FIU Herbert Wertheim College of Medicine
FLORIDA INTERNATIONAL UNIVERSITY

Departmental Policy
POLICY NO.: 200.02.106P

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 for patient safety during consented procedures.

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. This policy excludes FIU Health Broward, and 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 marking the site of procedure. All members of the team are active participants during the *Time out*, 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:

Universal Protocol: The Joint Commission enacted in 2004 the term Universal Protocol through expert consensus on principles and steps for preventing wrong patient, wrong procedure and wrong side / site of the procedure.

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: For the purposes of this policy 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.*

Preferred **language:** This is the language the patient is most comfortable in communicating with their provider. The patient will sign the consent form in their *preferred* language.

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 not limited to the following: performing a procedure on the wrong patient, wrong procedure, or incorrect side / site.

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

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 decision as to whether to undergo a proposed procedure, intervention, or type of care.

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.* 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 EMR

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

A pre-procedural standardized checklist exists to ensure 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 t***o the procedure and or sedation, vital signs, pertinent diagnostic testing, and radiology test results, if applicable. A pregnancy test will be completed 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 equipment, 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 discrepancy with the team when detected

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. This third identifier also serves to clarify when patient specimens are obtained during a procedure so that the specimen is properly designated to the right patient.
- The patient's room number or physical location is never utilized as a *Patient Identifier* for safety.

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

3. Consent Form:
Obtaining Informed Consent

a. It is the treating provider's responsibility to obtain the informed consent. The physician must provide information to the patient about the nature of the procedure, risks, benefits, and alternatives, in a manner that is understandable to the patient so that the patient can make an independent, and voluntary decision whether to proceed with the procedure. The provider will review and discuss the consent form with the patient prior to the procedure.

b. The consent form is completed in the patient's *preferred* language (Creole, Spanish, and English). The consent form is not valid if it is not completed in the patient's *preferred* language because the patient lacks the understanding to be able to communicate and ask questions with the provider.

c. If the patients *preferred* language is other than (English, Spanish, or Creole) please utilize the official Interpreter Services through the Language Line: Pacific Interpreters 1.866.421.3463 . An access code is required to utilize Language line and can be obtained by your clinical site leader.

d. **Procedure for languages other than Creole, Spanish, English**. Contact Pacific Interpreters read them a copy of the English Consent that includes all the information pertinent to the procedure (i.e. name of procedure, risks) and they will translate the information through the language telephone line. The patient will sign the English version of the consent form, as well as the physician and the witness. A note will be placed in the EMR that states the Language Line in the patient's preferred language officially translated the English version of the consent. Include the full name of the Interpreter and the language line utilized for translation services.

Example: The patient signed the English version of the consent that was officially translated in Mandarin by the interpreter Jane Doe through Pacific Interpreters.
For additional details, see HWCOM Administrative Policy: *Interpreter Services through the Language Line No.:* (Policy under revision)

e. Should not contain any abbreviations and the actual naming of the procedure should be spelled out to avoid confusion and prevent procedural errors. Clearly identify which side/ site will have the procedure done.

Example:
L elbow I & D (Incorrect, use of abbreviations on the consent form)
Left elbow incision and drainage (correct)

f. List all risks related to the procedure on the consent form

g. Patient, provider and witness signature required

h. Scan the signed consent in the patients *preferred* language in the EMR (Electronic Medical Record). In addition, scan an English unsigned consent in the EMR.
For additional details see Departmental Policy: *Informed Consent No.:* (Policy under revision)

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 and when performing the procedure in a different location would negatively affect patient quality or safety.

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 his / her initials at the site mark.

e. Bilateral sides and mid line sites *do not* require site marking

In the Event, 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 a Successful *Time Out*:

- Team does not complete a **Full stop**
- Staff 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 Adverse Events but not Limited to the following:

- Failure to obtain an appropriate consent (incomplete, Incorrect, improper)
- 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

For additional details see HWCOM Administrative Policy: *Incident Reporting No.:* **200.03.100A**

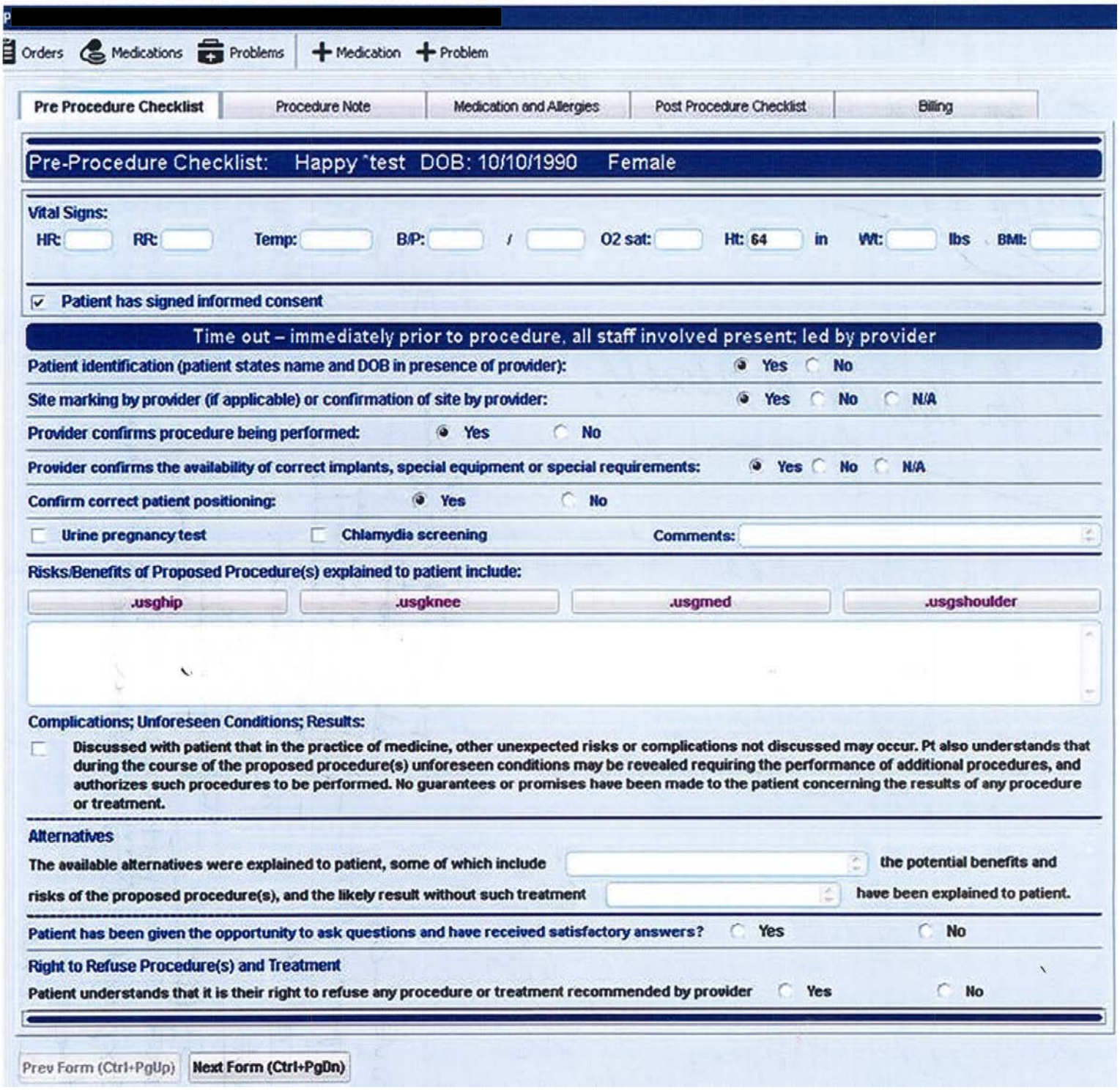
SUPPORTING/REFERENCE DOCUMENTATION:

- The Joint Commission, Ambulatory Health Care Accreditation Program. National Patient Safety Goals, effective January 2019. 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*: Interpreter Services Through the Language Line No.: (Policy under revision)*
- HWCOM Departmental Policy*: Informed Consent No.: (Policy under revision)*
- Attachment : *Pre- Procedure Checklist- Time out* Tool

Time-Out


[redacted]
Orders
Medications
Problems
Medication
Problem
Pre Procedure Checklist
Procedure Note
Medication and Allergies
Post Procedure Checklist
Billing
Pre-Procedure Checklist: Happy "test DOB: 10/10/1990 Female
Vital Signs:
HR: RR: Temp: B/P: / 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
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
Comments:
Risks/Benefits of Proposed Procedure(s) explained to patient include:
.usghip
.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 have been explained to patient.
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
Prev Form (Ctrl+PgUp)
Next Form (Ctrl+PgDn)