

RIVERSIDE COUNTY REGIONAL MEDICAL CENTER

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Subject: UNIVERSAL PROTOCOL	Effective date: 06/11/02	Policy No. <p style="text-align: right;">604.1</p>	
	Supersedes: RCRMC Policy No. 604.1, revised 01/20/09	Revised Date: <p style="text-align: right;">03/17/09</p>	
Departments Consulted: Operating Room (OR) Medical Records	Reviewed & Approved by: Medical Executive Committee Management Team	Approved by: <p style="text-align: center;"><i>[Signature on File]</i></p> <hr style="width: 100%;"/> <p style="text-align: center;">Douglas D. Bagley Hospital Director/CEO</p>	

PURPOSE

To improve patient safety by preventing procedural errors, including the prevention of wrong site, wrong procedure, wrong-person surgery and wrong-person non-surgical invasive procedures.

POLICY

1. Riverside County Regional Medical Center (RCRMC) has established and shall maintain the Universal Protocol, which includes:
 - Conduct of a pre-procedure verification process
 - Addressing any missing information or discrepancies before starting a procedure.
 - Ensuring the procedure site is marked
 - Performing a time-out immediately prior to starting a procedure.

2. RCRMC surgical staff shall ensure that all relevant documents and related information or equipment are:
 - Available prior to the start of a surgical procedure or non-surgical invasive procedure
 - Correctly identified, labeled, and matched to the patient identifiers
 - Reviewed and are consistent with the patient's expectations and with the team's understanding of the intended patient, procedure, and site

3. The intended site for a procedure will be identified by marking it, and the type of mark (the proceduralist's initials) will be unambiguous and used consistently throughout the hospital. Exceptions are listed in Attachment I.

4. RCRMC surgical staff will conduct a final assessment (time-out) that the correct patient identity, site, positioning, and procedure are identified and that, as applicable, all relevant documents, related information, and necessary equipment are available.

DEFINITION

Pre-Procedure Verification: An ongoing process of information gathering and verification, beginning with the decision to perform a procedure, continuing through all settings and interventions involved in the pre-procedure preparation of the patient, up to and including the time-out just before the start of the procedure.

PROCEDURES

1. Verification of the correct person [use of two patient identifiers; i.e., name and date of birth (DOB)/medical record number (MR#)], correct site, and correct procedure will occur at the following times:
 - At the time the procedure is scheduled.
 - At the time of preadmission testing and assessment.
 - At the time of admission, or entry into the facility for a procedure, whether elective or emergent.
 - Before the patient leaves the pre-procedure area or enters the procedure room.
 - Anytime the responsibility for care of the patient is transferred to another member of the procedural care team, (including the anesthesia providers) at the time of, and during, the procedure.
 - With the patient involved, awake and aware, if possible.
2. When the patient is in the pre-procedure area, immediately prior to moving the patient to the procedure room, the Pre-Operative Checklist (Pre-procedure Verification Checklist) will be used to review and verify that the following items are available and accurately matched to the patient:
 - Relevant documentation (for example, history and physical (H&P), nursing assessment, and pre-anesthesia assessment)
 - Accurately completed and signed, procedure consent form
 - Correct diagnosis and radiology test results (for example, radiology images and scans, or pathology and biopsy reports) that are properly labeled
 - Any required blood products, implants, devices and/or special equipment for the procedure.
3. A licensed independent practitioner or other provider who is privileged or permitted by RCRMC to perform the intended surgical or non-surgical invasive procedure will mark the procedure site using his/her initials. This individual will be involved directly in the procedure and will be present at the time the procedure is performed. For example, physician residents are allowed to perform site marking if all of the following are true:
 - The resident is a licensed practitioner
 - The resident is privileged or permitted to perform the surgical or non-surgical invasive procedure
 - The resident will be present during the procedure and actively involved.

Note: Final confirmation and verification of the site mark will take place during the time-out. If a different mark, other than initials, is required due to the type of procedure, the reason for the different mark will be documented in the chart.
4. For all procedures involving incision or percutaneous puncture or insertion, the intended procedure site will be marked.
 - The marking takes into consideration laterality, the surface (flexor, extensor), the level (spine), or specific digit or lesion to be treated.
 - Note: for procedures that involve laterality of organs but the incision(s) or approaches may be from the mid-line or from a natural orifice, the site will be marked and the laterality noted.
5. The procedure site will be marked initially before the patient is moved to the location where the procedure will be performed and will take place with the patient involved, awake, and aware, if possible.

6. The mark will address the following:
 - Is made at or near the procedure site or the incision site. Other non-procedure site(s) will not be marked unless necessary for some other aspect of care.
 - Includes the surgeon's or proceduralist's initials, with or without a line representing the proposed incision.
 - Is made using a marker that is sufficiently permanent to remain visible after completion of the skin prep and sterile draping. Adhesive site markers are not to be used as the sole means of marking the site.
 - Is positioned to be visible after the patient has his/her skin prepped, is in his/her final position, and sterile draping has been completed.
7. For spinal procedures, in addition to pre-operative skin marking of the general spinal region, special intraoperative radiographic techniques will be used for marking the exact vertebral level.
8. A defined, alternative process will be established by the surgeon/proceduralist for patients who refuse the marking or who cannot easily be marked according to the following conditions:
 - For cases in which it is technically or anatomically impossible or impractical to mark the site (mucosal surfaces, perineum, premature infants), the alternative method of wristband use for identifying the correct site and side will be used.
 - For example, a write-on, temporary wristband will be placed on the patient who refuses a body marking. The proceduralist will write directly onto the wristband the patient's name and DOB and/or MR# and an identifier for the intended procedure and site before the wristband is placed on the patient.
 - For minimal access procedures that intend to treat a lateralized internal organ, whether percutaneous or through a natural orifice, the intended side will be indicated by a mark at or near the insertion site, and will remain visible after completion of the skin prep and sterile draping.
 - For teeth, the operative tooth name(s) and number will be indicated on documentation or the operative tooth (teeth) will be marked on the dental radiographs or dental diagram. The documentation, images, and/or diagrams will be available in the procedure room before the start of the procedure.
9. A time-out will be initiated consistently by a designated member of the procedure team.
10. The time-out will include active communication among all relevant members of the procedure team.
11. The time-out will be conducted in a standardized fail-safe mode (that is, the procedure is not started until all questions or concerns are resolved).
12. The time-out will be conducted prior to starting the procedure and, ideally, prior to the introduction of the anesthesia process (including general/regional anesthesia, local anesthesia, and spinal anesthesia), unless contraindicated.
13. The RCRMC *Universal Protocol Time-Out* form, #381, will be used, and the time-out will have the following characteristics:
 - It will be standardized (as defined by the time-out section on the surgical site form)
 - It will be initiated by a designated member of the procedure team
 - It will involve the immediate members of the procedure team, including the proceduralist(s)/surgeon(s), the anesthesia providers, the circulating nurse, the operating room (OR) technician, and other active participants as appropriate for the procedure, who will be participating in the procedure at its inception.

- It will involve interactive verbal communication between all team members, and any team member will be able to express concerns about the procedure verification.
 - It will include a defined process for reconciling differences in responses.
14. During the time-out, other activities will be suspended, 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.
15. During the time-out, the procedure will not proceed until every team member agrees about the surgical/procedure site. If disagreement persists, the issue will be presented to the department chair or designee for resolution.
16. When two or more procedures are being performed on the same patient, a time-out will be performed to confirm each subsequent procedure before it is initiated.
17. The time-out will address the following:
- Correct patient identity
 - Confirmation that the correct side and site are marked
 - An accurate procedure consent form
 - Agreement on the procedure to be done
 - Correct patient position
 - Relevant images and results are properly labeled and appropriately displayed
 - The need to administer antibiotics or fluids for irrigation purposes.
 - Safety precautions based on patient history or medication use.
18. The completed components of the Universal Protocol and time-out will be documented clearly.

ATTACHMENT: I **Exceptions to Site Marking**

MEC Approved: 03/12/09

ATTACHMENT I

EXCEPTIONS TO SITE MARKING

1. Single organ procedures
2. Endoscopies without intended laterality
3. Procedures with no predetermined site of insertion such as line placement and other interventional procedures.
4. An obvious wound or lesion that is the site of the intended procedure. However, if there are multiple wounds or lesions and, only some of them are to be treated, and the decision and direction for which ones are to be treated are determined at some time prior to the procedure itself, then the sites to be treated should be marked as soon as possible after the decision is made.
5. 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.

FOR EACH OF THESE MARKING EXCEPTIONS, THE OTHER REQUIREMENTS OF THIS POLICY, *Universal Protocol*, APPLY.

This Form Must be Completed for ALL Invasive Procedures Requiring a Consent

- A time-out will be conducted immediately before starting any procedure. Ideally, a time out should be conducted prior to the introduction of the anesthesia process.
- The time-out will be initiated by the proceduralist member of the of the procedure team.
- The immediate members that will be involved with the procedure (proceduralist, anesthesiologist, nurse, operating room technician or any other if applicable) will be involved in the time-out.
- When two or more separate procedures are being performed on the same patient, a time-out will be performed to confirm each subsequent procedure before it is initiated.
- When performing the time-out EVERY element must be addressed regardless of the type of case.

Each element of the time-out should be verbalized and agreed by all members involved:

Elements of the Time-out	√ Check if agreed by all members
1. Other activities have been suspended to the extent possible without compromising patient safety.	✓
2. Correct patient is identified with two patient identifiers (name, DOB or medical record number)	✓
3. Name on the consent is validated against the patient identifiers.	✓
4. Correct position of the patient is confirmed or discussed (If it will be done after anesthesia is provided)	✓
5. Chart documentation for the indication/need for the procedure validated	✓
6. The correct side and site is confirmed with the consent	✓
7. Additional safety precautions based on patient history or medication use were discussed	✓
8. The correct side and site is marked with the physician's/proceduralist's initials. If a patient refuses the marking or it is technically or anatomically impossible or impractical to mark the site (mucosal surfaces, perineum, premature infants), a temporary wrist band will be placed on the side of the procedure containing the patient's name and the information on the intended procedure and site.	✓
9. There is agreement by all members on the procedure to be done.	✓
10. The need for relevant diagnostic images and laboratory tests was discussed by the physician/proceduralist. If images needed, they are properly labeled and displayed.	✓
11. The need for preoperative antibiotics administration has been addressed and documented	✓
12. The need of fluids for irrigation or any other special material or equipment was discussed	✓

Patient Refused Site Marking (please see reverse for instructions)

TITLE	PRINT NAME	SIGNATURE	DATE	TIME
Physician / Proceduralist	Jorge White, MD	<i>Jorge White, MD</i>	8/12/09	1100
RN/LVN	Sara Jones, RN	<i>Sara Jones RN</i>	8/12/09	1100
Anesthesiologist (if applicable)	Larry Howell, DO	<i>L. Howell, DO</i>	8/12/09	1100

Riverside County Regional Medical Center
Moreno Valley, California

**UNIVERSAL PROTOCOL
"TIME-OUT"**