POLICY TITLE: Universal Protocol - Time Out

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SUMMARY & PURPOSE: Universal Protocol and Time out is a process that ensures we follow certain safety steps prior to initiating a consented procedure by verifying correct patient, correct procedure and correct side/site. The term Universal Protocol – Time out has been adopted as best practice during consented procedures as a safety measure.

SCOPE/APPLICABILITY: This policy applies to the Herbert Wertheim College of Medicine (HWCOM) Clinical Locations where faculty, students and/or staff consent patients for procedures. The HWCOM clinical locations are FIU Health Modesto Maidique, (“MMC”), Green Family Foundation NeighborhoodHELP Mobile Health Centers and Household visits. This policy excludes the Linda Fenner 3D Mobile Mammography Center.

For the faculty, students and staff that are performing consented procedures in the affiliated hospitals and outpatient centers, the policies and procedures of those institutions will govern their responsibilities.

POLICY: Wrong patient, wrong procedure and wrong side/site surgical procedures must be prevented.
In order to be compliant with this policy a pre-procedure standardized checklist process is conducted called a Time out that includes several steps, including marking the site prior to the procedure when possible. All members of the team are active participants during the Time out process, including the patient if applicable. Consistent implementation of a standardized protocol is the most effective way in achieving patient safety and preventing an adverse incident.

DEFINITIONS:

**Patient Identification:** Correct patient identification is achieved when the healthcare worker can confirm the information given by the patient with the patient and the patient’s record.

**Patient Identifiers:** The Patient Identifiers for HWCOM are: (Full name and date of birth). Medical record identification number can be utilized as a third Patient identifier if necessary for patients with same name or names that look alike or sound alike or have same date of birth.

**Adverse incident:** An event that causes or has the potential to cause an unexpected or unwanted effect involving the safety of a patient, whether or not an injury has occurred. HWCOM faculty and staff will complete an incident report for adverse incidents. Examples of adverse incidents include but are not limited to the following: performing a procedure on the wrong patient, wrong procedure, or incorrect side / site or not completing an informed consent form.

**Performing Provider:** for the purposes of this policy, the performing provider refers to the provider that will be performing the procedure and leading the team in the Time Out process.

**Informed Consent:** A process of communication between a provider and the patient that results in the patient’s authorization or agreement to undergo a specific medical or consented procedure. Informed consent assures that the patient is given information related to their care in a manner that is understandable to them. The informed consent process acknowledges the patient’s right to ask questions and to make an informed and voluntary decisions as to whether to undergo a proposed procedure, intervention, or type of care. Patients would communicate with their provider regarding the nature of the procedure, risk, benefits, and alternatives to treatment in their preferred language.

**Preferred Language:** For the purposes of this policy, this is the language that the patient feels most comfortable in communicating with the provider and in reviewing and signing documents that may be required by the clinical setting. Example: The patient will sign the consent form in their preferred language. Example: Patient understands Spanish consent information versus an English consent.

**Interpreter Services through Translation Services:** Rendering an oral message from one language to another. An interpreter through translation services will use all available knowledge, skills and techniques to provide an accurate and understandable interpretation of all communication between the provider of medical services and the patient. Interpreter Services can also be utilized for deaf patients with an American Sign Language Interpreter.

**PROCEDURE:**

*Time Out Purpose and Process:*
- a. Is a patient safety tool
- b. Essential for preventing wrong patient identification, wrong procedure and wrong side / site
- c. Done prior to the start of any procedure
- d. *Is a PAUSE, Entire Team Stops and participates.* The entire team comes to a full stop and all team members participate in the Time out process. The patient is also an active participant, if applicable.
- e. The performing provider initiates the Time out and only the performing provider leads the Time out. This role cannot be delegated.
- f. The procedure is not started until all questions and the team resolves concerns during the Time out. This is the team’s opportunity to speak up for patient safety.
g. The *Time out* has the following characteristics
   i. It is standardized, as defined by HWCOM
   ii. It is initiated and lead by the *performing provider only*
   iii. It involves *all the members* of the procedure team.

h. When two or more procedures are being performed on the same patient, a second *Time out* must be performed before the second procedure is initiated.

i. If a member of the team temporarily steps out during the *Time out*, re-start the *Time out* upon their return.

j. During the *Time out, each member* individually will agree to the following:
   i. Correct patient identifiers (Name and Date of Birth)
   ii. Correct procedure
   iii. Correct side / site

k. Document the completion of the *Time-out* in the patient's electronic medical record (EMR)

**Pre-Procedural Checklist Process: (Time – Out Checklist. See Attachment A at the end of this policy)**

A pre-procedural standardized checklist ensures that every part of the pre-op time out procedure is completed. The checklist lists every step that *must be completed*. The provider performing the procedure will complete the pre-procedure standardized checklist during the *Time out*.

a. The provider and the team members performing the procedure will confirm the correct patient identification utilizing patient identifiers (Name and date of Birth), correct procedure and the correct side/ site, against the physician’s orders and the consent form.

b. Documentation must include a current and completed history and physical, signed procedure consent form *prior* to the procedure and or local sedation, vital signs, pertinent diagnostic testing, and radiology test results, if applicable. A pregnancy test will be completed when clinically indicated for women of childbearing age who are sexually active and who have the ability to become pregnant.

c. All Team members participating in the procedure will ensure that products, implants and/or special equipment are available *prior to the procedure*. Ensure that all necessary medications, equipment, and devices are *not expired* prior to the start of the procedure.

d. Prior to the start of the procedure, any discrepancies identified must be corrected and communicated to the provider and documented. All staff are empowered and required to immediately discuss any discrepancies.

**Utilizing Patient Identifiers**

**Process: Initial Patient Identification** - All patients are asked to provide their unique *Patient Identifiers*.

The following are the approved *Patient Identifiers* for HWCOM:

- Patient’s full name
- Date of Birth
- A third *Patient Identifier* should be utilized to ensure that the procedure is being performed on the correct patient. For instance, if there are two patients with the same name, the patient’s Medical Record Identification number can be used. In the Centricity EMR, the Patient ID # serves this purpose. The third identifier is necessary in instances of a patient name alert
because two (or more patients) have the same name, names close to being spelled the same and /or pronounced the same or have same date of birth. This third identifier also serves to clarify when patient specimens are obtained during a procedure so that the specimen is properly designated to the correct patient and labeled appropriately.

- The patient’s room number or physical location is never utilized as a Patient Identifier for patient safety.

For additional details see HWCOM Administrative Policy: Patient Identifiers No.: 200.02102A

3. Consent Form:
   Obtaining Informed Consent

For additional details on completing an informed consent please see HWCOM Administrative Policy: Informed Consent No.: 200.02.104A

4. Site Marking Purpose and Process:
   Prevents performing wrong side / site procedure, distinguishes left from right side

   a. Sites are marked when there is more than one possible location for the procedure
   b. The performing provider marks the procedural site before the procedure is performed and, if possible, with the patient’s involvement. Only the performing provider who is ultimately accountable for the procedure and will be present when the procedure is performed will mark the site.
   c. Students and or other staff members will not be allowed to site mark
   d. The mark is made at or near the procedure site and is sufficiently permanent to be visible after skin preparation and draping (if required). The provider performing the procedure will place an X and place his / her initials at the site mark.
   e. Bilateral sides and midline sites do not require site marking

In the Event that a Patient Refuses Site Marking:
   a. The performing provider will provide the patient with education to help them understand the importance and appropriateness of site marking. If the patient continues to refuse, the performing provider will determine whether to cancel the procedure. Risk Management/ legal Department can be consulted for any questions. The record should include patient’s refusal, advisement of risks of refusal and whether procedure was cancelled.
   b. When it is not applicable to mark the site, the performing provider will select N/A on the Pre-Procedure Checklist form in the EMR and add supporting comments as applicable.

Site Marking will not be done for the following:
   - Intrauterine Device Placement
   - Cryotherapy for Genital warts
   - Nexplanon™

Barriers to Completing a Successful Time Out:
   - Team does not complete a Full stop
   - Staff is preoccupied with multitasking, paperwork and not paying attention
   - Provider delegating site marking to a staff member
   - Not Involving the Patient
• Rushing and not completing the *Time out*

**Incident Reports are Completed for the Following but not limited to:**

• Failure to obtain an appropriate consent (incomplete, incorrect, improper, not completed)
• Wrong patient, wrong procedure, wrong side / site
• *Time out* not completed
• *Time out* delegated to a team member other than provider performing the procedure
• Utilizing expired equipment
• Any additional event deemed appropriate by the reporter

The online incident reporting system will be completed in the electronic system called Clarity. For additional details see HWCOM Administrative Policy: *Incident Reporting No.*: **200.03.100A**

**Clarity Icon**

**SUPPORTING/REFERENCE DOCUMENTATION:**

  2022 sections
  UP.01.01.01
  UP.01.02.01
  UP.01.03.01

**RELATED POLICIES, PROCEDURES, AND ASSOCIATED FORMS:**

• HWCOM Administrative Policy: *Incident Reporting No.*: **200.03.100A**
• HWCOM Administrative Policy: *Patient Identifiers No.*: **200.02102A**
• HWCOM Administrative Policy: *Informed Consent No.*: **200.02.104A**
• **Attachment A:** *Pre- Procedure Checklist- Time out Tool*
Time-Out

Pre-Procedure Checklist: Happy test DOB: 10/10/1990 Female

Vital Signs:
HR: [ ] RR: [ ] Temp: [ ] BP: [ ] / [ ] O2 sat: [ ] Ht: 64 in Wt: [ ] lbs BMI: [ ]

- [ ] Patient has signed informed consent

Time-out - immediately prior to procedure, all staff involved present: led by provider:
- [ ] Yes [ ] No

Patient identification (patient states name and DOB in presence of provider):
- [ ] Yes [ ] No

Site marking by provider (if applicable) or confirmation of site by provider:
- [ ] Yes [ ] No [ ] N/A

Provider confirms procedure being performed:
- [ ] Yes [ ] No

Provider confirms the availability of correct implants, special equipment or special requirements:
- [ ] Yes [ ] No [ ] N/A

Confirm correct patient positioning:
- [ ] Yes [ ] No

- [ ] Urine pregnancy test [ ] Chlamydia screening

Risks/Benefits of Proposed Procedure(s) explained to patient include:
- usgship
- usgknee
- usgmed
- usgshoulder

Complications; Unforeseen Conditions; Results:
- [ ] Discussed with patient that in the practice of medicine, other unexpected risks or complications not discussed may occur. Pt also understands that during the course of the proposed procedure(s) unforeseen conditions may be revealed requiring the performance of additional procedures, and authorizes such procedures to be performed. No guarantees or promises have been made to the patient concerning the results of any procedure or treatment.

Alternatives
The available alternatives were explained to patient, some of which include

- [ ] the potential benefits and risks of the proposed procedure(s), and the likely result without such treatment

Patient has been given the opportunity to ask questions and have received satisfactory answers?
- [ ] Yes [ ] No

Right to Refuse Procedure(s) and Treatment
Patient understands that it is their right to refuse any procedure or treatment recommended by provider
- [ ] Yes [ ] No