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### *Finance – Procurement Services & Value Implementation F-PS-0.04*

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At University of Iowa Hospitals and Clinics (UIHC), we are proactive in protecting the privacy of our patients to facilitate compliance with all government and University health and safety regulations and policies. Although we recognize the value of having sales representatives interact with our staff, we also have high expectations that all vendors will comply with UIHC Vendor Policy and with rules and additional guidelines established by individual departments and units. The detailing of products and services at the UIHC by Medical/Surgical/Pharmaceutical Representatives is a granted privilege, not a right.

#### **A. Registration**

Registration and daily badges at UIHC are required for all Medical/Surgical/Pharmaceutical Representatives from medical, surgical, medical device, and pharmaceutical companies. This policy applies to all Medical/Surgical/Pharmaceutical Representatives (e.g., distributors, information specialists, managers, scientific liaisons, medical affairs specialists, and tissue/bone representatives) selling products or services or providing information to UIHC staff that are involved in patient care activities (e.g., staff that provide patient care to inpatient care areas, clinics, O.R 's and invasive labs). All Medical/Surgical/Pharmaceutical Representatives from medical, surgical, medical device and pharmaceutical companies must be registered with RepTrax web-based community and compliant with credentials and policies.

Annual UIHC registration and badges may be required for vendors who provide service, repairs or rental deliveries or installations. Internal University, freight forwarders (e.g. UPS), floral and food delivery services and consultants of professional services are excluded. Construction vendors have a separate policy based within Safety and Security policies.

All Medical/Surgical/Pharmaceutical Representatives must be registered with the Purchasing Department to obtain a University of Iowa Vendor ID prior to engaging in any promotion or information activities - hereafter called "detailing" - involving their company's products and services at UIHC.

**NOTE: Detailing privileges are not transferable from one company representative to another.**

1. All Medical/Surgical/Pharmaceutical Representatives are required to register and comply with UIHC requirements via RepTrax web-based community *prior* to engaging in any promotion or informational activities involving their company's products and services at UIHC.
2. Members of the Procurement & Value Implementation (PVI) Services Department staff are available to meet with Medical/Surgical Representatives during the hours of 8 AM to

4:30 PM, Monday through Friday, with the exception of University holidays.  
Appointments are recommended. Appointments before 8AM and after 4:30PM can be arranged when necessary.

3. Medical/Surgical/Pharmaceutical Representatives need to follow all hospital policies and procedures when detailing as a representative of their company while visiting here at the UIHC.
4. Appointments with Pharmacy staff are scheduled through the Pharmacy Administrative Office (319-356-2577)

## **B. Identification Badge Check-in**

1. **All** Medical/Surgical/Pharmaceutical Representatives with credentials approved on RepTrax must check in and receive a vendor badge in PVI Services Department, Room 3057-1 SRF, upon **each** visit. The office is open 6:30 AM to 5 PM, Monday through Friday.
2. Between the hours of 5 PM and 6:30 AM Monday through Friday, weekends and holidays all vendors are required to sign in at the After Hours Vendor Check-In Kiosk located to the left of the Information desk at the Main Entrance.  
\*This badge must be worn above the belt and visible at all times while conducting business at the UIHC. Only during sterile procedures is it acceptable for the badge to be covered.
3. Badges are one-time use and do not need to be returned. For questions call PVI Services at 319-384-9800.
4. One time guests accompanying a registered vendor (e.g. regional sales manager) will need a vendor badge as well.
5. All visits, for whatever purpose, must be prearranged with the department, physician, or staff member prior to arrival at the UIHC.
6. Dress code: Company scrubs are not permitted, if scrubs are necessary for procedures, UIHC will issue white scrubs and shoe covers. Use of green staff scrubs is prohibited. All other dress should consist of casual business attire.

## **C. Business Associate Agreement requirements**

A Business Associate Agreement is not required for all vendors; however, it is required for all vendors who will be present for a patient procedure, will have direct patient contact, or access to any patient information in order to provide their services to UIHC. If a BAA is required it is the representative's direct employer who is responsible for having a BAA on file with UIHC.

### **Example:**

An employee of Company A (Manufacturer) is covered under company A's BAA.  
An employee of company B (Distributor of Company A's product) is covered under company B's BAA, not Company A's.  
If a representative is an Independent Contractor (possessing a separate Tax ID) said representative is required to have their own BAA.

Representatives working with UIHC staff on approved sponsored research studies are not required to have a BAA as long as the studies informed consent document includes language informing the subject of the presence of company personnel during study procedures and or interactions. Please contact the University of Iowa Hospitals and Clinics Joint Office of Compliance 319-384-8282 to make sure your company has a BAA on file, if not you will need to begin the process.

#### **D. New Products**

Be advised that hospital administration has a product review process mandated by our governing board. This process involves product evaluation, economic evaluation, training and inventory matters, etc.

1. New Product request (non- pharmaceutical) - will be managed through MedApproved a web-based product request management tool.
  - a. This will allow all communication to be funneled through one system.
  - b. Ensure that your product is being reviewed by all key decision makers.
  - c. Allows for transparency into our decision-making process including the ability to see what stage the product is in and an estimated decision date.
  - d. Reduces the number of visits and phone calls to the hospital to get status updates.
  - e. Automatic email alerts if additional information is required and updates including final decisions or requests for needed documents.
2. Vendors wishing to bring new product, systems or services into UIHC will need to visit [www.medapproved.com](http://www.medapproved.com), register and submit the request for University of Iowa Hospitals & Clinics.
  - a. A UIHC staff member must be chosen as a sponsor/champion, their name and email address are required.
  - b. Sponsor/Champions should be staff physicians, nurse managers, and department directors.
  - c. Once the request is submitted the sponsor will approve or decline their support of the request, if the request is declined by the sponsor you will be required to identify another sponsor and resubmit the request.
3. All requests for trial or purchase of a product not currently being utilized within UIHC is required to have prior approval by one or more Product Committees.
  - a. Each Product Committee meets monthly on specific dates; request submitted in a timely manner prior to these dates will be reviewed at the next meeting.
    - i. You may contact PVI Services for request deadlines
  - b. Approvals/Denials will be sent out after the committee's decision through MedApproved.
4. Product supplied for use to a UIHC Staff member prior to approval by a committee is prohibited. This product will be considered a no-charge item.
5. UIHC physicians are not authorized to act as agents to amend or renegotiate these provisions nor can they legally bind the institution in purchase/lease/rental agreements.

## E. Meetings and Communication

1. Meetings with UIHC staff will occur at the request of a staff member i.e. Physician/Nurse Managers/Assistant Nurse Manager/Educators/Faculty, etc., these meetings are to be by appointment only.
  - a. Verification of the scheduled appointment may be completed to insure compliance with hospital policy
  - b. A "Do Not Call" list of staff will be available and sales representatives are not to call or e-mail these staff members.
2. **Meeting places are restricted**
  - a. To staff offices, conference rooms in non-patient care areas or areas open to the general public.
3. Medical/Surgical/Pharmaceutical Representatives must leave the visited area immediately upon completion of an appointment.
4. Medical/Surgical/Pharmaceutical Representatives are not permitted in inpatient care areas, outpatient clinics, or pharmacy dispensing areas in order to protect patient privacy (except as allowed within the guidelines outlined in Section G and supplements A,F and G)
5. **Loitering** at the UIHC (a) in an attempt to facilitate a nonscheduled meeting, show a new product, education, etc. with a UIHC staff member is **prohibited**.
  - a. This includes but is not limited to corridors, cafeterias, patient care areas, MOR/ASC/Procedural rooms/corridors, staff office hallways, or any other area
6. UIHC telephones may not be routinely used; public telephones are available throughout the facilities. The use of cell phones is restricted in all patient critical care areas defined as Intensive Care Units, Intermediate Care Units, Emergency Treatment Center, Operating Rooms, Diagnostic and Radiological Imaging Rooms, Birthing Rooms and Neuro-Diagnostic areas.
  - a. In all other areas throughout the UIHC, cell phone use is restricted to areas greater than three feet from patient equipment.
  - b. Cell phone use is to be limited to work related topics when in the above mentioned areas. Personal calls are discouraged.
7. Overhead hospital paging systems are off limits to vendors. Other paging is limited to request by
  - a. The specific UIHC staff member only.
8. Departmental mailboxes and University campus mail systems are off limits to all vendors. Commercial mail services may be used to disseminate information to UIHC staff.
9. Vendors are required to pick up after meetings, in-services or displays. Leaving materials, empty boxes or information after meetings will be considered an infraction of the vendor policy.
10. Vendors are not to leave unsolicited promotional/boxes/information in any hospital location.
11. Vendors who need parking, may park in Ramp 3. Valet parking is restricted to use by our patients and their visitors.

## **F. Sales and Services**

- a) No product should be left in any area of UIHC without prior approval by a Product Evaluation Committee.
- b) Vendors leaving products without permission will be subject to discipline under section K. "Enforcement of Hospital Policy". Items without previous documented approval will not be paid for.
- c) PVI Services will help make arrangements with vendors and UIHC staff when products will be needed for evaluation or trial
- d) UIHC staff who have reported a Conflict of Interest (COI) with a company cannot request a new product nor vote on the purchase of a product, item, system in which they have a COI with.
- e) All vendors will be asked to provide a list of all UIHC employees that have a COI with their companies.
- f) We require that vendors not pressure UIHC staff during the bidding process  
The best way to expedite the process is to be prompt in returning calls and providing proposals and information as needed.
- g) When discussing your product with UIHC staff we ask that you:
  - a. Promote the facts, data and research about your product and it's benefits
    - i. Side by side studies
    - ii. Research
    - iii. Outside references
  - b. Refrain from negative comments about the competitors product line
    - i. Backhanded statements
    - ii. False information
    - iii. Attempts to sway the feedback of the end user will not be tolerated
- h) If the medical/surgical product merits further investigation or evaluation, it will be referred to the appropriate Department Director, Clinical Manager, and PVI Services Staff member.
  - a. 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.
  - b. For pharmaceutical products see additional Pharmacy requirements in section F7.
- i) OR – ASC loaner instrumentation - All reusable items need to be cleaned and sterilized by the Central Sterilizing Services Department (CSS) prior to use;
  - a. Cleaning and sterilizing instructions must be presented to CSS with all products. All items requiring processing must be in the CSS department by a minimum of 24 hours prior to the start of surgery for the MOR and ASC. See Supplements for the CSS OR policy on loaner instrumentation.
- j) Items requiring electricity will need to be evaluated by UIHC Bioengineering prior to use.

- k) Additional Pharmacy and Therapeutics Subcommittee and Department of Pharmaceutical Care Requirements:
- a. Industry-supplied drug samples, drug-containing devices, and vouchers may not be distributed to patients at UI Health Care.
  - b. UI Health Care faculty, staff, and trainees may not seek or accept industry-supplied drug samples for personal or family use.
  - c. Drug coupons are not permitted to be given to patients at the UIHC.
  - d. In order to meet patient educational needs, the Pharmacy and Therapeutics Subcommittee may approve industry-provided drug-related educational devices and/or written educational materials. These approved industry-provided drug-related educational devices will not contain active drugs and may be kept in specified clinics for patient teaching of drug administration.
  - e. Detailing of protocol, restricted, and non-stock drugs is limited to attending physicians and pharmacists. A list of protocol and restricted drugs is posted in the Pharmacy Purchasing Office.
  - f. Only UIHC and company-approved materials and not independently created or reproduced items, may be distributed to health care professionals or trainees within the UIHC.
  - g. Distribution of written promotional information regarding protocol, restricted, and non-stock drugs at journal clubs or displays is not permitted. Restricted drugs are defined as those drugs on the formulary whose use are limited to a specific clinical service(s).
- l) Additional Tissue Bank requirements: (See Supplement E for detail) all implantable material containing human cells must have prior approval through the Surgical Services Product Evaluation, Standardization and Review work group prior to use (except for sperm, oocyst, and vascular organs).
- a. Vendors must stop at the Tissue Bank before they accompany tissue to the OR. This will allow tissue to be accessioned into the inventory
  - b. Vendors of tissue not accessioned in the Tissue Bank before implantation will not be paid for tissue

## **G. Trials and In-services**

When discussing your product with UIHC staff we ask that you:

- a. Promote the facts, data and research about your product and it's benefits
- b. Refrain from negative comments about the competitors product line
- c. Provide education approved by UIHC staff that follows hospital policy and procedure guidelines.

Provide proper education on the use of products/supplies/equipment being utilized within UIHC while maintaining patient privacy. This includes but is not limited to products on trial, newly implemented or re-education of a current product line.

1. All in-servicing and or education must be preapproved by:
  - a. One of the Product Evaluation Committees and arranged by Department representative in conjunction with PVI Services as needed.
  - b. Pharmaceuticals -An Assistant Director of Pharmacy
  - c. Approval is to be obtained by UIHC staff and not by a vendor representative to

ensure:

- i. That all appropriate departments have been contacted for education
  - ii. UIHC Policies and Procedures area followed in relation to product use
  - iii. Product is available for use
  - iv. That in-service dates have been determined
  - v. Drop-in/unscheduled in-services are prohibited.
4. In-services must be held away from patient and visitors. Appropriate venues include Staff report rooms, Conference rooms, Staff lounges, Area designated by staff.
- a. In-services are prohibited at the nurses desk and patient care hallways
  - b. In-services are prohibited at the patient bedside unless it has been determined necessary to the successful use of the product –if this determination has been made by UIHC staff, the representatives company must have a BAA on file prior to the education occurring.
  - c. All in-services are to be conducting using the same guidelines under section F. Sales and Services.

## **Protocol**

### **After checking in at PVI Services**

#### **Representatives entering a unit for the purpose of In-servicing:**

- 1) Must report to the front desk or nurses' station.
- 2) Introduce them self and explain their purpose for being on the unit.
- 3) Must ask to speak with the Nurse Manager/Assistant Nurse Manager/Charge Nurse or pre-arranged contact if applicable.
- 4) If for any reason staff is unavailable to receive the in-service at a scheduled time the rep is to leave the unit.
- 5) Only material related to the product being in serviced is to be discussed or left for staff to review.
- 6) Are responsible for cleaning up the area after in-servicing if educational samples were used
- 7) Upon completion the representative must leave immediately following the in-service.

## **H. Vendor Supported Training Labs**

### **Purpose:**

To provide proper education on the use of products/supplies/equipment being utilized within UIHC.

### **Policy:**

1. Written Approval is required by one of the Product Committees
2. Only products/supplies/equipment that are currently purchased by UIHC
3. No new products are allowed to be shown or demonstrated during training
4. Contracts with the UIHC should contain the following Education Clause:
  - d. **Training:**

(Company) will provide technical training and education at your institution, as reasonably necessary, on the safe and effective use of its products, procedures and surgical techniques to health care professionals (HCPs) affiliated with your institution. In addition, (Company) may provide technical training and education at a location outside of your institution on the safe and effective use of its products, procedures and surgical techniques to HCPs affiliated with your institution. Any meals, travel and/or lodging provided in connection with such training and education will comply with the UIHC Conflict of Interest and the UI Travel policies.

- m) Use of UIHC or UI – CCOM space must be pre-arranged and approved by staff overseeing said area
- 7. Manufacturer Logoed vehicles will not be allowed to be parked in plain view of the public
- 8. Parking on UIHC property for the purpose of training requires clearance from Safety and Security and UI Parking.
- 9. Proper documents for the transport of Cadavers or other remains will need to be available for review.

#### **I. Single-Use Device (SUD) Reprocessing Program - OEM**

You and your company are hereby informed that the University of Iowa Hospitals and Clinics (UIHC) have initiated a single-use device (SUD) reprocessing program.

The **expectations** for you and your company are as follows:

- n) Do not speak negatively to any surgeon, nurse, or other UIHC employee about SUD reprocessing.
- o) Do not distribute any materials about SUD reprocessing to any UIHC employee. This includes verbal, written, email or any other communications.
- p) Do not offer seminars or CEU programs to UIHC employees designed to discourage or negatively impact participation with reprocessing.

Violation of this policy will result in disciplinary action in accordance with the hospitals enforcement policy and may trigger a re-evaluation of the products purchased from your company.

If you have any questions about the intent of this notice, please call PVI Services at 319-384-9800.

#### **J. Attendance at Hospital Meetings**

- 1. Attendance at meetings that are not open to the general public, including patient care conferences/tumor boards where protected health information is disclosed, is not permitted.
- 2. Attendance at Grand Rounds, Departmental meetings, Product Review and Standardization meetings, etc., is allowed by written invitation of conference leader or organizer only.



## **K. Enforcement of Hospital Policy**

These policies and regulations for Medical/Surgical/Pharmaceutical Representatives are to be followed rigidly. Any infraction may affect the entire company's representation at the UIHC. All UIHC staff will assist in monitoring the level of compliance and will report violations to the PVI Services Department or the UIHC Compliance Helpline at (319)384-8190. Upon notification of a potential policy violation, PVI Services, Pharmaceutical Services and/or the Joint Office for Compliance will investigate the matter to determine if a violation has occurred, and upon confirming a violation, will determine the seriousness of the infraction. In order to complete its investigation, UIHC may contact the vendor and may require the company representative(s) involved in the matter to be interviewed at the UIHC regarding the details surrounding the incident. Based on the seriousness of the infraction and the information obtained during the investigation, the resultant action may include a verbal reinforcement of the UIHC Statement of Vendor Policy or the disciplinary actions outlined below. A serious infraction which includes, but is not limited to, a violation of a HIPAA or JCAHO standards (or other accrediting organization requirements) may result in a higher level of disciplinary action.

Failure to comply with these policies may result in the following actions:

1. First infraction: A face-to-face meeting, a note in the file and possibly a letter of reprimand, loss of detailing and display privileges for one week or more.
2. Second infraction: A face-to-face meeting which includes a letter of reprimand with a copy being sent to the representative's immediate supervisor, and the company's possible loss of detailing and display privileges for one month or up to six months depending on severity of the infraction.
3. Third infraction: A face-to-face meeting which includes a letter of reprimand with a copy being sent to the representative's immediate supervisor, and the company's loss of detailing and display privileges to be defined and determined at the meeting or no further access depending on the severity of the infraction.
4. Upon request: A department can request a specific discipline be enforced based on past dealing with representatives and or a company this could involve a stronger or lighter discipline than recommended in this policy.
5. Do Not Call: All departments and staff have the right to request a vendor not be allowed Access to their department or staff at any time; this includes face to face meetings, emails, letters and phone calls. Violation of this request will result in one of the previously stated enforcement.

*NOTE: The representative of record is responsible for any violation of policies by any representative from his/her company. Disciplinary actions will be documented in the company's file in PVI Services.*

## **L. Declaration of Patient Information Confidentiality**

University of Iowa Hospitals and Clinics (UIHC) is legally required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of the health care information of all patients treated at our institution.

Your visit to UIHC may include contact with patients, viewing of computer-stored patient

information, viewing information from patient medical records, and/or incidentally overhearing confidential conversations. Under no circumstances may this information be discussed with anyone, unless otherwise required by law.

State and federal law protect the confidentiality of patient information that you might obtain during the course of your visit to UIHC. State and federal law prohibits you from making any disclosure of this information, unless a specific exception exists under the law that requires the disclosure.

Your signature on the Declaration of Patient Information Confidentiality is required. Understand that a violation of this Declaration can result in serious administrative action.

### **M. Vendor Credential Requirements**

1. All vendors will be required to join the RepTrax community which will assist us in managing vendor credentials.
2. If you will be visiting staff within UIHC you will need to provide evidence within RepTrax of Measles, Mumps and Rubella (MMR) vaccination or immunity, annual tuberculosis (TB) status and Varicella vaccination or proof of immunity. You will also need to provide certification and training for Evidence of Employer Product/Service Competency.
3. All vendors will need to review all policies and documents provided online via RepTrax and must pass the review test with a score of 90% or higher.
4. Sponsored Research Coordinators and Clinical Educators are required to join RepTrax at the base level you may be asked to provide verification of TB and MMR at the time of visit.

### **N. Recalls**

1. Risk And Safety Management Alert System (RASMAS). RASMAS is the web based recall and alert notification service utilized by UIHC.
2. Recall notifications are managed by PVI Services, notification to PVI Services along with other UIHC staff and departments is required.
  - a. Recalls
  - b. Alerts
  - c. Bulletins
  - d. Field Letters
1. While UIHC appreciates the relationships a company may have with a specific physician or department, when a product is being removed from the institution due to a recall or an identified product failure/issue, this action must be documented, in our system.
2. Removal of product without communication or documentation is forbidden.

\*All data taken from EOC-Safety-01.020 Management of Product and Device Alerts/Recalls

### **O. Product Failures and/or Incidents**

1. In the event a medical device, system, supply fails either before or during use that device is to be retained at UIHC until further notification.
2. Removal of item from UIHC is a violation of the Vendor Policy (F-PS-0.04) and the Medical Device Reporting Policy (EOC-Equipment-07.002)

- a. Once a failure/incident has been identified it is UIHC's duty to investigate the event to its fullest.
- b. If it is determined that there has been no negative outcomes associated to the event UIHC may return the device to the manufacture for investigation and follow up
- c. The manufacturer is expected to report back findings via email or certified letter verbal communication either in person or via phone are not acceptable.

\*All data taken from EOC-Equipment-07.002 Medical Device Reporting Policy

## **P. Conflict of Interest/Conflict of Commitment**

To reinforce our commitment to upholding the highest possible ethical standards and to foster greater transparency, University of Iowa Health Care has implemented a revised Conflict of Interest/Conflict of Commitment policy. The policy is available at

### **Definitions**

"Conflict of interest" (COI) involves a situation in which faculty, staff, or student employees have financial or other personal considerations that may compromise, or have the appearance of compromising, their professional judgment or integrity in teaching, clinical care, conducting or reporting research, or performing other University obligations. (Adapted from UI Operations Manual)

"Conflict of Commitment" (COC) occurs when an employee engages in an outside activity that interferes, or appears to interfere, with fulfillment of the employee's obligations to the University, even if the outside activity is valuable to the University or contributes to the employee's professional development and competence. (From UI Operations Manual; <http://www.uiowa.edu/~our/opmanual/ii/18.htm>).

"Industry" is defined as any person or company seeking to do or doing business with University of Iowa Health Care, including any pharmaceutical, medical device, medical publishing, or medical equipment companies.

Use of UIHC name is to be submitted to the Joint Office of Marketing and Communications. Promotion of a company product is strictly prohibited by the UIHC Conflict of Interest Policy. <http://www.uihealthcare.com/about/conflictinterest/index.htm>

#### **M. CORRESPONDING POLICIES AND SUPPLEMENTS:**

Supplement A Medical/Surgical/Pharmaceutical Representatives Presence in Procedural Areas

Supplement B – Medical/Surgical/Pharmaceutical Representatives, Presence in the Perioperative Division-(MOR/ASC)

Supplement C-Dept. of Central Sterilization Services/Special Dept. Procedures for MOR

Supplement D -Dept. of Central Sterilization Services/Special Dept. Procedures for ASC

Supplement E – Tissue Bank Policy: the Ordering, Receiving and Returning of Human Tissue

Supplement F – Home Care Company and Nursing Facility Representatives

Infection Prevention Supplements

- A. Surgical Attire
- B. Traffic Patterns in the Operating Room Suite
- C. Infection Control: Standard Precautions and Isolation

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## Supplement A

### Medical/Surgical/Pharmaceutical Representatives Presence in Procedural Areas

#### PURPOSE:

To ensure that only authorized company representatives access the procedure areas  
To maintain confidentiality of patients' protected health information  
To provide accurate, timely communication between physicians, ambulatory care managers and the Medical /Surgical/ Pharmaceutical Representatives

#### POLICY:

1. Approval for presence in procedure areas may be granted if the following required criteria are met:
  - a. The representative's employer company has a current, signed business associate agreement in the Joint Office of Compliance, AND
  - b. There is a clinical need, approved by a Nurse Manager, Assistant Nurse Manager or UIHC Physician.
  - c. If there is a clinical need (b) but there is no signed Business Associate Agreement, the physicians must obtain written patient consent for the representative to be present during the procedure.
2. Representatives shall sign in and obtain authorization to be present in the hospital at the UIHC PVI Services Department office prior to coming to the procedure care areas.
  - a. UIHC personnel will verify that the company has a current Business Associate Agreement, and provide a dated badge, white scrubs, and shoe covers if needed.
  - b. If the representative will need access before 6:30 A.M., he/she must obtain a badge via the After Hours Vendor Check-In Kiosk located to the left of the Information Desk at the Main Entrance.
3. Representatives shall not have access to procedure schedules.
4. Representatives shall sign in with the procedure room designee before entering the patient care area. Multiple representatives from the same company must each sign in separately. Representatives shall leave the area immediately upon completion of authorized work.
5. Representatives may be present only for which approval has been granted with a maximum of two per company per procedure. Additional approval must be obtained for exceptions.
  - a. Representatives may not scrub in or open sterile supplies.
  - b. Representatives may detail only the products for which a clinical need has been identified.
  - c. Sterile products must be supplied in a manner consistent with UIHC Infection Control Policies.
6. Emergent Cases. In the event of an emergent case the procedure area designee will obtain

information from the physician regarding a need for a representative.

7. Trials of equipment, instruments, and supplies requiring presence of a representative follow established vendor policy procedure. All new products require a completed request submitted through MedApproved with a UIHC staff approval to sponsor this product/system prior to trialing. Failure to follow this policy will result in enforcement of Hospital Vendor Policy.

## **PROCEDURE:**

### **Physicians**

Prior to the day of surgery, indicate to the procedure area designee that the presence of a representative is a clinical need, the name of the company and indicate if scrubs are needed.

### **Representative**

1. Check in at PVI Services, obtain a badge and white scrubs and shoe covers.
2. After changing into surgical attire, sign in with the designated procedure staff person
3. Introduce yourself to the designee in a procedure area and identify the physicians with whom you will be working.

### **Procedure Area Designee**

1. Verify that the clinical need for the representative is indicated.
2. Tell the representative the location of the procedure suite.
3. Verify that the representative is wearing the appropriate badge.

### **Representative**

1. Go to the assigned procedure suite.
2. Identify yourself to the procedure room nurse.
3. Sign out with the designated staff person upon completion of authorized work.
4. Change into street clothes, leaving white scrubs in the changing room.
5. Failure to leave the area at the end of the case will be a violation of the Vendor Policy.

## Supplement B

### Medical/Surgical/Pharmaceutical Representatives, Presence in the Perioperative Division (MOR/ASC)

#### PURPOSE:

1. To ensure that only authorized company representatives access the perioperative patient care areas
2. To maintain confidentiality of patients' protected health information
3. To provide accurate, timely communication between surgeons, perioperative nursing, and the company representatives.

#### POLICY:

A. Approval for presence in perioperative patient care areas may be granted, if the following required criteria are met:

1. The representative's employer company has a current, signed business associate agreement in the Joint Office of Compliance, AND
2. There is documentation of a clinical need provided by the surgeon on the Patient Information Card (PIC), OR
3. If there is documentation on the PIC described in (2.) above but there is no signed business associate agreement, the surgeon must obtain written patient consent for the representative to be present during the procedure.
  - Form G-2dII CONSENT FOR OBSERVATION OF OPERATIVE PROCEDURE

B. Representatives shall receive and agree to the "Statement of Vendor Policy".

C. Representatives shall sign in and obtain authorization to be present in UIHC at the PVI Services

Department office prior to coming to the perioperative care areas.

1. Check the Operating Room schedule to validate that a clinical need is indicated on the PIC.
2. UIHC will verify that the company has a current business associate agreement, and provide a dated badge, white scrubs, and shoe covers for the representative.
3. Vendor Badges may be picked up in PVI Services between the hours of 6:30 AM and 5 PM Monday through Friday. Badges are to be obtained from 5PM to 6:30 AM Monday through Friday, weekends and Holidays at the After Hours Vendor Check-In Kiosk. Located to the left of the Information Desk at the Main Entrance. For questions call PVI Services 319-384-9800.

D. Representative's access to surgery schedules shall be limited to procedures they have been specifically invited to attend by UIHC staff.

Necessary information (e.g. OR room #) is available from the Control Desk. Access to other procedures schedules in an attempt to increase business is discouraged (prohibited)

E. Representatives shall *sign in* with the Control Desk Supervisor before entering the patient care area. Multiple representatives from the same company must each sign in separately. Representatives shall *sign out* with the charge nurse upon completion of authorized work. The badges are one time use only and must be properly disposed of daily.

F. Representatives may be present only in the operating room or area for which approval has been granted.

1. No more than two vendors will be allowed in an operating room at one time.
  - a. Special exceptions must be communicated to nursing leadership for that service and approved by the Medical Director.
2. Representatives may not manipulate or operate equipment other than which they are detailing.
3. Representatives may not sterilize instruments, remove items from a sterilizer, or open sterile supplies.
4. Representatives may not scrub in for surgery.
5. Representatives may detail only the product(s) for which a clinical need has been identified
6. Representatives may not use cell phones in the Operating Room suite.

G. Emergent Cases. In the event of an emergent case the nurse manager will obtain information from the surgeon regarding a need for a representative and indicate the need, if there is one, on the PIC.

H. Trials of equipment, instruments, and supplies requiring presence of a representative follow established procedure. The discipline needing the support (i.e. nursing or surgeons) will indicate the need on the PIC following established procedure. Communication of the need for a representative should occur between the surgeons and nursing.

## **PROCEDURE:**

### **A. Surgeon**

Prior to the day of surgery, indicate on the Patient Identification Card (PIC) if the presence of a representative is a clinical need, and if so, the name of the company. If the vendor/company is not listed access will be denied unless approved by the Nurse Manager or Assistant Nurse Manager

1. The letter "V" will appear on the surgery schedule after the surgical team to indicate that a representative (vendor) will be present during the procedure.

### **B. Representative: these are required steps or administrative action will become necessary**

1. Check in with PVI Services Department and obtain a badge and white scrubs.
2. Additional information and restrictions for representatives detailing products within UIHC are available from Financial Services Statement of Vendor Policy.
3. After changing into surgical attire, sign in with the charge nurse.



4. Introduce yourself to the charge nurse and identify the surgeon with whom you will be working.

### **C. Control Desk Supervisor/Charge Nurse**

Verify that the clinical need for the representative is indicated on the surgery schedule.

1. If there is no "V" indicated on the surgery schedule or Patient Information Card (PIC), the representative is not permitted in the perioperative area. Notify the nurse manager or designee.
2. Tell the representative the number of the assigned operating room.

### **D. Representative**

1. Go to the assigned operating room.
2. Identify yourself to the circulating nurse.

### **E. Circulating Nurse**

1. Verify that the representative is wearing the appropriate badge and that the surgery schedule has "V" indicated for the procedure.

### **F. Representative**

1. Sign out with the charge nurse upon completion of authorized work, properly dispose of vendor badge.
2. Change into street clothes.

## Supplement C

### Dept. of Central Sterilization Services/Special Dept. Procedure res for MOR

#### PURPOSE

To provide instructions for handling loaner instruments brought to UIHC from outside sources.

#### POLICY

To process surgical instruments and implants acquired from an outside source (e.g., consignment, rented, borrowed) in a timely manner, prior to patient use. Loaner instruments are defined as instruments, implants, or trays the vendors provide to the UIHC on a temporary basis for a specific case. These instruments are either shipped in via a carrier (UPS, FedEx, etc.) or brought in by a sales representative.

#### PROCEDURES

##### Representatives and Operating Room Shared Responsibility

Loaner instruments must be sent into the UIHC 24 -36 hours prior to the scheduled surgical start time. Trays brought into the UIHC will be taken to room 0327-2 JCP CSS for processing. Surgical supply chain coordinator will be notified.

##### Representatives' Responsibility

The sales representative will perform the following tasks in order to prepare these items for surgery:

1. Room 300-1 GH and 0327-2 JCP will be used by the vendor representative for unpacking and inspecting all loaner instruments and completing the necessary processing instructions (see representative's directions below). These areas will also be used for storage of shipping materials and preparing the instruments for shipment after the case has been completed.
2. In Room 300-1 GH and 0327-2 JCP will be a plastic bin of packaging supplies. In this gray bin are items you will need to prepare the trays for surgery.
3. Remove a reusable colored/white (miscellaneous) label tag and affix one of these tags to each tray or set. This tag will be used by CSS for tracking and identification of the tray or set.
4. Complete the Sales Rep/Loaner Tray form (please print). This form must accompany the trays each time instrument sets are processed. This form provides basic information that allows CSS to track and process trays together.
  - a. Fill out all pertinent Vendor/Rep Information.
  - b. Indicate 'Requesting Surgeon, Today's Date (date trays are delivered to CSS), Procedure Information' with date, time and location.
  - c. List each tray individually. Fill in corresponding ID number tag. Indicate if tray contains implants.
  - d. Attach cleaning and sterilization instructions.
  - e. Circle correct sterilization method if it is compatible with manufacturers'

recommendations.

- f. Complete sterilization parameters as indicated in the manufacturer's instructions.
  - g. Using an autoclavable pen, copy the name that you want the OR to call your tray and the ID number onto a SPM label that is in the gray bin, tear off label at perforation.
  - h. Attach SPM labels (to be used for identification after the tray or set is wrapped), sterilization and cleaning instructions to the Sales Rep/Loaner Tray Form with a paper clip. Each instrument tray or set must include complete cleaning and sterilization instructions each time you bring the tray in for processing. Failure to provide cleaning and sterilization instructions will result in delays in processing. No exceptions will be made to this policy. Cleaning and sterilization instructions can be faxed to (319) 356-0484. You will need to go to room 0806 JPP in Central Sterilizing Services to obtain the fax and attach it to the form.
  - i. If the tray contains an implant, the sales representative will need to pull an implant sticker and place it with the SPM labels and tell us which tray contains the implant by putting an "I" on the Sales Rep/Loaner Tray Form. This will alert the Central Sterilizing staff to the fact that the sterilization load must contain a biological. This is a JCAHO requirement.
5. The vendor representative will deliver the loaner instrument trays or sets, the completed Sales Rep/Loaner Tray Form, the SPM labels, and the cleaning and sterilization instructions to Central Sterilizing Services' (CSS) decontamination area, which is located off elevator G in the lower level. The room number is 0327-2 JCP and the main telephone number is 356-2534. This must be done 24 hours before the scheduled time/date of the case. Items that must be gas sterilized must be delivered to CSS 48 hours prior to when the case is scheduled due to the long sterilization cycle time. If these timeframes cannot be met, the sales representative will have to coordinate with the CSS department (supervisor or person in charge) and the Operating Room (Nurse Manager and supply chain coordinator) for processing.

#### CSS Responsibility

*When the loaner instruments are delivered to the decontamination area, the CSS staff will:*

1. Scan each tray to decontamination.
2. Retain cleaning instructions and pass all remaining paperwork (log sheet, sterilization info and labels) to the assembly area.
3. Wash instruments per manufacturer's instructions.
4. Save the cleaning instructions to use upon receipt of trays after surgery.

*When the loaner instruments are received in the set assembly area the CSS staff will:*

1. Scan each tray prep/receive.
2. When tray is completely dry, scan pp/pk and wrap tray as you would any other tray.
3. Attach the handwritten SPM label and the corresponding identification label prepared by the sales rep to the tray
4. Send all paperwork (Sales Rep/Loaner Tray form and sterilization instructions) to sterilizer area with the trays.

*When the loaner instruments are received in the sterilization area the CSS staff will:*

1. Review the sterilization instructions and if nothing unusual is found proceed with normal sterilization process. If there are special instructions for sterilization, follow special sterilization instructions; if in doubt, contact a CST III.
2. Scan tray into the sterilizer, if tray contains an implant a biological must be run.
3. After completion of sterilization process, CSS tech will place cool trays on the cart that has been placed in the sterilizer area for this purpose. Autoclave operator will need to make sure that the staff setting up the case carts is aware of the loaner trays so that these trays can be added to the case cart before it is set up. A copy of the Sales Rep/Loaner Tray form will be placed on top of the case cart. If case cart is already in the OR then trays will need to be sent up with a note telling core staff which room and cart to place the trays on. The Sales Rep/Loaner Tray form will be only way of knowing that these trays are needed on a case cart.
4. Scan trays to the appropriate case cart. Send yellow copy of form with trays; file white copy in the sterilizer file drawer. The pink copy goes with the daily sterilizer records.

### **Sales Representative/Operating Room Nursing Responsibility**

1. After the surgical procedure nursing staff will place all loaner instruments into the correct loaner pan and set them on the dirty case cart that will be sent to decontamination. These instruments will need to be sorted by the CSS staff and cleaned as appropriate. Loaner trays and implants that were not opened will have tape/seals broken and returned by the sales representative to the Sales Rep room 300-1 GH or 0327-2 JCP after the case.
2. After each case if the trays are not used, CSS will deliver sterile trays to room #5335

### **CSS Responsibility**

When the loaner instruments are received in the decontamination area the CSS staff will:

1. Scan the loaner trays into decontamination.
2. Place all loaner trays to the side; process all other trays as normal.
3. When time allows, accumulate all loaner trays and clean following the cleaning instructions that were saved from previous day.
4. After decontamination, accumulate all trays on a cart in the instrument assembly area. A nursing assistant from the OR will come down at some point each evening probably after 11 PM to pick up these trays and transport them to the loaner instrument storage room, 6521 JCP in the OR. They will then return the cart to CSS. When room 0327-2 is open for vendors, CSS staff will transport items to 0327-2 and place on shelf.

### **Vendor Responsibility**

Within 24 hours after the completion of the case the vendor representative will:

1. Remove identifying tags from the tray and return tags to appropriate receptacle.
2. Missing items will need to be located by the vendor representative. The vendor representative will contact a CST III or the in-charge person if a CST III is not here, before going into the CSS department to locate any missing loaner instruments.

3. It will be your responsibility to have the loaner instruments removed from the UIHC in 24 hours, unless the same instruments are needed for a case scheduled for the next day. If they are needed, the same process as shown above will need to be followed.
4. Sterile trays are not to be stored in 300-1 GH. If trays are not used on the case scheduled for, open and discard wrapper. Room 300-1 GH is not a sterile area and should not be considered as such.
5. Any claim for broken or missing parts and/or instruments and/or implants must be filed with UIHC within 24 hours after use. After 24 hours have elapsed since surgical case end time any filed claim for lost or broken instruments or implants will not be considered.
6. Twenty-four hours after processing and being placed on shelf, items must be removed. If they have not been removed they may be taken to the shipping dock for disposition.

**Sales Rep/ Loaner Tray Form (sample)**

VendorName \_\_\_\_\_

Tray Name \_\_\_\_\_

Tray # \_\_\_\_\_ of \_\_\_\_\_ Tag  
~~##~~

Requesting Surgeon \_\_\_\_\_

Case # (patient's initials)

OPEN \_\_\_\_\_ Have \_\_\_\_\_

Available \_\_\_\_\_

Procedure Date/Time \_\_\_\_\_

Sterilization Instructions - Attach Manufacturer's Instructions to this form  
 \*NOTE: All items on this form MUST have identical sterilization parameters

**Receipt in CSS**

Date \_\_\_\_\_ Time \_\_\_\_\_

Name \_\_\_\_\_

Sterilized By \_\_\_\_\_

Attach Load Sticker Here \_\_\_\_\_

\_ Returned to Area: Date \_\_\_\_\_

Location \_\_\_\_\_

Initials \_\_\_\_\_

Steam \_\_\_\_\_ Gas \_\_\_\_\_ Sterrad \_\_\_\_\_

Exposure \_\_\_\_\_

Time \_\_\_\_\_

Exhaust \_\_\_\_\_

Time \_\_\_\_\_

Temperature \_\_\_\_\_

## Supplement D

### Dept. of Central Sterilization Services/Special Dept. Procedures for ASC

#### PURPOSE

To provide instructions for handling loaner instruments brought to UIHC from outside sources.

#### POLICY

To process surgical instruments and implants acquired from an outside source (e.g., consignment, rented, borrowed) in a timely manner, prior to patient use. Loaner instruments are defined as instruments, implants, or trays the vendors provide to the UIHC on a temporary basis for a specific case. These instruments are either shipped in via a carrier (UPS, FedEx, etc.) or brought in by a sales representative.

#### PROCEDURES

Representatives and Operating Room Shared Responsibility Loaner instruments must be sent into the UIHC prior to the day of surgery. The trays will be taken to vendor room 41013 PFP and Diane Williamson or O.R. charge nurse will be notified.

#### Representatives Responsibility:

The Sales Representative will perform the following tasks in order to prepare these items for surgery.

1. Room 41013 PFP will be used by the vendor representative for unpacking and inspecting all loaner instruments, storage of shipping materials, completing the necessary processing instructions (see representatives directions below) and preparing the instruments for shipment after the case has been completed.
2. In Room 4100-Z nursing charge desk, will be a counter with necessary packaging supplies to prepare the trays for surgery.
3. Remove a metal disc, which is labeled as "ASC Sales Rep Loaner Inst tray-XX" and place one of these tags into each tray or set. This tag will be used by CSS for tracking and identification of the tray or set.
4. Complete the Sales Rep/Loaner Tray three-part form (please print). This form must accompany the trays each time instrument sets are processed. This form provides basic information that allows CSS to track and process trays together.
  - a. Fill out all pertinent Vendor/Rep Information.
  - b. Indicate Requesting Surgeon, Today's Date (date trays are delivered to CSS), and Procedure Information with date, time and location.
  - c. List each tray individually. Fill in corresponding ID# from metal disc. Indicate if tray contains implants.
  - d. Attach cleaning and sterilization instructions.
  - e. Circle correct sterilization method.
  - f. Complete sterilization parameters as indicated in the manufacturer's instructions.
  - g. Using an autoclavable pen, copy the name that you want the OR to call your tray and the ID number onto a SPM label that is in the gray bin, tear off label at perforation.
  - h. Attach SPM labels (to be used for identification after the tray or set is wrapped),

sterilization and cleaning instructions to the Sales Rep/Loaner Tray Form with a paper clip. Each instrument tray or set **must** include complete cleaning and sterilization instructions each time you bring the tray in for processing. Failure to provide cleaning and sterilization instructions will result in delays in processing. No exceptions will be made to this policy. Cleaning and sterilization instructions can be faxed to 319-3564430. You can ask for the Charge Nurse to obtain the fax for you and then attach it to the form.

- L If the tray contains an implant, the sales representative will need to pull an implant sticker and place it with the SPM labels and tell us which tray contains the implant by putting an 'I' on the Sales Rep/Loaner Tray Form. This will alert the Central Sterilizing staff to the fact that the sterilization load must contain a biological. This is a JCAHO requirement.

5. The vendor representative will deliver the loaner instrument trays or sets, the completed Sales Rep/Loaner Tray Form, the SPM labels, and the cleaning and sterilization instructions to ASC Central Sterilizing Services' (CSS) decontamination area, which is located back hallway of ASC area. On the wall outside the room is a phone, which should be used in order to get someone to come to the door. The room number is 41233 PFP and our main telephone number is 356-7925 or 356-8366. This must be done before 1600 the day before the scheduled date of the case. Items that must be gas sterilized must be delivered to ASC CSS prior to Noon the day before the case is scheduled due to the long sterilization cycle time. If these time frames cannot be met the sales representative will have to contact the ASC in charge desk – please contact Store Keeper III (319) 356-8366 for instructions on what they need to do to get these items processed.

## Supplement E

### **Tissue Bank Policy: the Ordering, Receiving and Returning of Human Tissue**

**PURPOSE:** Human tissue is an essential, expensive, and often unique product required for some surgical procedures. Tissue must be traceable from source to implantation in order to allow look back to occur if it is found to be defective or infected. This policy outlines the method by which tissue will be requested from the Tissue Bank for a specific case, received in the operating room on the day of surgery, and returned to the Tissue Bank if it is unused.

**POLICY:**

**A.** All implantable material containing human cells passes through the Tissue Bank prior to use (except for sperm, oocytes, and vascular organs).

1. Sales representatives may not bring tissue to the OR, except for corneas in emergent cases. All tissue must be ordered through the tissue bank from the distributor. Sales representatives may pick up tissue from the tissue bank for transport to the OR.
2. Vendors of tissue not accessioned in the tissue bank before implantation will not be paid for the tissue.

**B.** The surgical team alerts the Tissue Bank of their need by placing an order on the IPR A-1a form.

1. Tissue orders should be placed preferably one week and at least two working days prior to an elective surgery. a) Tissue orders with specific parameters (e.g., exact dimensions) may require additional time for procurement and thus orders should be placed as soon as possible once the need for the tissue has been identified.
2. Tissue orders required on a semi-emergent or emergent basis will be placed at the earliest possible opportunity by calling the Tissue Bank at 6-3709.
3. Tissue bank personnel will advise as to the availability of requested tissue, either from the bank or from a vendor if not in stock.
4. If the order is unclear or requires specific measurements to be determined prior to ordering, Tissue Bank personnel will contact the surgeon to provide clarification.

**C.** Tissue currently in the inventory of the Tissue Bank is placed on reserve for the specific patient.

**D.** Tissue not currently in inventory that is sized for a specific patient is ordered from a list of qualified vendors by Tissue Bank personnel, using the specifications listed on the IPR A-1a form as a guideline.

1. Tissue Bank personnel contact qualified vendors from the current vendor list to obtain specification sheets on suitable candidate tissue and send these to the surgical team for review and final selection of the tissue.
2. Tissues are ordered after the Tissue Bank receives notification from the surgeon of for final approval.



3. If the surgeon prefers for the Tissue Bank to obtain the tissue from a particular vendor that may be noted on the A-1a.

E. Tissue Bank personnel notify the surgeon if requested tissue is not available or is backordered.

F. Unusual tissue requests (as detailed below) require that the surgeon obtain approval from the Surgical Product Evaluation, Standardization, and Review Work Group prior to placing the order with the Tissue Bank. This process is initiated by submitting an O.R. /ASC Staff Product Request Form to this Work Group. Tissues that require approval include:

1. Tissue from non-qualified vendors
2. Tissue for which equivalent tissue could be purchased from another vendor for less expense
3. Tissue that closely approximates current inventory
4. Non-FDA approved tissue. Institutional Review Board (IRB) approval must be obtained prior to evaluation by the Product Evaluation, Standardization, and Review Work Group.

## Supplement F

### Home Care Company and Nursing Facility Representatives

The Department of Social Service is very interested in home care, durable medical equipment, and community facility programs and services as they assist patients and families in making arrangements for any needed continuing care following discharge from the hospital.

Community home care/DME/hospice/facility representatives are encouraged to provide written resource information that can be shared with all Social Service staff via our Outlook mailing list. Medical/Surgical/Pharmaceutical Representatives who wish to detail products and services and discuss the level of care and/or types of equipment/services offered with UIHC Department of Social Service staff must follow the procedures outlined in the UIHC Vendor Policy.

Community home care/DME/hospice/facility representatives are permitted in patient care areas only in the following circumstances:

- j. The company/facility representative has scheduled an appointment through Social Service to meet with a UIHC patient and/or family member for the purpose of providing discharge in-service and information.

**OR**

- k. The company/facility representative has scheduled an appointment through Social Service to meet with a UIHC patient and/or family for the purpose of evaluating the patient for possible transfer to their company/facility.

If you have questions regarding this matter, please contact, Social, Patient and Family Services at (319) 356-7664.

## **Infection Prevention Supplement A**

### **Vendor Surgical Attire**

**PURPOSE:** To provide effective barriers that prevent the dissemination of microorganisms to the patient.  
To promote environmental control and high level cleanliness within the surgical environment.

**DEFINITION:**

Clean: free of visible soil, blood, body fluids or other potentially infectious material, not worn outside of the hospital building.

- A. All vendor representatives entering the semi-restricted and restricted areas of the operating room suite must wear:
  - 1. Designated Main Operating Room (MOR)/ Ambulatory Surgery Center (ASC), white colored scrubs must be worn in the perioperative area.
  - 2. Surgical attire must be clean, hospital supplied and laundered apparel, designated as surgical attire (i.e. scrub pants, scrub top, optional warm-up jacket)
  - 3. Clean, lint free, surgical head cover must cover all hair.
  - 4. Vendor I.D. Badge
  - 5. Under garments (e.g. T-shirts) must be completely covered by the surgical attire.
  - 6. No long sleeve shirts or turtle necks will be allowed under the surgical attire.
  
- B. Warm-up Jackets are available for persons not scrubbed.
  - 1. All undergarments must be completely contained within the surgical attire and jacket.
  - 2. Warm-up jackets should be snapped or unsterile cover gowns should be tied to avoid accidental contamination of the sterile field.
  - 3. Freshly laundered long-sleeve warm-up jackets should be worn by all non-scrubbed personnel. Long sleeve attire helps to contain skin squames cells shed from bare arms.
  
- C. Head coverings must cover all hair. Single use head coverings should be removed and discarded daily. Personal cloth hats must be contained within a disposable head covering.
  
- D. If a vendor remains in the hospital building but is outside the perioperative area they must wear a cover gown or a lab coat covering their surgical attire.
  
- E. Scrub attire will not be worn outside the hospital building.
  
- F. Scrub attire is changed when wet or soiled.

- G. Failure to comply with the Dress Code for the Main Operating Room will result in disciplinary actions.
- H. Attire items are discarded and placed in receptacles:
  1. Mending (Clean/unworn garments only)
  2. Laundry Receptacle
  3. Trash Receptacles (Disposable only)
- I. Surgical masks covering the mouth and nose are worn in the restricted areas when sterile activities are underway and when scrubbed persons are present.
  1. Masks have a high (95%) filtration efficiency.
  2. Masks are never lowered to hang loosely around neck, placed on top of head or put in a pocket.
- J. Masks are changed/removed:
  1. After each patient's procedure.
  2. When re-entering the operating room.
  3. As indicated by contamination and other events.
- K. Footwear is sturdy, clean, and dedicated for use within UIHC.
  1. Shoe covers are optional and may be worn when contaminated with blood, body fluid, or liquids are anticipated.
    - a. Shoe covers should be changed when re-entering the MOR
  2. Hose or socks that cover the feet and ankles are worn in the operating room.
- L. When scrubbed, all jewelry must be removed (finger rings, bracelets, and watches may not be worn when scrubbed). Necklaces and earrings must be completely covered.
- M. Fingernails are short and clean.
  1. Porcelains/acrylic nails are not worn in the operating room.
  2. When nail polish is worn, the polish is not chipped and under four days old.
- N. Makeup and cologne are used minimally.
  1. Certain emergencies may occur in the operating room that will make it necessary for appropriate people to come immediately into the operating room suite without changing into O.R. attire. These include but may not be limited to:
    1. Patient emergencies
    2. Smoke or fire
    3. Security problems
    4. Patient transportation needs

**PROCEDURE:**

*Mosby Surgical Attire*

Created from UIHC policy SS-09.001 Surgical Attire - 11/13

## Infection Prevention Supplement B

### Traffic Patterns in the Operating Room Suite

**PURPOSE:** To maintain high level cleanliness of the operating room suite;  
to minimize the risk of transmission of infectious disease;  
To maintain the security of the operating room environment;

**DEFINITION:**

**Unrestricted area:** The area serving as a transition between other areas of the hospital and the operating room suite

**Semi-restricted area:** The area of the operating room suite in which peripheral support activities are performed.

**Restricted area:** Operating rooms where sterile procedures are performed or sterile supplies are opened.

- A. The operating room suites are divided into three zones: unrestricted, semi-restricted, and restricted.
- B. The **unrestricted** zone includes:
  - 1. Offices of support and administrative staff,
  - 2. Main hallway to the charge desk in the MOR
  - 3. PSCU, PACU, SSRF
  - 4. 6th floor surgical lounges
- C. Traffic in the unrestricted zone is limited to those authorized to be in the area.
- D. Attire in the unrestricted zone may be street clothes or operating room attire. UIHC policy requires that all manufacturer representatives wear name badges, these badges are obtained in Procurement and Value Implementation (PVI) Services.
- E. The **semi-restricted zone** includes areas beyond the red lines, from entrances to the operating room suite to the operating room doors, and includes:
  - 1. Storage areas for clean and sterile supplies (e.g. inner core of the MOR and MOR East),
  - 2. The corridors within the operating room suite.
- F. Traffic in the semi-restricted zone is restricted to patients, necessary employees, students present for learning experiences, and manufacturer's representatives with approval.
- G. Surgical attire is required in the semi-restricted zone, including: clean, hospital laundered scrubs, hat, name badge, and optional warm-up jacket and shoe covers.  
See Surgical Attire Supplement
- H. The **restricted zone** includes all operating rooms.
- I. Air pressure in the restricted zone remains positive to the outer corridor.
  - 1. Doors to pass-through cupboards and the operating room are closed when not in use.
  - 2. The air pressure is set in the "occupied" mode at all times.

- J. Surgical attire in the restricted zone includes: clean, hospital laundered scrubs, hat, hospital-dedicated shoes, street cloths, exposed arms must be covered, shoe covers and masks are worn in the operating rooms when sterile supplies are open.  
See –! — ..!;!!
- K. **Traffic patterns** support movement of clean and sterile supplies from the cleaner areas toward the less clean areas of the outer hallways.
1. Supplies are removed from outside shipping boxes prior to transfer into the semi-restricted zone. No outside shipping boxes are permitted in the semi-restricted or restricted zones.
  2. Clean and sterile supplies are transferred to the operating room from the inner corridors.
  3. Soiled supplies are removed from the operating rooms, and transported in closed containers, through the outer corridors to decontamination areas.
    - a. Contaminated instruments are cleaned in the soiled utility room. After decontamination, instrument trays are assembled in the clean utility rooms.
- L. Vendor Traffic
1. Manufacturer representatives make up approximately 25%-30% of the door opening in the operating room. 32% of all openings are unnecessary.
    - a. Obtaining instruments
    - b. Taking phone calls
    - c. Other unknown reasons
  2. Distractions in the OR suite include but are not limited to
    - a. Unrelated cell phone conversations
    - b. Conversations with staff regarding topics not key to specific procedure
      - i. Other patient conditions
      - ii. Politics
      - iii. Career choices
  3. Reduce Traffic wherever possible
    - a. More efficiency in bringing supplies/implants into room before incision
    - b. Additional sizes when appropriate
    - c. Use pass through cabinets
    - d. Only leave when necessary
- M. Noise
1. Noise levels have been directly related to increase i.e. unrelated conversations, cell phones.
    - a. Surgical site infections
    - b. Surgical errors
    - c. Increased response time & decreased accuracy
    - d. Impaired understanding of verbal communication

Created from UIHC policy SS-09.012 Traffic Patterns in the Operating Room Suite - 11/13

## Infection Prevention Supplement C

### Infection Control: Standard Precautions and Isolation

**PURPOSE:** To minimize the risk of transmission of infectious disease from patient to patient, healthcare worker to patient, and patient to healthcare worker.

- A. Air pressure in the operating rooms remains positive.
  - 1. Doors to pass-through cupboards and the operating room are closed when not in use.
  - 2. During opening sterile packages and completing surgical procedures
  - 3. The air pressure is set in the "occupied" mode.
  - 4. When operating rooms are not in use air pressure may be set in the "unoccupied" mode.
  
- B. Traffic is controlled; personnel are limited to those involved in patient care or learning experiences.
  
- C. Single use items are discarded following use unless approved for reprocessing.
  
- D. Personnel with infectious diseases or open lesions are restricted from patient care activities Communicable Disease Work Restrictions.
  
- E. Standard precautions are used for all patients, including patients with known infections or infectious diseases that are transmitted through contact with blood or body fluids (e.g. hepatitis B virus, hepatitis C virus, human immune deficiency virus).
  - 1. For direct patient care activities.
  - 2. For non-patient care activities involving contact with potentially infectious material.
  
- F. Personal protective equipment used is dependent upon the degree of exposure anticipated.
  - 1. Operating Room Circulator/Observers:
    - a. Eyewear, masks, and/or gowns are worn when exposure to blood or body fluids (e.g. splash) is anticipated.
    - b. gloves are worn when exposure to blood or body fluid is anticipated, such as:
      - 1) When touching blood or body fluids and mucous membranes.
      - 2) When handling items/surfaces soiled with blood or body fluids.
      - 3) When handling specimens.
      - 4) The no-touch technique may be substituted for wearing gloves when handling soiled items (e.g. counting sponges).
  - 2. Operating Room Scrubbed Persons
    - a. Protective eyewear, masks, gown, and gloves are worn.
      - 1) In ophthalmologic procedures involving negligible risk of splatters, protective eyewear is not required.

- B. team members scrubbing in after the start of a procedure should gown and glove themselves from a separate table or area that is not patient contaminated.

**H.** Hands hygiene is performed:

- 1. before entering Operating Room
- 2. Hand washing is performed when hands are visibly soiled.

**I.** Contamination is contained.

- 1. Sterile and clean items are separated from contaminated items (i.e. not placed together in case cart).
- 2. Patient contaminated equipment, instruments, linens, and supplies are contained during transport.

Created from UIHC Policy SS-09.003 Infection Control: Standard Precautions and Isolation  
11/13



## Infection Prevention Supplement D

### Hand Hygiene

**PURPOSE:** To reduce transmission of microorganisms that are a potential source of healthcare-associated infections,  
To identify situations when hand hygiene is required or indicated,  
To standardize hand hygiene practices.

**DEFINITIONS:** Alcohol-based hand rub: an alcohol-containing preparation applied to the hands to reduce the number of viable microorganism on the hands. Such preparations contain 60% - 90% ethanol or isopropanol.  
Antimicrobial soap: soap (i.e., detergent) containing an antiseptic agent.  
Antiseptic agent: antimicrobial substances applied to the skin to reduce the microbial flora (e.g., alcohols).  
Decontaminate: reduce bacterial counts on hands by performing antiseptic hand rub or antiseptic hand wash.  
Hand hygiene: a general term that applies to:  
1) handwashing with plain soap,  
2) antiseptic handwashing with antimicrobial soap and water  
3) Antiseptic hand rubbing with an alcohol-based hand rub.  
Handwashing: washing hands with plain liquid (i.e., non-antimicrobial) soap and water.  
Hand antisepsis: refers to either antiseptic handwashing with antimicrobial soap or using alcohol-based waterless products.

- A. Perform *hand antisepsis* with an alcohol-based hand rub:
1. Before and after contact with patients and their environment,
  2. Before putting on sterile gloves when inserting a central line, and before inserting indwelling urinary catheters, peripheral vascular catheters, or other invasive devices that do not require a surgical procedure
  3. If moving from a contaminated body site to a clean body site during patient care (e.g., after suctioning the endotracheal tube or before changing a central venous catheter dressing,
  4. After removing gloves, because hands may be contaminated during or after glove removal.
- B. Perform *hand hygiene* with plain soap and water or an antimicrobial soap and water:
1. When caring for any patient with diarrhea,
  2. When hands are visibly dirty or contaminated with blood and/or body fluids,
  3. Before eating and after using the restroom.

## **EQUIPMENT:**

Alcohol-based waterless hand rubs

**Or**

Non-antimicrobial soap or antimicrobial soap

Hot and cold running water

Paper towels

## **PROCEDURES:**

### A. Hand Antisepsis with Alcohol-Based Waterless Hand Rubs (gel or foam)

1. **Be sure hands are not dirty.** If hands are dirty wash hands first using instructions from section B.
2. Apply 3-5 ml (a thumbnail-sized amount) of alcohol-based hand rub to hands.
3. Spread gel or foam all over hands; pay attention to the palms, backside of hands, fingers, fingertips, between fingers, and nail beds,
4. Rub the gel or foam into hands until dry (approximately 15-30 seconds). After many uses, the hand rub may cause the hands to feel "sticky", at this point, wash hands with soap and water.

### B. Washing Hands Only

1. Adjust running water to a warm temperature,
2. Adjust the force of the water to prevent splashing water onto the area around the sink,
3. Wet hands,
4. Use soap dispenser with foot, knee, or hand controls and dispense enough soap to achieve a rich lather,
5. Rub soap into a lather for at least 15 seconds,
6. Rub all areas of the fingers including fingertips, nail beds, palms, back and sides of hands,
7. Rinse hands well,
8. Dry hands with paper towels,
9. Turn off faucets using paper towel to protect hands from getting dirty again and throw towel in trash.

### C. Skin Care

1. Hospital-approved hand lotions or creams that are compatible with latex and chlorhexidine (CHG) will be available

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