DESCRIPTION/OVERVIEW
The Universal Protocol focuses on safety for all surgical and non-surgical invasive procedures where general anesthesia or deep sedation is used. All members of the procedural team are responsible for ensuring that a complete time-out has taken place, and have the ability to suspend the procedure until they are satisfied with the time-out.

REFERENCES
- The nationally recognized practice standard as defined by the American Academy of Orthopedic Surgeons and the American College of Surgeons statement on ensuring correct patient, correct site, and correct procedure surgery.
- The Joint Commission (TJC) 2009 Hospital Accreditation Standards. Universal Protocol standards UP.01.01.01, UP.01.02.01, and UP.01.03.01.

AREAS OF RESPONSIBILITY
Person Performing Procedure(s), e.g.: Licensed Independent Practitioner (LIP), Peripherally Inserted Central Catheter (PICC) Nurse, Wound, Ostomy & Continence Nurse (WOCN):
1) Documents site and procedure when determining a patient needs a procedure, including procedures that will be performed at the bedside, in the clinic, or in the operating room.
2) Consulting physicians document site and procedure when performing preprocedure testing or assessment.
3) Participates in the time out procedure and documentation.
4) If performing an invasive procedure without other staff, physician completes the Universal Protocol documentation.

Nurse:
1) Ensures all needed items are available and accurately matched to the patient by completing the preprocedure process and documentation.
2) Initiates the time out procedure.
3) Participates in the time out procedure and documentation.

Medical Assistant:
In procedures where a nurse is not participating in the procedure, the Medical Assistant performs the following functions:
1) Ensures all needed items are available and accurately matched to the patient by completing the preprocedure process and documentation.
2) Initiates the time out procedure.
3) Participates in the time out procedure and documentation.

Ancillary Staff:
1) Documents correct patient, correct site, correct procedure when performing preprocedure testing or assessment.
2) Participates in the Universal Protocol procedure and documentation if present for the procedure.
PROCEDURE

I. Non-Operating Room Invasive Procedures:

Conduct a pre-procedure verification process.

1) Verification of the correct person, correct site, and correct procedure occurs at the following times:
   1.1 At the time the procedure is scheduled
   1.2 At the time of preadmission testing and assessment
   1.3 At the time of admission or entry into the facility for a procedure, whether elective or emergent
   1.4 Before the patient leaves the preprocedure area or enters the procedure room
   1.5 Anytime the responsibility for care of the patient is transferred to another member of the procedural care team, including the anesthesia providers, at the time of, and during, the procedure.

2 The preprocedure verification is a process of information gathering and verification.

2.1 The nurse (or physician if the nurse is not involved in the procedure) conducts the preprocedure verification process to ensure that all relevant documents and related information or equipment are:
   2.1.1 Available prior to the start of the procedure.
   2.1.2 Correctly identified, labeled, and matched to the patient’s identifiers.
   2.1.3 Reviewed and are consistent with the patient’s expectations and with the team’s understanding of the intended patient, procedure, and site.

2.2 Preprocedure verification includes:
   2.2.1 Correct patient
   2.2.2 Correct procedure
   2.2.3 Correct site
   2.2.4 Procedural and sedation consents
   2.2.5 Site marking, if applicable
   2.2.6 Relevant documentation
      2.2.6.1 For example, history and physical, signed procedure consent form, nursing assessment, and preanesthesia assessment.
   2.2.7 Correct and labeled test results present
      2.2.7.1 For example, radiology images and scans, or pathology and biopsy reports) that are properly displayed
   2.2.8 Any required blood products, implants, devices, and/or special equipment for the procedure

Mark the procedure site

1. Marking the procedure site allows staff to identify without ambiguity the intended site for the procedure. (For those procedures in which site marking is not required, the other requirements of the Universal Protocol still apply.)

2. For all procedures involving incision or percutaneous puncture or insertion, where laterality and/or level are involved, the intended procedure site is marked.
   Note: For procedures that involve laterality of organs, but the incision(s) or approaches may be from the midline or from a natural orifice, the site is still marked and the laterality noted.

3. The site marking takes place with the patient involved, awake and aware prior to prepping and draping, if possible.

4. The procedure site is marked by a licensed independent practitioner or other provider who is permitted by the hospital and qualified through a residency program to perform the procedure.
individual will be involved directly in the procedure and will be present at the time the procedure is performed.

4.1. Note: Final confirmation and verification of the site mark takes place during the time-out.

5. The site is marked with a site-marking pen, and is designated by the initials of the LIP marking the site.

6. For patients who refuse site marking or when it is technically or anatomically impossible or impractical to mark the site (mucosal surfaces, perineum, premature infants), follow an alternative process and note patient refusal on the Universal Protocol documentation.

6.1. A wrist band will be placed on the patient, stating the patient’s name and the procedure being performed.

6.2. If the procedure relates to laterality, a wristband will be placed on the patient stating the procedure and patient’s name.

6.3. Examples of other situations which may involve alternative processes include:

6.3.1. Minimal access procedures treating a lateralized internal organ, whether percutaneous or through a natural orifice

6.3.2. Interventional procedure cases for which the catheter/instrument insertion site is not predetermined (for example, cardiac catheterization, pacemaker insertion)

6.3.3. Teeth

6.3.4. Premature infants, for whom the mark may cause a permanent tattoo

7. Exceptions to Site Marking:

7.1. Procedures in which there is no predetermined site of insertion such as cardiac catheterization and other interventional procedures.

7.2. An obvious wound or lesion that is the site of the intended procedure.

7.3. When the person performing the procedure does not leave the patient once the decision is made to perform the procedure…for example an emergent bedside procedure.

7.4. Site markings are not required for epidural anesthesia for the patient in labor.

**Time Out**

1. A time-out is conducted immediately prior to starting the invasive procedure or making the incision. The purpose of the time-out immediately before starting the procedure is to conduct a final assessment that the correct patient, correct site, and correct procedure are identified. The time-out has the following characteristics:

1.1 It is standardized by following this policy and procedure, and documenting on one of the approved forms. The time-out includes the following:

1.1.1 Correct patient identification

1.1.2 Correct site

1.1.3 Correct procedure

1.2 It is initiated by the designated team member.

1.3 It involves the immediate members of the procedure team.

1.4 When two or more procedures are being performed on the same patient, and the person performing the procedure changes, a time-out is performed to confirm each subsequent procedure before it is initiated.

1.5 Exceptions to Time Out:

1.5.1 A time-out is not required for procedures for pain management, such as cervical & lumbar epidural injections if the person performing the procedure does not leave the patient once he/she enters the room to perform the procedure.

**Documentation:**
1. The Universal Protocol is clearly documented using one of the following options.
   1.1. Non-OR Universal Protocol Form
   1.2. Procedural Sedation Flow sheet

II. Surgical Services Invasive Procedures:
Conduct a pre-procedure verification process

1. Each inpatient and outpatient area performing elective or urgent invasive procedures which require specific informed consent will participate in a preprocedure prior to start of the procedure. Documentation of the preprocedure can be on the time out checklist, time out sticker, nursing record or in the designated area on the procedural sedation documentation flow sheet. The patient or guardian, and members of the operative/procedural team will be actively involved in this process to enhance the reliability of said identification. All patients undergoing a planned operation/invasive procedure shall have the operative procedure and surgical site actively verified by representatives of the operative/invasive procedure team.

   1.1.1. If, during the process of verification of correct patient, procedure, or site, any procedural or site discrepancies are identified, the entire process will immediately halt. The patient will not be taken into the operating/invasive procedure room. The holding/procedure nurse, anesthesiologist, operating room nurse, and surgeon/proceduralist will meet and review the patient’s medical record, and all other relevant information with the patient/guardian, to determine which procedure/site is planned. The patient will not proceed into the operating/procedure room until all representatives of the team are in agreement.

   1.1.2. If the patient is scheduled for multiple operations/invasive procedures that will be performed by the multiple surgeons/physicians, all items on the checklist must be verified for each operation/invasive procedure that is to be performed. Each separate operative/invasive procedural site will be initialed by the surgeon/physician performing each separate operation/invasive procedure.

Mark the procedure site

2. For surgical procedures, no patient shall leave the holding area if the procedure and site has not been verified and operative site clearly marked by the surgeons’ initials on or near the anatomical site of the proposed operative/invasive procedure. This cannot be delegated to a RN—the LIP must mark the site prior to the patient receiving narcotics, sedation, or anesthesia.

   2.1 Marking will be done with surgical skin markers only. The site will be marked before entering the operating room. Site marking should be done for any procedure that involves laterality, multiple structures (e.g. digits) or levels (e.g. spine). The performing LIP or designee will mark the site so that it is visible in the operative field after the patient is prepped and draped. For spinal procedures, in addition to the pre-operative marking of the general spinal region, C-arm needle placement technique will be utilized.

   2.2 Site marking is not required for procedures that do not relate to laterality, digits or levels such as a mid-line sternotomy, caesarean section, laparotomy and laparoscopy, cardiac catheterization or other interventional procedures for which the site of insertion is not predetermined. Situations in which marking the site would be impossible or technically impractical (ureteroscopy/neonates) a specific colored (blue) ID wrist band will be placed on the patient. Wristband will state name and procedure.

   2.3 Site marking for eye procedures will occur directly above the eye with the initials of the LIP.
2.4 If the patient refuses marking of the site, the time out checklist is completed with notation of patient refusal. A bracelet may be offered as an alternative to marking.

2.5 Teeth that require extraction should be marked on the radiographs when possible. Due to the unpredictability of dental decay and patients not allowing x-rays or an exam to occur, site identification and verification will be the mouth or the oral cavity.

**Time Out**

3. A time out procedure must be conducted in the location where the procedure will be performed (OR, Endoscopy, Radiology, patient room, etc.) immediately before the start of any invasive procedure or surgical incision. The timeout procedure will be initiated by the circulating/procedure nurse prior to the start of procedure. All members of the procedural team will verbally confirm:

3.1 Patient’s name and Date of Birth
3.2 Procedure to be performed and correct position of patient
3.3 Site location and laterality including marking, if applicable
3.4 Prophylactic antibiotics needed/given before skin incision
3.5 Correct radiographic data available if applicable
3.6 Special equipment/implants/requirements available if applicable
3.7 The surgeon will state “If anyone has any concerns or sees anything they think is unsafe, I expect you to speak up. What questions do you have?”

4. The procedure will not proceed unless there is total agreement among all team members. Time out time and participants will be noted in the chart.

5. In the event of a life or limb-threatening situation, every attempt will be made to actively confirm the correct operative/invasive procedure site without unduly delaying appropriate emergency care.

**Implementation**

6. Step One: Pre-Operative assessment and verification by OR Holding/Procedural Staff/Nurse.
6.1 Patient verification using two of the following identifiers:
   6.1.1 Patient name
   6.1.2 Patient date of birth
   6.1.3 These can be stated or obtained from information on patient armband.

7. Correct operative/procedure consent confirmation. Operative/Invasive Procedural permit verified through verbal interrogation of patient:
   7.1 Patient/Guardian is able to state awareness of procedure to be performed and by whom.
   7.2 Surgical site and side verified and documentation of verification done
   7.3 History and physical and consent must match the above verification
   7.4 Inpatients: for surgical marking of skin, surgeon/proceduralist may mark proper site using a surgical skin marker either on the unit or on arrival in the holding area.

**DEFINITIONS**

- Pre-procedure: The initial verification process when preparing for an invasive procedure.
- Time Out: The final verification process just prior to beginning the invasive procedure.

**SUMMARY OF CHANGES**

- Replaces ID and Verification of Selected Operative Invasive Procedural Site and Side policy.
- Updated to include a section for invasive procedures performed in Non-Operating Room areas (ambulatory, bedside, emergency department).
- Updated to meet TJC’s 2009 Universal Protocol guidelines.
- Updated to reflect TJC’s 10/09 change of minimum requirements as deep sedation and general anesthesia.
- Added the role of Medical Assistants.

RESOURCES/TRAINING

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DOCUMENT APPROVAL & TRACKING

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<td>Erin Doles, Administrator, Professional &amp; Support Services</td>
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ATTACHMENTS

Non-OR: Universal Protocol/Time Out form
Procedural Sedation Form (available under “Forms” section in Policies, Procedures & Guidelines Document Management site)
Non-OR Universal Protocol/Time Out

Definition:
The Universal Protocol focuses on safety for all surgical and non-surgical invasive procedures where GENERAL ANESTHESIA or DEEP SEDATION is used.

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<td>Including:</td>
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<td>Correct patient</td>
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<td>Correct procedure</td>
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<td>Correct site</td>
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<td>Relevant documentation</td>
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<td>Procedure consent</td>
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<tr>
<td>Correct test results present</td>
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<td>Blood products, procedural devices/implants present; Lot #</td>
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<td>Site marking complete.</td>
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Signature: ___________________________   Date & Time: ___________________________

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<tr>
<td>Procedure Being Performed:</td>
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<tr>
<td>Correct Patient</td>
<td>Yes No Confirm 2 forms of ID to procedure orders (Name and Date of Birth).</td>
</tr>
<tr>
<td>Correct Site</td>
<td>Yes No</td>
</tr>
<tr>
<td>Correct Procedure</td>
<td>Yes No</td>
</tr>
<tr>
<td>Entire Team Present</td>
<td>Yes No Circle all that apply: MD RN Tech RCP RT APP MA</td>
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Note: Time Out section should be signed by person documenting checklist.