



Patient Safety Refresher

Universal Protocol

Boarding Pass or Time Out

The **Universal Protocol** was created to prevent wrong person, wrong procedure, wrong site surgery in hospitals and outpatient settings. The Universal Protocol consists of three steps:

1. A pre-operative/ pre-procedure verification process
2. Marking the operative/procedure site
3. A Time Out (final verification) which is performed immediately before starting the operation/procedure

The SHC administrative policy requires that the Universal Protocol be conducted under the following conditions:

- All inpatients and outpatients undergoing invasive procedures requiring consent and anesthesia and/or moderate sedation
- All inpatients and outpatients undergoing invasive procedures requiring consent that do NOT require anesthesia and/or moderate sedation, a Time Out only is required

The steps to comply with the Universal Protocol at SHC are:

1. Pre-procedure or pre-operative verification. This verification ensures that all documents are available prior to the start of the procedure. Missing information and/or discrepancies must be addressed before the start of the procedure. This verification includes:
 - Patient Identification with Two Identifiers (patient name, Medical Record number, date of birth)
 - History and Physical in the Medical Record
 - Signed Consent in the Medical Record with the correct procedure verified
 - Site Marked and Verified (the patient should be involved in site marking if possible). The site must be marked and verified for procedures involving right/left distinction, multiple structures (e.g., fingers, toes), or multiple levels (as in spinal procedures). The site must be marked with a "YES" so that the mark will be visible after the patient has been prepped and draped. In most cases, the provider performing the procedure will be responsible for marking the site.
2. Time Out (final verification). The Time Out is a deliberate pause in activity involving clear communication (that includes active listening and verbal confirmation of the patient, procedure, site and side) among all members of the surgical/procedural team. The procedure is not started until any questions or concerns are resolved. The Time Out includes verifying:
 - Correct patient identity
 - Correct procedure verified with consent
 - Correct site and side (verified with site marking as per policy)
 - Correct patient position
 - Availability of correct implants and any special equipment or requirements



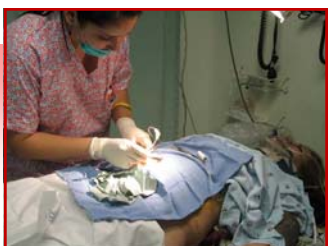
DOCUMENTATION:

A. SHC Boarding Pass (Universal Protocol) Form (#15-2229). The Boarding Pass Form is completed for:

All inpatients and outpatients undergoing invasive procedures requiring consent and anesthesia and/or moderate sedation

B. For Outpatients in the Emergency Department (ED), clinics and other outpatient departments undergoing Invasive Procedures Requiring Consent that do not require anesthesia and/or moderate sedation, document:

1. Using a check box for "time out" on procedure and/or other specified forms used in outpatient departments, or
2. Dictating "a time out was completed" in the dictated procedure note, or
3. Documenting that "a time out was completed" in the written procedure note, or
4. Use only Section II: Time Out of the SHC Boarding Pass (Universal Protocol) Form (#15-2229).



COMMONLY ASKED QUESTIONS about the UNIVERSAL PROTOCOL

Is there any exemption to the Universal Protocol for invasive procedures requiring consent that need to be performed EMERGENTLY? Yes. In the case of an emergent procedure or emergent surgery, site marking and documentation are not required as long as the physician deems the surgery/procedure to be an emergency (life-threatening). In this instance, the physician must document the circumstances in the progress notes. The physician will be responsible for identifying the correct patient, correct procedure, and correct site and document that in the progress notes.

I am performing an invasive procedure in the hospital that does not require moderate sedation or anesthesia. How do I document the Universal Protocol? Documentation of the Universal Protocol is performed using the SHC Boarding Pass (Universal Protocol) Form (#15-2229). Only Section II : Time Out is required to be completed.

I am performing an invasive procedure in the clinic or Emergency Department that does not require moderate sedation or anesthesia. How do I document the Universal Protocol? Only a Time Out is required. Use one of the following documentation methods: 1. A check box for "time out" on procedure and/or other specified forms used in outpatient departments, 2. Dictate "a time out was completed" in the dictated procedure note, or 3. Write that "a time out was completed" in the written procedure note, or 4. Use only Section II: Time Out of the SHC Boarding Pass (Universal Protocol) Form (#15-2229).

What procedures fall within the scope of the Universal Protocol? The Universal Protocol applies to all operative and other invasive procedures requiring consent that expose patients to more than minimal risk, including procedures done in settings other than the operating room such as a special procedures unit, endoscopy unit, interventional radiology suite, Emergency Department, clinics and other outpatient departments. Most procedures that involve puncture or incision of the skin, or insertion of an instrument or foreign material into the body, including, but not limited to, percutaneous aspirations, biopsies, cardiac and vascular catheterizations, and endoscopies are within the scope of the Protocol.

What procedures are not in the scope of the Universal Protocol and do not require documentation? Documentation of the Universal Protocol is not required for noninvasive procedures. Certain routine "minor" procedures such as venipuncture, peripheral IV line placement, insertion of NG tube, or Foley catheter insertion are not within the scope of the Protocol and do not require documentation.

Is a Time Out required when only one person is involved with an invasive procedure? Should someone else be brought in to participate in the Time Out? No. Even when there is only one person involved with the procedure, a brief pause to confirm the correct patient, procedure, and site is required. It is not necessary to engage others in this verification process if they would not otherwise be involved in the procedure.



What are the exemptions for site marking? Exemptions at SHC include:

- Procedures done through or immediately adjacent to a natural body orifice (e.g. endoscopy, tonsillectomy, hemorrhoidectomy, procedures involving the genitalia).
- Procedures that do not require right/left distinction such as mid-line sternotomies, laparotomy, laparoscopy, or when the site is not predetermined.
- Teeth - BUT, indicate operative tooth name(s) on documentation OR mark the operative tooth (teeth) on the dental radiographs or dental diagram.
- Single organ cases (e.g., Cesarean section, cardiac surgery). Interventional cases for which the catheter/instrument insertion site is not predetermined (e.g. cardiac catheterization).
- Premature infants, for whom the mark may cause a permanent tattoo.
- Cases in which the individual doing the procedure is in continuous attendance with the patient from the time of decision to do the procedure and consent from the patient through to the conduct of the procedure.
- Wounds or lesions that are obvious (note if there are numerous wounds and lesions and the target is not obvious, site marking should be done).

Some patients object to site marking because they don't want to walk out of the clinic/hospital with a visible mark? Can these patients refuse? Patients can refuse site marking. When patient refuses site marking, the patient will be presented with a waiver form to sign. If the patient refuses to sign the waiver, the provider should document the refusal in the procedure note.

For more information about the Universal Protocol, please contact the:

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