



**TRIHEALTH, INC.
CORPORATE POLICY**

TITLE: Clinical Procedure Verification: Universal Protocol	
SECTION: 02	POLICY NUMBER: 11.00
EFFECTIVE DATE: 06/2003	REVIEWED/REVISED DATE(S): 09/2004, 03/2007, 01/2008, 02/2009, 04/2010, 08/2010, 12/2011, 07/2013, 12/2013, 02/2014, 05/2017, 06/2018
<p><u>AFFECTED AREAS</u></p> <ul style="list-style-type: none"> • All areas that perform operative and other invasive procedures that expose patients to more than minimal risk. Areas include but not limited to: Operating Room, Procedural Areas, Labor & Delivery Cesarean Section Area, Diagnostic Areas, Emergency Room, Ambulatory Settings and at the patient bedside. • Any area that performs the puncture or incision of the skin, insertion of an instrument, or insertion of a foreign material into the body • Invasive procedures may be performed for diagnostic or treatment-related purposes. • Procedures specifically excluded from the Universal Protocol are radiation oncology, lithotripsy, and performance of dialysis, certain routine minor procedures such as venipuncture, peripheral IV line placement, or insertion of n/g tube or Foley catheter. <p>This policy acknowledges that other relevant and applicable policies and procedures exist that have been drafted, approved, and adopted by entities (and departments) within TriHealth and are specific to those departments or entities. Interpretation of these other policies must comply with the principles adopted by Corporate Policy #12_01.00, "Corporate Policies, Development & Implementation".</p>	
POLICY OWNER: Director, Perioperative Services	
<p>APPROVED BY: Patient Care Committees Director, Cardiac Services Director, Diagnostic Services Corporate Policy & Procedure Committee President of Health Services & System COO President & CEO</p>	

PURPOSE

To provide a standardized process that defines all steps/procedures employed by physicians and caregivers to maximize patient safety in the following areas:

1. Ensure the patient identification process is followed

- The pre-procedure verification is an ongoing process of information gathering and confirmation.
2. Ensure the effectiveness of communication among caregivers
 3. Ensure site marking occurs as applicable
 4. Ensure the Time Out process occurs immediately before puncture or incision of the skin, insertion of an instrument, or insertion of foreign materials into the body occurs.
 5. Decrease the potential for wrong-site, wrong-patient, and/or wrong-procedure occurrences.
 6. Abbreviations for “right” and “left” are not used in the documentation

SOURCE OF TRUTH STATEMENT

Pre-procedure verification is an ongoing process of information gathering and confirmation of correct patient, correct procedure, and correct site. For surgical procedures, the surgery schedule or Surgery Add-On Form is a document that documents the patient, procedure and site. Other documents that may be available to provide additional sources of information for the verification process include the History & Physical, Consent for Surgical or Medical Procedure or Treatment and Administration of Sedation and/or Anesthesia form, Scheduling Authorization Form (SAF), and x-rays. Any discrepancy noted between any of these source documents is to be addressed by the identifying individual by contacting the physician to resolve the discrepancy. The patient will not go into the operating/procedure room until the discrepancy is resolved. No aspect of the operative procedure may start, including anesthesia block procedures, until the discrepancy is resolved.

BACKGROUND:

- TJC Std: UP 01.01.01; UP 01.02.01; Licensure
UP.01.03.01; NPSG 01.01.01 Other:
- Regulatory Agencies:

POLICY/PROCEDURE

Prior to the initiation of all operative and other invasive procedures that expose patients to more than minimal risk including any procedure that involves the use of elective electrical current, the puncture or incision of the skin, insertion of an instrument, or insertion of foreign materials into the body for either diagnostic or treatment-related purposes the following steps must be completed:

- If there is no pre-procedural area, site marking and other components of the procedure verification process can be performed in the procedure room/patient bedside prior to the procedure with the patient awake, alert, and oriented.

Pre-procedure Verification:

1. The pre-procedure verification is an ongoing process of information gathering and confirmation.

2. The RN or Caregiver responsible for the initial assessment of the patient performs pre-procedure verification(identify the patient) by asking the patient/guardian to state (not confirm):
 - Their full name
 - Date of Birth
 - Site(s) and /or sides (s) for the procedures
 - Procedure(s)
 - When patient is unable to verbalize, RN or Caregiver will verify with Licensed Provider order, Acknowledgement of Consent, patient armband, family if present, etc. as applicable
3. This pre-procedure verification information must correspond with the initial procedure order and/or scheduled procedure site or appropriate procedure order from Licensed Provider.
4. If care of the patient is to be transferred to another department and/or caregiver, the staff and patient, if applicable, will reconfirm:
 - Patient name and date of birth
 - Procedure(s)
 - Correct side/site(s) marked, if applicable
 - Verification will include matching the armband to appropriate documentation
5. The Universal Protocol/Procedure Verification form will be completed as the patient progresses through their treatment phase for the specified procedure. No abbreviations will be used to describe laterality, i.e. Right, Left, Bilateral.
6. Pre-procedure checklist is to be completed, with the patient involved in the verification process when possible, prior to entering the procedure area. The checklist is reviewed with verification that the following are available (if applicable) and are accurately matched to the patient:
 - Updated History and Physical
 - Pre-anesthesia assessment
 - Correct side/ site(s) marked
 - Nursing assessment
 - Accurate, complete, and signed procedure acknowledgement of consent form
 - Required blood products

Site Marking:

Prior to the initiation of all operative and other invasive procedures that expose patients to more than minimal risk including any procedure that involves the puncture or incision of the skin, insertion of an instrument, or insertion of foreign materials into the body for either diagnostic or treatment-related purposes the following steps must be completed:

1. Marking the site is required for all procedures involving an incision or percutaneous puncture or insertion, right/left distinction, multiple sites, multiple structures such as

fingers or toes. For procedures that involve laterality of organs, but the incision(s) or approaches may be from midline or from a natural orifice, the site is still marked and the laterality noted. For cases in which it is technically or anatomically impossible or impractical to mark the site (mucosal surfaces, perineum, premature infants, ureteral stents) the Body Diagram found in the Universal Protocol/ Procedure Verification Checklist will be marked to identify the correct side and site. If Body Diagram is used, it must be present and visible during Time Out.

2. Identify appropriate procedure from prescribing authority.
3. The Universal Protocol/Procedure Verification form will be completed as the patient progresses through their treatment phase for the specified procedure. No abbreviations will be used to describe laterality, i.e. Right, Left, Bilateral.
4. The RN or Caregiver responsible for the initial assessment of the patient must identify the patient by asking the patient/guardian to state (not confirm):
 - Their full name and Date of birth
 - Site(s) and /or side(s) for the procedures Procedure(s)
5. This above information must correspond with the initial procedure order and/or scheduled procedure site. For cases requiring site marking, the licensed provider (in this document, provider will refer to surgeon or proceduralist) who is privileged or permitted by the hospital to perform the intended procedure and is directly involved and present at the time the procedure is performed MUST mark the procedural site prior to moving the patient to the location where the procedure is to be performed. In cases which will involve more than one surgeon working on more than one site, it is preferable to have all of the surgeons see and mark the patient on the day of the surgery in the pre-procedure area. Alternatively, if one or more of the surgeons will not be present at the beginning of the procedure, the appropriate site marking can be done on the Body Diagram sheet when the patient signs the consent in that surgeon's office.
 - The operative site must be marked with the surgeon's or proceduralist's initials in conjunction with the patient/guardian.
 - A marker that is sufficiently permanent to remain visible and will not wash off when the site is prepped will be used.
 - The marked site must be positioned so it is visible after the patient is prepped and draped.
 - The patient and/ or guardian must verbally acknowledge right, left, multiple sites/ structures, multiple procedures, and level(s) of spine. The patient/ parent/legal guardian should participate in site marking whenever feasible.

- If the patient /parent/legal guardian is unable to verbally identify site and /or procedure, this fact must be documented on the OR/procedure record in comments.
 - If the patient refuses to have site marked after being provided with information as to why site marking(s) is to be done, the refusal must be documented on the Universal Protocol/Procedure Verification form. The site marking(s) must be documented on a Body Diagram that will remain with the chart. If Body Diagram is used, it must be present and visible during Time Out.
 - If there is no pre-procedural area, site marking and other components of the procedure verification process can be performed in the procedure room prior to the procedure with the patient awake, alert, and oriented.
6. It is required to mark the location of entry into a patient with the proceduralist's initials. For example, initials at the initial trocar insertion site for laparoscopic procedures or marking the initial "needle stick" site for endovascular procedures would be in this category.
7. Exceptions to site marking are:
- Endoscopies
 - When intra-procedural imaging is used to provide confirmation of the correct side/lesion, site marking is exempt.
 - Teeth indicating the operative tooth name(s) on documentation or marking the operative tooth (teeth) on the dental radiographs or dental diagram on the Universal Protocol/ Procedure Verification Checklist
 - Premature infants, for whom the mark may cause a permanent tattoo
8. If the patient requires multiple surgeries during their stay, marks from previous procedures should be removed and new markings for each new procedure are required.
9. Skin marking of the general spinal region for all spinal cases is required, in addition to intra- operative radiographic techniques to mark the exact vertebral level. This includes marking of general region for epidural steroid injection.

Patient Verification Pre-procedure/Pre-op

1. The staff will ask the patient to verbalize:
 - Patient name and date of birth
 - Procedure(s)
 - Correct side/site(s), if applicable
 - Verification will include matching the armband to appropriate documentation
 - If patient is unable to verbalize, staff verifies patient armband and consent

Pre-procedure Time Out (for pre-procedure blocks/lines)

1. A pre-procedure “Time Out” must be performed and documented in the Procedure Verification Form for pre- procedures performed before the scheduled procedure.
2. Pre-procedures include but not limited to: blocks, epidurals, local injections, etc., done before the scheduled procedure.
3. This pre-procedure “Time Out” occurs prior to the start of the pre-procedure with the Licensed Provider (e.g. anesthesia provider, resident, etc.), a member of the surgical/procedural team/RN or Caregiver at bedside assisting, and whenever possible, the patient, to confirm correct patient, correct procedure, and correct site prior to pre-procedure start
4. The pre-procedure timeout will include:
 - Patient name and date of birth
 - Agreement of the procedure(s) to be performed as identified on Acknowledgement of Consent form
 - Name of pre-procedure
 - Correct site(s) marked

Entering the Operative/Procedural Room (Patient Verification):

2. The staff, including the anesthesia provider as applicable, will ask the patient to verbalize:
 - Patient name and date of birth
 - Procedure(s)
 - Correct side/site(s) marked, if applicable
 - Verification will include matching the armband to appropriate documentation
 - If patient is unable to verbalize, staff verifies patient armband and consent
3. Staff will verify the following:
 - History and Physical immediately updated prior to procedure
 - Pre-Anesthesia assessment
 - Accurate, complete Acknowledgement of Consent
 - Any required blood products
 - Availability of correct implant(s) or special equipment as applicable
 - Any required diagnostic tests as applicable
 - Diagnostic imaging studies are properly labeled and displayed, and verified by patient name/birth date and/or physician as applicable
 - Preoperative antibiotics administered as applicable

Time Out:

1. The time out is conducted immediately prior to the start of the procedure, with the entire team present. Note: In the OR, for a case that does not require Laterality, the time out can be performed during pause for prep dry if all team members are present and surgeon requests the time out process begin.

2. The staff and Licensed Provider(s) must confirm a “time-out” process with all staff present in the room by stopping all activities.
3. All staff and Licensed Provider(s) will verbally acknowledge the information being shared and maintain focus with “time-out” process. No other activities can take place during this process.
4. Any team member may express concerns about the procedure verification and time out process.
5. In the event there is a discrepancy during the verification process, all activities shall be halted until verification is accurate.
6. “Time Out” Process:
 - The “time-out” will be interactive with all members of the team actively involved in the “time out” process.
 - The “time-out” will be initiated by the Licensed Provider.
 - RN/Caregiver will facilitate the process to assure all components of the “time-out” are completed. The “time-out” includes communication of the following information to the team:
 - Patient name and date of birth.
 - Agreement of the procedure(s) to be performed as identified on acknowledgement of consent form.
 - As applicable, the correct side/site is marked and visible, and verbally acknowledged by all team members.
 - The RN/caregiver will identify that all components of the timeout are confirmed.
 - All team members must verbalize agreement. If there are any concerns, the procedure will not proceed until concerns are addressed.
 - The provider will give the direction to start the procedure.
7. Documentation will be completed in the Electronic Documentation System. In the event of the computer documentation system being unavailable, downtime procedures will go into effect to maintain patient care operations.
 - If the completion of the timeout process cannot be documented in Electronic Documentation System, it will then be documented on the Universal Protocol/Procedure Verification Checklist.
8. When two or more procedures are being performed on the same patient, the person performing the procedure changes, and/or there is a second incision, perform a “Time Out” before each procedure is initiated. Additional “Time Out” will be documented.

Emergent Situations:

1. In emergent, life-threatening circumstances these steps (pre-procedure verification, site marking or Time Out) are exempt if any steps of the process would add more risk than benefit.

DEFINITIONS

Licensed Provider: Provider refers to surgeon, proceduralist or resident who is privileged or permitted by the hospital to perform the intended procedure

Laterality: right, left, or bilateral

Procedures: In this policy, “procedure” refers to any operative or invasive procedures involving an incision or percutaneous puncture or insertion

REFERENCES

Association of perioperative Registered Nurses. (2016). Guideline for patient information management. In Conner, R. (Ed.). *Guidelines for Perioperative Practice*. doi: 10.6015/psrp.16.01.e1

Association of perioperative Registered Nurses. (2016). Guideline for transfer of patient care information. In Conner, R. (Ed.). *Guidelines for Perioperative Practice*. doi: 10.6015/psrp.15.01.583

The Joint Commission Accreditation and Certification Manual. (2018). National patient safety goals. In *The Joint Commission E-dition* (UP.01.01.01; UP.01.02.01; UP.01.03.01; NPSG.01.01.01).

OTHER AREAS/POLICIES OR PROCEDURES OF REFERENCE

Physician Orders: Verbal, Telephone, and Faxed (#02_29.00)
Charting on the Intraoperative Nursing Record

UNIVERSAL PROTOCOL PROCEDURE VERIFICATION CHECKLIST

A **PRE-PROCEDURAL ASSESSMENT - *Complete prior to procedure at bedside or sending patient to another area***

Name of Procedure(s): (Procedural site spelled out with laterality, avoid abbreviations. Must include levels for spine procedures)

Date of Procedure: _____

- Verified Patient Name and Date of Birth. Must Use TWO Patient Identifiers: Verbal, Identification Band, Other _____
- Acknowledgement Of Informed Consent Signed And Witnessed - Corresponds with Patient/Parent/Legal Guardian Verbally Stated Procedure(s), and Scheduled Procedure(s), Form that is signed and dated.

Signature/Title: _____

B Patient/Parent/Legal Guardian Signature if Refused Site Marking- must mark the site on the diagram on back of sheet
Signature person/guardian refusing _____

C **SBAR - *Complete whenever there is a hand-off to procedural unit/person***

D **PRE PROCEDURE(S) TIMEOUT for blocks/lines - *Complete for Verification of correct site/side for invasive intervention prior to main procedure.***

- Not applicable
- Procedural site spelled out with laterality, avoid abbreviations.
- Correct Position and Side/Site(s) Marked Not applicable
- Patient Name And Date of Birth

Name of Pre - Procedure: _____

Signature Of Person Coordinating Pre-Procedure Timeout(s): _____ Date: _____ Time: _____

E **PRE-PROCEDURE CHECKLIST -**

- Preoperative N/A

Signature/Title: _____

2nd Signature/Title (if needed): _____

Date: _____ Time: _____

Date: _____ Time: _____

E

Verification Is Completed by the Physician and the Procedural Team Members Immediately Prior to Procedure Start:

1. Patient name and date of birth
2. Agreement of procedure(s) to be performed as identified on consent form.
3. Correct side/site marking(s) is marked and visible and verbally acknowledged by all team members N/A (Not Applicable)

Signature of Person Coordinating Timeout(s) : _____ Date: _____ Time: _____



