason: _____

Requested Date(s) or Procedure(s): _____

Supervising Physician Attestation

I agree to accept supervision of, and responsibility for, the activities and actions of the HCIR.

Date

Supervising Physician

Attestation:

I hereby agree to release, indemnify and hold harmless Stormont-Vail HealthCare its medical staff members, employees and agents from all liability related to my status as a HCIR in the hospital. I have received and read the guidelines for HCIR activities in the hospital setting and agree to abide by them. I also understand the necessity of maintaining, and will maintain as privileged and confidential, all information which I may learn about Stormont-Vail HealthCare, including, but not limited to, patient diagnoses, courses of care and treatment, prognosis, personal lives, relationships and concerns, family matters and all information contained in conversations between patients and Stormont-Vail HealthCare staff or patients and physicians, or between physicians and Stormont-Vail HealthCare staff and/or students pertaining to any patients.

I certify that the information I have given is true, correct, and complete and I agree to this Attestation.

Date

Signature of HCIR

Approvals

Date

Anesthesia Director or Designee (if surgical experience)

Date

Hospital Department Director

APPENDIX A
Stormont-Vail Regional Health Center
Health Care Industry Representatives (HCIR) Insurance Requirements
in accordance with the HCIR Policy

Proof of professional liability, general liability, and products liability in the minimum amounts of \$1,000,000 per occurrence and \$3,000,000 in the aggregate. Acceptable alternatives are written proof (e.g. a copy of the certificate of insurance or a letter with a copy of an endorsement naming the HCIR as an additional insured) of the following:

- The HCIR has been added to the manufacturer's Products coverage as an additional insured or the product coverage has been modified to delete any exclusion for instruction, demonstration, training, advice, installation, service, and repair by an HCIR.
- If the general liability coverage includes products and completed operations, the general liability has been endorsed to include the HCIR as an additional insured. This policy may also need to be modified to delete any exclusion for demonstration, instruction, training, advice, installation, service or repair by the HCIR
- The manufacturer may also be self-insured. If the company does not have a certificate of insurance naming the HCIR as an additional insured, they must provide a letter describing their self-insurance coverage, the limits offered, and specifically name the HCIR as an additional insured. Self-insurance options may be reviewed by the Risk Management department at Stormont-Vail HealthCare.
- The HCIR may provide proof of an individual insurance policy with the applicable general and professional liability coverage, with acceptance of the manufacturer's policy for products liability.

The certificate holder should be listed as:

Stormont-Vail HealthCare
1500 SW 10th Avenue
Topeka, KS 66604-1353

Note: This policy addresses HCIRs whether an employee of the company or an independent contractor with the company.

Types of Business Liability Insurance

General Liability Insurance: This form of business liability insurance is the main coverage to protect a business from injury claims, property damages, and advertising claims. General liability insurance is also known as Commercial General Liability.

Professional Liability Insurance: This coverage protects a business or individual against malpractice errors, negligence and omissions. Depending on a profession, it may be a legal requirement to carry such a policy (e.g. physicians). Technology consultants often need coverage in independent contractor work arrangements.

Product Liability Insurance: This coverage protects a business selling or manufacturing products in the event a person becomes injured as a result of using the product.