Universal Protocol - Non-Operating Room

Purpose: To outline the process whenever an invasive bedside procedure is to be performed to ensure the following:

- The correct procedure is done
- On the correct patient
- On the correct anatomical site.

Scope: The Universal Protocol must be performed before any invasive procedure that is more than a minor procedure (e.g., drawing blood, inserting NG tube or a Foley catheter, or starting an IV).
The Universal Protocol should also be used in emergency procedures unless the licensed independent practitioner determines that doing so would delay care to the point of becoming detrimental to the patient's safety

Definitions

Non-OR setting
Any location that is not designated as a licensed operating room

Procedure
Any therapeutic or diagnostic invasive intervention that penetrates the patient's skin or enters an orifice.

The Licensed Independent Practitioner Is defined as the individual who is ultimately accountable and will be present when the procedure is performed. In the case of procedural interventions this is the individual who has been granted the privileges or competency to independently perform the specific procedure.

Licensed Provider
Any provider who maintains an up-to-date license that allows them to practice in their specific field of medicine. This includes but is not limited to MD, DO, RN, LVN, CRNA, NP, CNM and PA. The licensed provider may or may not be a licensed independent practitioner based on their ability to practice independently

Protocol

Step 1. Obtain Consent

After the decision is made by the treating *Licensed Independent Practitioner* to undertake a procedure, a licensed provider should obtain consent from the patient prior to performing the procedure. Consent can be either verbal or written based on the expectations of LAC+USC Medical Center's Policy and individual departments. If consent cannot be obtained due to the patient clinical condition the licensed provider should make a good faith effort to contact family, conservator, or other relatives. Even when consent cannot be obtained, the licensed provider should still address all other aspects of the Universal Protocol as best possible.

During the consent process the licensed provider should confirm the following:

- Patient's identity

- The intended procedure
- The anatomical site of the procedure with the patient
- Discuss risks/benefits of the procedure and alternatives, if any.

When written consent is obtained the licensed provider must utilize the pre-approved template consent tool (iMedConsent) which must be:

- Signed by the patient or legal representative
- Signed by the individual performing the procedure

The written consent must remain in the patient's medical record and be completed prior to initiating the procedure.

Note: Use Medical Center approved form T-LAC101228 (Att. 2 - Universal Protocol - Procedures Performed Outside of the Operating Room) or its electronic equivalent to document steps 2-4. This form must remain in the patient's medical record.

Step 2. Conduct Pre-procedure Verification

In preparation for the procedure the licensed provider will involve the patient when possible and verify correct patient, correct procedure, correct site, and correct side. The licensed provider is responsible for reviewing relevant documentation, e.g. Consent and labeled diagnostic and radiology results and ensuring availability of required equipment and blood products.

Use Medical Center approved form T-LAC101228 (Att. 2) or its electronic equivalent for documenting the completion of this step.

Step 3. Mark the Site

After review of all documentation the anatomical site will be marked by a licensed independent practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed. In limited circumstances, the licensed independent practitioner may delegate site marking to an individual who is permitted by the organization to participate in the procedure and has the following qualifications:

- An individual in a medical residency program who is being supervised by the licensed independent practitioner performing the procedure; who is familiar with the patient; and who will be present when the procedure is performed
- A licensed individual who performs duties requiring a collaborative agreement of supervisory agreement with the licensed independent
- practitioner performing the procedure (an advanced practice registered nurse or physician assistant) who is familiar with the patient; and who will be present when the procedure is performed

The site will be marked in such a way that it remains clearly visible after skin preparation and draping is complete. Site marking will be done in conjunction with the patient and whenever possible prior to any sedation or anesthesia (regional or local). Site marking will:

- Take into consideration the laterality
- Surface (flexor, extensor)

- Level (spine)
- Or specific digit or lesion to be treated
- The site(s) shall be marked with the word “Yes” using ink that will remain visible after the skin prep is done and the patient is draped, especially if change in the patient’s position is involved.

If marking the site is not technically possible, the patient is a neonate, or if the patient makes an informed refusal of site marking, an alternate marking of the site on either a diagram of the body or on appropriate radiographs will be made.

Note: Site marking is not required when the individual doing the procedure is continuously with the patient from the time of the decision to do the procedure through to the performance of the procedure.

- **EXCEPTIONS** To Site Marking:
  - Endoscopies without intended laterality.
  - Procedures with no predetermined site of insertion (e.g. cardiac catheterization).
  - Obvious lesions and wounds (unless multiple lesions exist and only some will be treated).
  - Midline, single organ procedures **do not** require site marking.
  - Neonates (alternative needed).
  - Teeth

Use Medical Center approved form T-LAC101228 (Att. 2) or its electronic equivalent for documenting the completion of this step.

Step 4. Perform a Time Out

- Immediately prior to initiating the procedure, the *Licensed Independent Practitioner* must initiate a “Time-Out” with all members of the team performing the procedure and with the patient when possible. During the “Time Out”, all activities should cease, to the extent possible without compromising patient
- safety, so that all relevant members of the team are focused on the active confirmation of the correct patient, procedure, site, and other critical elements.
- During the “Time Out”, the *Licensed Independent Practitioner* must confirm:
  - The patient’s identity by using two patient identifiers
  - State the time that the time-out is being performed at
  - The procedure to be conducted
  - The anatomical site.

NOTE: If a *Licensed Independent Practitioner* is conducting a procedure without any assistance a good faith effort should be made to call upon another individual to participate in the “Time Out”. If this cannot be done without significantly delaying or interrupting the progress of the intended procedure it is acceptable to conduct the “Time Out” in conjunction with only the patient and the *Licensed Independent Practitioner*.

Step 5. Document the Universal Protocol Completion

Use Medical Center approved form T-LAC101228 (Att. 2 - Universal Protocol - Procedures Performed Outside of the Operating Room) or its electronic equivalent to

document the Universal Protocol completion. This form must remain in the patient's medical record and be completed for all invasive procedures as defined above. It is also acceptable to document completion of the "Time Out" in the body of the text of a handwritten procedure note or where specified in the electronic procedure note.

REVISION DATES

August 13, 2013; July 11, 2017; August 13, 2018; March 01, 2023