I. SCOPE:

A. This policy applies to the Medical Staff and all personnel in any area at [insert Hospital name] (“Hospital”) where operative and invasive procedures are performed including, but not limited to, bedside procedures, OR, ER, ICU, Interventional Radiology and Cardiac Catheterization lab (except when catheter/instrument insertion site is not predetermined). The Medical and Hospital Staff are responsible for implementing and ensuring compliance with this policy.

B. This policy applies to all procedures involving incision or percutaneous puncture or insertion. For all procedures involving laterality, levels, or multiple structures, the intended procedure site is marked. The marking takes into consideration laterality, the surface, (flexor, extensor), the level (spine), or specific digit or lesion to be treated. The patient or legal representative shall participate in the procedure preparation, identification, and marking process. However if the patient is unable to respond for any reason all steps in this protocol will be completed as further defined in the policy.

Site Marking includes but are not limited to the following:

- Any procedure on an extremity
- Multiple structures (such as fingers and toes)
- Spinal procedures (in addition to pre-operative skin marking of the general spinal region, special intra-operative radiographic techniques are used for marking the exact vertebral level)
- Unilateral procedures on the eyes, ears, sinuses, mouth, face or neck
- Thoracotomies and thoracoscopies
- Procedures involving the joints
- Inguinal hernia repairs
- Unilateral procedures involving the breasts, ureters, kidneys, ovaries and testicles
- Chest tubes
- Any procedure that relies on radiological studies for site designation
- Peri and post-operative acute and chronic pain related anesthesia blocks
C. Special Considerations
For procedures that involve laterality of organs but where the incision(s) or approaches may be from the mid-line or from a natural orifice, the site is still marked and the laterality noted.

- Routine minor procedures such as venipuncture, peripheral IV line replacement, insertion of an NG tube, or Foley catheter insertion are not within the scope of this policy.

- This policy does not apply to interventional procedure cases for which the catheter/instrumental insertion site is not predetermined (e.g., cardiac catheterization, pacemaker insertion)

II. PURPOSE:

The purpose of this policy is to establish a standard procedure for identifying the correct patient, procedure and anatomical side/site prior to all operative and invasive procedures.

An alternative process is in place for patients who refuse site marking or who cannot easily be marked under the following conditions:

- For cases in which it is technically or anatomically impossible or impractical to mark the site the hospital places a temporary, unique wrist band on the side of the procedure containing the patient’s name, and a second identifier for the intended procedure and site. Examples include:
  - mucosal surfaces,
  - perineum,
  - premature infants, an alternative method for visually identifying the correct side and site is used (since a mark may cause permanent tattoo).

- For minimal access procedure that intend to treat a lateralized internal organ, whether percutaneous or through a natural orifice, the intended side is indicated by a mark at or near the insertion site, and remains visible after completion of the skin prep and sterile draping.
• For teeth, the operative tooth names(s) and number are indicated on documentation or the operative tooth (teeth) is marked on the dental radiographs or dental diagram. The documentation, images, and/or diagrams are available in the procedure room before the start of the procedure.

III. POLICY:

Except for procedures specifically excluded in this policy, the Hospital shall identify the correct patient, procedure and anatomical side/site prior to all operative and invasive procedures.

IV. PROCEDURE:

A. Prior to Procedure

1. Verification of the correct person, procedure, and site occurs:

   a. At time procedure is scheduled

   b. At time of pre-admission testing

   c. On admission into facility

2. Prior to the procedure, the pre-procedural nurse shall ask the patient to state (not confirm) his/her name and check one other patient identifier, (i.e., medical record number, account number or birth date). For non-verbal patients, the pre-procedural nurse will confirm the patient’s name and one other patient identifier, (i.e., medical record number, account number, or birth date) by matching the wristband against the medical record. In all cases two patient identifiers will be used.

The physician or appropriate licensed independent practitioner (LIP) who is privileged by the Hospital to perform the procedure in conjunction with the patient shall clearly mark the procedure side/site with the word “Yes” to enhance the reliability of the process. This shall occur before the patient is moved to the location where the procedure will be done. Marking shall take place with the patient involved, awake, and aware if possible. To avoid
confusion, the physician or appropriate LIP performing the procedure shall state the side/site and point to it with the patient. If the patient is a minor or unable to verify the procedural side/site, the patient’s legal representative (parent, legal guardian, health care proxy) shall work with the physician or appropriate LIP performing the procedure to identify the procedural side/site. If the patient’s legal representative is not available, then the physician or appropriate LIP performing the procedure shall mark the procedural side/site. If the patient/legal representative refuses marking of the site, the site will be reconfirmed verbally, and refusal and reconfirmation shall be documented in the medical record.

3. The procedure site is marked by a physician or appropriate LIP or other provider who is privileged or permitted by the Hospital to perform the intended surgical or non-surgical invasive procedure. The individual will be involved directly in the procedure and will be present at the time the procedure is performed.

4. For purposes of this policy, the surgeon/physician or appropriate LIP performing the procedure is ultimately responsible for the verification process and shall verify the surgical site during the time out process.

5. To improve the adherence of the site marking, it is recommended that the area first be wiped with isopropyl alcohol prior to marking. After the skin is dry, the procedural side/site shall be marked with the word “Yes” using a surgical marking pen.

6. To prevent confusion, the non-operative/procedure sites or sides shall not be marked, unless required for another aspect of care.

7. The method of marking any type of mark shall be consistent throughout the organization.

8. The procedural site mark, as described in this policy, must be visible to the procedural team after the surgical prep and draping has been applied. The visibility of the mark shall be documented in the procedural record.

9. In the case of multiple level surgeries such as spinal surgery, the levels that are to be operated on need to be written next to the mark (i.e., L4, L5). Intra-
operative x-rays with immovable markers will be used to determine the location and level of surgery (towel clips and other objects would not be considered an immovable object). Needles used to identify the level of intervention should never be removed until the case is initiated once radiographic confirmation is completed. The x-ray will be reviewed by the operating surgeon for confirmation. Fluoroscopy imaging and traditional radiographic imaging may both be used to help the surgeon in determining correct level. Once confirmed, the image will be stored for comparison after the incision is made. Patients will state where their pain is located (left or right side) in the pre-procedural phase.

10. In the case of multiple sides/sites during the same procedure, each side and site must be marked.

11. While side/site marking for dental procedures is exempt, documentation of the operative tooth name(s) or marking of the operative tooth (teeth) on the dental radiograph is required.

12. The surgical side/site will be marked for laparoscopic cases that involve operating on organs that have laterality (i.e., kidneys, ovaries).

13. A member of the team/nursing staff who needs to perform treatment (i.e., eye drops) prior to the site being marked must follow the patient verification process as outlined in Subsection IV.A. of this policy.

14. When an anesthesia block is to be performed prior to procedure a checklist is utilized to ensure all steps of universal protocol for minimum checklist requirements. (See Attachment A)

15. “Time-out” must be performed immediately before starting the procedure. The “time-out” process shall be conducted in the location where the procedure will be done and shall involve the entire operative procedural team. All members of the team shall engage in the time out process and individually respond to verify the following using the informed consent:

- Correct patient identity
- Confirmation that the correct side and site are marked
- An accurate procedure consent form
16. When two or more procedures are being performed on the same patient or by different procedure teams, a time-out is performed to confirm each subsequent procedure before it is initiated.

17. The timeout is the last thing to be completed before incision. If physician or appropriate LIP performing procedure leaves patient after timeout but before procedure incision, another timeout must be performed.

All components of the above process shall be completed and documented on the verification checklist or in the Electronic Health Record (see Attachment B) prior to the start of the procedure.

Any discrepancies identified during the verification process and/or during the “time-out” process must be resolved prior to the start of the procedure.

B. Verification

1. For scheduled operative/invasive procedures, the proposed side/site must be clearly identified on the scheduling form. Illegible forms will be rejected. The words “right” and “left” must be completely spelled out. Abbreviations will not be accepted. In all cases, the terms “right” and “left” shall refer to the patient’s right and the patient’s left.

2. The physician or LIP shall discuss the operative/invasive procedure with the patient before anesthesia/moderate sedation. The patient shall verbalize agreement of the correct procedure and surgical site, and the discussion and patient verbalization shall be documented in the medical record.
3. A time-out shall be conducted on all procedures where this protocol applies even in emergency situations. The extra few seconds taken to assure the procedure is being conducted on the correct patient or site is of utmost importance.

4. Physicians or LIPs who refuse to follow the Universal Protocol and Time Out shall be referred to Peer Review.

5. All relevant documentation including the consent form, H&P, and diagnostic data shall be verified by the pre-procedural nurse/procedural team. If there are any discrepancies or uncertainties, the pre-procedural nurse/procedural team shall call the surgeon/physician for clarification prior to the start of the procedure.

6. Communication barriers (sight and hearing impairments, a non-English-speaking patient, as well as the patient’s emotional status) shall be addressed by all caregivers so that the patient is able to fully participate in preoperative discussions. Measures taken to address communication barriers shall be documented in the medical record.

C. Responsible Person

The ____[insert title]____ is responsible for ensuring that all individuals adhere to the requirements of this policy, that these procedures are implemented and followed at Facility and that instances of non-compliance with this policy are reported to the ____[insert title of senior individual with leadership/operational oversight for the area]____.

D. Enforcement

All Hospital staff and Medical Staff whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this policy. Failure to comply with this policy will be subject to appropriate performance management pursuant to all applicable policies and procedures, including the Medical Staff Bylaws, Rules and Regulations.

V. REFERENCES:

- American College of Surgeons
Title: UNIVERSAL PROTOCOL FOR PREVENTING WRONG SITE, WRONG PROCEDURE, WRONG PERSON SURGERY

- Illinois State Medical Society; Wrong-Site Surgery 6/18/99
  Joint Commission Sentinel Event Alert: Issue 6 Lessons Learned: Wrong-Site Surgery
- American Society for Surgery of the Hand
- Joint Commission. National Patient Safety Goals; FAQs, May 2003
- Joint Commission 2009 National Patient Safety Goals
- Joint Commission Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery and Guidelines for Implementing the Universal Protocol
- North American Spine Society 2011
- American Society of Regional Anesthesia (May, 2014) Pre-Block Checklists, pg. 17

VI. ATTACHMENTS:
- Attachment A: Anesthesia Block Checklist Requirements
- Attachment B: Universal Protocol Downtime Form
Anesthesia Block Checklist Requirements

**Procedural Verification**

- Verified patient using 2 identifiers
- Verified surgical informed consent has been obtained and matches scheduled procedure
- Verified updated H&P is on the chart
- Completed/confirmed pre-anesthetic evaluation
- Reviewed pertinent laboratory and diagnostic tests
- Verified patient allergies
- Reviewed anticoagulants/medications

**Site Marking**

Anesthesia provider marked the regional anesthetic site with the word “yes.”

The patient/guardian was involved in the site marking.

**Time Out**

In the presence of a second verifier (not performing/assisting in procedure):
- Patient identification
- Informed consent matched to procedure and site mark
- Monitors placed and emergency equipment readily available

**Post procedure Handoff**

Report
- Medications that were administered (Other)
- Procedure performed (Other)
- Need for additional monitoring/unexpected findings (Other)
Universal Protocol Downtime Form

**UNIVERSAL PROTOCOL/TIME-OUT SAFETY CHECKLIST**

**BEFORE INDUCTION OF ANESTHESIA / PROCEDURAL SEDATION  ►►►**

<table>
<thead>
<tr>
<th>SIGN IN: OR Circulating Nurse/Procedural Nurse/Anesthesiologist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure site marked by Surgeon:</td>
</tr>
<tr>
<td>□ N/A (Premature infants, site not pre-determined, or exception)</td>
</tr>
<tr>
<td>□ Patient refusal of marking (document refusal and re-confirmation of site/site in medical record)</td>
</tr>
<tr>
<td>Site marked by: ____________  ____________  Time: ____________</td>
</tr>
<tr>
<td>Confirm the following with patient:</td>
</tr>
<tr>
<td>□ Identity</td>
</tr>
<tr>
<td>□ Site</td>
</tr>
<tr>
<td>□ Procedure</td>
</tr>
<tr>
<td>□ Consent</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ANESTHESIOLOGIST / OR CIRCULATING RN / PROCEDURAL RN:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia safety check completed</td>
</tr>
<tr>
<td>Pulse Oximeter on patient and functioning</td>
</tr>
<tr>
<td>Does patient have:</td>
</tr>
<tr>
<td>□ Allergy?</td>
</tr>
<tr>
<td>□ Yes, allergies reviewed</td>
</tr>
<tr>
<td>□ Difficult Airway/Aspiration Risk?</td>
</tr>
<tr>
<td>□ No  □ Yes, equipment assistance available</td>
</tr>
<tr>
<td>□ Risk of &gt;500mL blood loss (4mlkg in Children)</td>
</tr>
<tr>
<td>□ No  □ Yes, adequate intravenous access and fluids planned</td>
</tr>
<tr>
<td>□ Necessary Equipment available</td>
</tr>
</tbody>
</table>

**BEFORE SKIN INCISION / PROCEDURE  ►►►**

**STOP!**

**ALL ACTIVITIES CEASE**

- Surgical/Procedural Team verbally confirm:
  - Correct patient identity
  - Correct side and site
  - Consent form is accurate
  - Agreement on the surgery to be done
  - Correct patient position
  - Site marking is visible after prep/drape
  - Essential imaging properly labeled and displayed
  - Correct implants present
  - Special equipment present
  - Antibiotic (pre-hylastyl) given
  - Fluids for irrigation
  - Safety precautions based on patient history and/or medication use

- **Nursing reviews:**
  - Sterility (including indicator results)
  - Equipment issues or concerns

- **Surgeon reviews:**
  - Critical issues or unexpected steps
  - Operative/procedural duration
  - Anticipated blood loss

**TIME OUT COMPLETED BY:**

Name/Signature: ____________  ____________

Date: ____________  ____________  Time: ____________

**BEFORE PATIENT LEAVES OPERATING ROOM OR PROCEDURE ROOM**

**SIGN OUT: Team Debriefing**

**ALL TEAM MEMBERS:**

Surgical/Procedural Team verbally confirm

- Name of procedure recorded
- Surgical/procedural counts are correct
- N/A
- Specimens are labeled
- N/A
- Equipment problems addressed
- N/A
- Surgical/Procedural Team reviews key concerns for recovery and management of the patient

- □ OR CIRCULATING RN / PROCEDURAL RN

Signature: ____________  ____________

Print Name: ____________

Date: ____________  ____________  Time: ____________

- □ 2ND SIGNATURE for relief staff (as needed)

Signature: ____________

Print Name: ____________

Date: ____________  ____________  Time: ____________

Based on the WHO Surgical Safety Checklist developed by World Health Organization

Universal Protocol/Time-Out Checklist

PATIENT LABEL  Updated 03-04-18: TDC

09-28-16