# Universal Protocol and Time Out

# Purpose

To outline the process for verifying the correct site, procedure, patient, and implants for operative or other invasive procedures. This process will include three major components: the preoperative verification process, site marking, and Time Out.

The components of this policy incorporate evidence-based strategies to reduce the incidence of wrong site, side, patient, procedure, or implant events.

# Persons Affected

This policy applies to all facility teammates and business associates (contractors, consultants, temporaries, volunteers, physicians, clinicians, and other workforce members), including all

personnel affiliated with third parties.

# Definitions

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| **Term** | **Definition** |
| Wrong | Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant Not in accordance with intended site, side, patient, procedure, or implant. This includes expired implants.  *ASC Quality Collaboration, Implementation Guide, Version 11* |
| Operative Procedure | An operative procedure is a surgical or invasive diagnostic procedure performed by qualified providers in an operating room, procedure room, interventional radiology, or Cath lab. |
| Invasive Procedure | Procedures involving a skin incision or puncture, or insertion of an instrument or foreign material into the body including, but not limited to, nerve blocks, percutaneous aspiration, selected injections (e.g. pain injections), biopsy, percutaneous cardiac and vascular diagnostic or interventional procedures, laparoscopies, and endoscopies. Excluding venipuncture, intravenous therapy, foley catheter insertion, and other low-risk nursing-related  interventions. |
| Verification | The process of checking the consistency between consent, orders, H&P, schedule, diagnostic studies, and the verbal response of the patient/guardian to assure the correct patient, correct procedure, and correct procedure site. |
| Laterality | The side of the patient's body (e.g., left, right, or bilateral). The right and left  are defined as the patient's right and left. |
| Site | The specific anatomic location as indicated by the description of the body part(s) and level or digit to be subjected to intervention (e.g., shoulder, knee, hip, back, abdomen, chest, and cervical disc level) |

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| Universal Protocol | Developed by the Joint Commission and is designed to ensure correct patient identity, correct scheduled procedure, and correct surgical site – consists of the following three components: 1. A pre-procedure verification process 2.  Surgical site marking 3. Surgical "time out" immediately prior to starting the procedure. |

# PREOPERATIVE/PROCEDURAL VERIFICATION PROCESS

**Policy**

1. Verification of the correct patient, procedure, site, and laterality will occur:
   1. At the time the procedure is scheduled
   2. During the pre-procedural call and/or chart preparation
   3. Upon entry into the facility
   4. At the time of admission to the pre-procedural area
   5. When the responsibility for the care of the patient is transferred to another caregiver
   6. Before the patient leaves the preoperative area or enters the procedure/operating room.
2. If possible, the patient will be awake and participate during this process.
3. Patients with a language barrier will have a qualified interpreter available to ensure the accuracy of the information reviewed in the verification process. Interpreter services shall be documented in the medical record.
4. Two patient identifiers will be used to verify a patient's identity, such as name and date of birth.
5. If the patient is a minor or incapable of confirming the information, an individual authorized by state guidance will verify the information.
6. A pre-procedure checklist will be completed for all procedures/surgeries to ensure that all relevant documents/equipment/devices/implants (if applicable) are available.
7. Discrepancies will be resolved as soon as they are identified. Team members and the patient, if possible, will agree on the resolution of identified discrepancies.
8. Discrepancies will be resolved before transfer to the procedure/operating room and/or proceeding with the Time Out and commencement of the procedure.

# Procedure

*Scheduling*

1. The scheduler will obtain the following information when scheduling an operative or other invasive procedure:
   1. correct spelling of the patient's full name
   2. patient's date of birth
   3. name of the procedure be performed, site, and laterality
   4. the name of the physician who will perform the procedure
   5. implants and/or special equipment required, if applicable
2. On the surgery schedule and relevant documents, the words "right", "left", or "bilateral" should be spelled out.

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*Pre-procedural call and/or chart preparation*

1. The RN or other healthcare provider will
   1. verify the patient's identity using at least two identifiers
   2. verify the scheduled procedure as stated by the patient and compare this to the schedule and other information currently available in the medical record (orders, H&P, consents, diagnostic studies, etc.).

*Upon entry into the facility*

1. The admission clerk will
   1. verify the patient's identity using at least two identifiers
   2. verify the scheduled procedure as stated by the patient and compare this to the schedule.

*Admission to the pre-procedural area and/or when assuming care of a new patient*

1. The pre-procedural nurse will identify the correct patient by using two patient identifiers and having the patient or authorized representative state their full name and birth date. Confirm name band information matches the patient’s stated information.
2. The pre-procedural nurse will identify the correct procedure, site, and laterality as stated by the patient and compared to the following documents:
   1. Consent for procedure/surgery with signatures
   2. Physician orders
   3. H & P/Progress notes/Consultations
   4. Procedure schedule
   5. Other relevant documentation (radiology, diagnostic reports, etc.)

*Before transferring to the procedure/operating room and/or when assuming care of a new patient*

1. The OR nurse will identify the correct patient by using two patient identifiers and having the patient state their full name and birth date. Confirm name band matches the information confirmed.
2. The OR nurse will identify the correct procedure, site, and laterality and procedure as stated by the patient and compared to the following documents:
   1. Consent for procedure/surgery with signatures
   2. Physician orders
   3. H & P/Progress notes/Consultations
   4. Procedure schedule
   5. Site marking
   6. Other relevant documentation (radiology, diagnostic reports, etc.)

*Regional Anesthesia*

1. The anesthesia provider and nurse assisting with the block will independently verify the correct site and laterality by reviewing informed consent documentation, the patient record, preoperative notes, the marked surgical site, and through discussions with the patient/family.

*Ophthalmologic Intraocular Lens Implant Procedures*

1. For ophthalmologic intraocular lens implant procedures, additional verification steps should be taken to ensure correct surgery and implant:

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* 1. Original source data for all pre-procedure measurements, calculations, desired post- operative refraction, and selected lens implant style and power are reviewed by two members of the surgery team prior to commencing the intraocular lens implant procedure.
     1. The physician performing the procedure is primarily responsible for verifying this information.
     2. The role of the second check is to confirm the process and can be performed by the OR nurse.
  2. When lens calculation is performed in the OR , the surgeon and one other member of the team will verify together that the selected lens appropriately matches the intraoperative calculation prior to implant.

# SITE MARKING

**Policy**

1. Site marking will be performed on all invasive/operative procedures that involve laterality, multiple structures (fingers and toes), or multiple levels (spinal surgery).
2. The procedure/operative site will be marked prior to the patient entering the procedure/operating room.
   1. If the procedure is performed without the patient being moved to a different location, the site shall be marked prior to the Time Out and commencement of the procedure.
3. The procedure site is marked by the licensed independent practitioner (LIP) ultimately accountable for the procedure, who will be present when the procedure is performed.
   1. In limited circumstances, the LIP may delegate site marking to an individual permitted to participate in the procedure, who will be present during the procedure, is being supervised by the LIP, and is familiar with the patient (i.e., Resident, Advanced Practice RN, or Physician's Assistant).
4. The patient will be actively involved with the site marking process if possible.
   1. Preoperative sedation can be administered based on the patient's needs as determined and ordered by a LIP or anesthesia provider and may be administered prior to site marking if required.

# Procedure

*Site Marking*

1. The person marking the site will use a mark with sufficient permanence to remain visible until the procedure is performed.
   1. Adhesive markers are not the sole means of marking the site.
2. Before marking the site, the person marking the site will verify the patient's identity, consent, orders, H & P/Progress notes/Consultations, schedule, and other relevant documentation (radiology, diagnostic reports, etc.) to confirm accuracy.
3. The person marking the site will ask the patient or designated caregiver to state the procedure, site, and side of surgery and have the patient provide visible responses, if appropriate, such as pointing.
4. If discrepancies arise during the site marking process team members are responsible for speaking up.

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1. Relevant team members will review primary source documentation, and the team and, if possible, the patient will agree on the resolution of identified discrepancies.
2. Discrepancies will be resolved before proceeding with site marking.
3. The site is to be marked at or adjacent to the incision site at a location that will be visible after the patient is prepped and draped.
4. The mark must be unambiguous (e.g., using the surgeon's initials or clearly defined terminology such as "YES", or "CORRECT"). The exact marking modality should be defined and consistent throughout the facility. Do NOT use "X" to mark the operative site.

*Regional Anesthesia*

Regional anesthesia procedure site is marked by the provider performing the regional anesthesia procedure.

1. After confirming the patient's identity, the anesthesia provider will use a standardized mark distinct from the one used for the surgical site to mark the perioperative nerve block site.
2. Place the mark close to the injection site to ensure it is visible in the prepped and draped field.
3. The regional anesthesia procedure site is marked while the patient is alert enough to participate whenever possible.
4. Repeat the marking process when there are multiple injection sites.

*Spine Site Marking*

1. Spine surgery or procedures require a two-stage marking process.
   1. The general spinal region, not the specific vertebra, will be marked by the licensed independent practitioner in the preoperative area.
      1. Markings will be completed on the front of the region for the anterior approach and the back of the region for the posterior approach.
      2. When laterality is designated, the site marking will be placed on the correct side.
   2. In the operative procedure room, the exact vertebral level will be marked using standard radiographic marking techniques with opaque instruments marking the specific boney landmarks.
2. The procedural physician or surgeon completes final verification by comparing the preoperative and intraoperative imaging (if preoperative imaging was completed).

*Exceptions for Site Marking*

The following procedures or sites do not require marking:

1. Single organ procedures (e.g., heart, hysterectomy, endoscopies, rectal or vaginal procedures)
2. Undetermined insertion sites (e.g., central venous catheter, cardiac catheterization)
3. Random biopsies where the site is determined by a pre-procedural CT or ultrasound study immediately prior to the biopsy (e.g., renal biopsy)
4. Minor procedures include venipuncture, peripheral intravenous line placement, nasogastric tube insertion, or foley catheter insertion.

*Alternative Site Marking*

1. For patients who refuse site marking or when it is technically or anatomically impossible or impractical to mark the site (see examples below): Use your written, alternative process to ensure that the correct site is operated on

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* 1. Mucosal surfaces or perineum
  2. Procedures involving laterality of organs where the incision or approach may be from the midline or from a natural orifice (e.g., ureteral stent placement, peripheral vascular cases
  3. Teeth

1. Alternative site marking should be completed by the licensed independent practitioner (LIP), that is ultimately accountable for the procedure.
2. Alternative site marking must be visible and reviewed during the Time Out.
3. Examples of alternative processes:
   1. A diagram is marked by the provider performing the procedure and visually verified during preoperative verification and Time Out processes.
   2. An armband placed on the correct side with the procedure, site, and level indicated on the band, signed by the provider, and visually verified during preoperative verification and Time Out processes.

# TIME OUT

**Policy**

1. Before the start of any invasive procedure using the surgical consent, there will be a final verification of the correct site, correct procedure, correct laterality, and the correct patient., referred to as the "Time Out."
2. The Time Out must be completed collaboratively using active verbal participation by the entire OR team: Surgeon/proceduralist, circulating nurse, scrub personnel, anesthesia care provider, surgical assistant, and radiology technician (as applicable).
   1. The Time Out cannot begin until all relevant team members are present and ready for the Time Out.
3. All other activities, including the playback of music, must cease to ensure all team members can hear the Time Out. Additionally, no instrumentation shall be handed to the surgeon before the Time Out procedure.
4. A Time Out will be completed immediately prior to the start of the procedure (after prep and drape).
5. Each team member at the field will verbally confirm the presence of site marking during the Time Out.
6. If discrepancies arise during the Time Out, team members are responsible for speaking up.
   1. Relevant team members will review primary source documentation, the team and, if possible, the patient will agree on the resolution of identified discrepancies.
   2. All discrepancies will be resolved before proceeding with a new complete Time Out and commencement of the procedure.
7. A Time Out must be performed before each procedure if two procedures are being performed at different sites on the same patient or the person performing the procedure changes.
8. The OR circulator will document the Time Out completion on the OR record.
9. If an anesthesiologist needs to perform a treatment (e.g., a peripheral nerve block prior to the start of the surgery in the operating room), the anesthesiologist and the assisting team member will complete a Time Out.

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1. When an implant is introduced to the sterile field at any time after the initial Time Out, a pause must occur, and a formal implant Time Out will be performed and documented.

# Procedure

*Procedural or Operative Time Out*

1. The Time Out should be completed using a standardized format that includes the elements of of an evidence based safe surgical checklist.
2. The provider or primary RN/circulating RN will initiate the Time Out by asking the team if everyone is ready for the Time Out.
3. Time Out will not begin until everyone participating in the Time Out replies in the affirmative.
4. Activity will cease, and all people present during the Time Out will be quiet and attentive to the process, answering questions and participating as appropriate to their role.
5. The primaryRN/ circulating RN will introduce any new staff members, providers, or visitors as needed.
6. Using the surgical/procedural consent, the operative plan, including stating the procedure, site, level and laterality (as applicable) will be verified. RN will confirm in real-time against the consent.
7. Equipment and instrumentation necessary for performing the scheduled procedure is immediately available and functional in the operating/procedure room.
8. Each team member at the field will verbally confirm the presence of site marking during the Time Out.
9. If implants are predetermined, implant verification will occur. This verification will include all implant specifications (e.g., size, type, laterality, expiration date, etc.)
   1. For intra-ocular lens implants, confirm the inner packaging label matches the outer package label, type/unique identifier, and diopter, then confirm with A-scan, ORA, or other primary source documentation, and check the expiration date.
10. The primary RN/circulating RN will manage the checklist/tool to ensure all items have been addressed (including verbalization of fire risk score and any necessary precautions implemented).

*Block Time Out*

1. The Block Time Out should be completed using a standardized format that includes the elements of an evidence-based checklist.
2. The Block Time Out is required regardless of the location of where the block is performed (e.g., preop, PACU, OR, etc.)
3. The provider or primary RN will initiate the Time Out by asking the team if everyone is ready for the Time Out.
4. The Time Out will not begin until everyone participating in the Time Out replies in the affirmative.

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1. Activity will cease; the people present at the time of the Time Out will be quiet and attentive to the process, answering questions and participating as appropriate to their role.
2. The provider will share the block plan, including stating the block procedure, site, and laterality. RN will confirm in real-time against the consent.
3. The presence of site marking will be verbally confirmed by each team member participating in the block Time Out.
4. RN will manage the checklist/tool to ensure all items have been addressed.

*Implant Time Out*

1. The Implant Time Out should be completed using a standardized format that includes the elements of an evidence-based checklist. .
2. An additional implant timeout will be performed when an implant is added to the field at any time after the initial Time Out.
3. Activity will cease; the people present at the time of the Time Out will be quiet and attentive to the process, answering questions and participating as appropriate to their role.
4. This implant Time Out should be completed in a collaborative manner using active verbal participation by the entire OR team.
5. No implant may be passed to the field before the implant verification procedure and only following verbal confirmation by the scrub and surgeon.
   1. This verification will include all implant specifications (e.g., size, type, laterality, expiration date, etc.)

# Training

The Governing Body, Medical Executive Committee, and facility Administrator/CEO are responsible for educating and communicating this policy to all medical staff, allied health members, and facility staff. All staff will complete training upon hire and annually thereafter.

# Compliance, Monitoring, and Reporting

The compliance and implementation of this policy are the responsibility of the Medical Executive Committee, the Medical Director (if applicable), and the facility's Administrator/CEO.

Facility Clinical staff members and medical and allied health professional staff involved in patient care should be assessed for compliance with this policy utilizing aRisk Assessment tool on an annual basis. Results from the assessments should be reviewed by facility

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leaders to identify possible performance gaps and included in teammate performance and medical and allied health professional staff reappointment reviews.

A minimum of five assessments per month must be completed, with assessment findings submitted via the online variance reporting system. Results from the monthly assessment(s) should be reviewed for process compliance and to identify opportunities for improvement on a continuous basis. Findings should be reported to the Governing Body/Medical Executive Committee/Quality Committee at least quarterly.

# Enforcement

Any teammate found to have violated this policy may be subject to disciplinary action, up to and including termination of employment. Physicians and/or Allied Health members who violate this policy may be subject to disciplinary action by the Medical Executive Committee and/or Governing Board, up to and including termination of privileges.

Business associates found to have violated this policy may be subject to financial penalties, up to and including termination of contract. It is the responsibility of the facility's Administrator/ CEO and Governing Body to ensure compliance with this policy.

# References

Association of Perioperative Nurses (AORN): Sentinel Events: Prevention and Reduction of Wrong- Patient, Wrong-Site, Wrong-Procedure Events. (2014). [https://www.aorn.org/education/staff-](https://www.aorn.org/education/staff-development/prevention-of-sentinel-events/wrong-site-surgery) [development/prevention-of-sentinel-events/wrong-site-surgery](https://www.aorn.org/education/staff-development/prevention-of-sentinel-events/wrong-site-surgery)

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Agency for Healthcare Research and Quality (AHRQ): Wrong-Site, Wrong-Procedure, and Wrong- Patient Surgery (Sept. 7, 2019). [https://psnet.ahrq.gov/primers/primer/18/wrong-site-wrong-](https://psnet.ahrq.gov/primers/primer/18/wrong-site-wrong-procedure-and-wrong-patient-surgery) [procedure-and-wrong-patient-surgery](https://psnet.ahrq.gov/primers/primer/18/wrong-site-wrong-procedure-and-wrong-patient-surgery)

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# Contact Information

If you have questions or concerns regarding this policy, please contact facility leadership.

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