Salem Health Hospitals & Clinics

Universal Protocol – Patient Procedure Verification Site Marking & Time-Out
Clinical House Wide Policy and Procedure

Applicable Campus	Department Name	Approval Authority
Salem Health & West Valley Hospital	General Clinical House Wide	Director, Surgical Services

Effective Date January 2019 SH **Effective Date** January 2020 WVH	**Next Review Date** December 2021 SH **Next Review Date** December 2021 WVH

List Stakeholders Position or Committee	Document Status	Date of Approval
Surgical Governance	Reviewed	06/2018
VP Surgical Services	Revised	06/2018
Director Surgical Services	Reviewed	06/2018
Director SHMG Multispecialty Clinics	Reviewed	08/2018
Director SHMG Family Practice Clinics	Reviewed	08/2018
Accreditation & Patient Safety Manager	Reviewed	08/2018
Medical Executive Committee	Reviewed	11/2018
WVH Manager Outpatient Services	Reviewed	10/2019
WVH Director of Clinical Operations	Reviewed	10/2019
WVH Medical Care Advisory Committee	Reviewed	12/2019
Final Approval Date SH	Reviewed	12/2018
Final Approval Date WVH	Reviewed	12/2019

Describe briefly the most recent revision made to this policy, procedure or protocol & why:

4/2021 Minor changes moving location of safety statement in required elements, and changing the wording so the physician can use their own words to invite people to speak up.

Policy Content

This policy and procedure is to help prevent wrong patient, wrong procedure and wrong site occurrences. This policy pertains to all operative and other invasive procedures as defined on Salem Health's Invasive Procedure List regardless of what Salem Health setting (operating room, at the bedside, or in a procedure areas outside of the operating room) the surgery/invasive procedure is being performed.

It is the policy of Salem Health to comply with National Patient Safety Goals, thereby preventing wrong patient/wrong procedure/wrong site occurrences relative to all operative and other invasive procedures, regardless of the setting (operating room, at the bedside, or in procedure areas outside of the operating room) in which the surgery/procedure is done.

Steps/Key Points Procedure

I. Pre-Operative/Pre-Procedure Verification Process

A. Provider's verification of the correct person, procedure and site, (as applicable), should occur with the patient involvement (or family member if the patient is not able to participate), in the following situations:
   1. At the time the surgery/procedure is scheduled;
   2. At the time of preadmission testing and assessment;
   3. At the time of admission or entry into the hospital or Salem Health outpatient clinic;
   4. Before the patient leaves the pre-procedure room or enters the procedure room;
   5. Anytime during the pre-procedural process when the responsibility for care of the patient is transferred from one caregiver to another; and

6. During the Time Out process.
7. Salem Health Medical Group Clinic Providers will use the approved EPIC universal protocol smart phrases for documentation of the pre-procedure verification.

B. Providers will use an approved checklist, to review and verify the following, using the patient's name and medical record number, before the patient leaves the pre-procedure area, or in the case of bedside procedures, before commencement of the procedure.
   1. Relevant documentation, which at a minimum is a current H&P (Refer to Medical Staff Rules and Regulations)) and pre-anesthesia assessment, if anesthesia or moderate or deep sedation is planned;
   2. Accurate, complete and signed consent form which conforms to the Informed Consent Policy;
   3. Relevant diagnostic test results and/or radiographic images;
   4. Required blood products, implants, devices, or other special equipment needed for the patient is present or readily available.

C. Providers will resolve any discrepancies identified through the verification process prior to the patient arriving in the invasive procedure area or, in the case of bedside procedures, prior to initiation of the procedure.

II. Site Marking

A. Providers will mark the site(s) for all cases listed on Salem Health's Invasive Procedures List and Exceptions (Attachment A), taking into consideration laterality; surface, (e.g., flexor or extensor); the level, (spine): or specific digit or lesion to be treated. When performing a bilateral procedure, marking is not necessary.

B. Salem Health site marking must occur in the pre-procedure area, prior to the patient's move to the procedure room; staff is prohibited from moving the patient from the pre-procedure area into the operating room or procedure room if the site is not marked by the physician as described below:
   1. The provider or proceduralist who is privileged or permitted to perform the intended surgical or nonsurgical invasive procedure, and who is directly involved in the procedure and present at the time of the procedure, must mark the site.
   2. For procedures that involve laterality of organs, (i.e., right or left ureteroscopy), and the incision(s) or approaches may be from the midline or from a natural orifice, the site is still marked and the laterality noted; or place the orange armband, to indicate laterality. Please note exceptions specific to gynecological procedures outlined in Attachment A.
   3. For imaging guided procedures, when laterality is an issue, (i.e., breast biopsies), a mark must be placed on the correct side in the pre-procedure area by following alternative marking as described below, with specific site marking being accomplished by visual confirmation, through the use of the imaging techniques.
   4. Neurosurgeons may use fiducials and markers associated with the imaging-guided navigation system for intracerebral tumor resection (craniotomies).
   5. For spinal procedures, in addition to pre-operative site marking of the general spinal region, special intraoperative radiographic techniques are used for marking the exact vertebral level.
   6. For cases in which it is technically or anatomically impossible or impractical to mark the site, an orange armband will be placed on the correct side in a location that remains visible after prepping and draping.

C. Salem Health site marking includes the following characteristics:
   1. It is made at or near the procedure site or the incision site;
   2. It includes the provider's or proceduralist's initials of first name, middle name, and last name;
   3. It is made with an indelible marker so that it remains visible after completion of the skin prep and sterile draping. Stickers or removable marks will not be used:
      a. Eyes: An indelible dot is placed above the operative eye in ocular cases and the surgeon will initial the orange band; for surgeries in orbial area, sinus, eyelid or face, the surgeon may mark the location of the surgery if it is left uncovered and part of the surgical field.
      b. Ears: An indelible mark is placed behind the operative ear for procedures
   4. In an emergent, life threatening situation when the provider or proceduralist does not leave the patient, site marking may be eliminated.
   5. See Attachment A for exceptions to site marking requirements
   6. Orange armbands will be used to indicate laterality as stated above, for patients who refuse site marking.

III. Time-Out

Exceptions to the time out process are emergent, life threatening situations when the procedure must start before the entire team is present; at the time other persons enter the procedure room, a verbal discussion occurs which contains, at the minimum, a patient assessment and the plan.

A. Anesthesia leads time-out immediately before induction or anesthesia-related procedures.

B. The provider/proceduralist leads the time-out immediately before the procedure. The patient should be prepped and draped with site marking visible as appropriate according to the surgery scheduled.

C. Everyone must stop all activities and actively participate.

D. Required elements:

1. Patient verification;
2. Procedure verification;
3. Side/site marking verification, if applicable;
4. Safety precautions stated, based on the patient's history;
5. All team members identified and verbalize agreement that all are ready to proceed, and any discrepancies are resolved before proceeding; and
6. The leader makes a safety statement inviting team members to speak up with any safety concerns or questions at any time.
7. The time-out date and time are documented

E. Repeat the time-out when; the provider or proceduralist is replaced by another provider or proceduralist during the same procedure or when there are more procedures being performed on the same patient which requires a different provider(s) or proceduralist(s) and/or team(s). Examples of when this is required include:
   i. An anterior-posterior perineal repair performed by a Urologist followed by a hysterectomy performed by a Gynecologist,
   ii. The Intensivist inserts a central vascular line before the Cardiologist arrives to do a periocardiocentesis

F. One person time-out
   1. The provider leads the time out immediately before the procedure
   2. One person time out with the patient and the provider is acceptable if the provider verifies the patient, the site and the correct procedure prior to starting the procedure.
   3. Required elements:
      a. Patient verification completed
      b. Procedure verification completed
      c. Site marked, if applicable
      d. Safety precautions if applicable based on the patient's history.

IV. A "Hand-off" must be performed if a member of the surgical team is permanently replaced by another member following Transfer of Care Communication (Hand-off) Policy.

Review and Revision History		
History	Review or Revision	Date
Update		05/2021
WVH	Review	01/2020
WVH	Review	12/2018
SH- Revised Additional stakeholders included to support adherence to policy in clinic settings. Provided additional details related to applicable settings. Added verification that the informed consent matches the procedure scheduled/planned. Added additional details related to site marking for surgeries involving facial structures vs. ophthalmology cases per provider request. Added details that the patients should be prepped and draped with site marking visible when the time out is performed. Updated Safety Statement to align with information posted in operating rooms. Update logo.	Revision	12/2018
WVH- Reformatted	Revision	06/2017
SH- Update NPSG 2015, clarify to apply to all providers/proceduralist.	Revision	03/2016
SHWV	Review	03/2016
	Revision	08/2015
	Revision	10/2014
	Revision	06/2012
	Revision	01/2012
	Revision	08/2011
	Revision	08/2009
	Review	12/2006
	Revision	03/1998

New Policy	Review	02/1995

Equipment or Supplies - Insert N/A if not applicable
N/A
Form Name and Number or Attachment Name - Insert N/A if not applicable
Attachment A - Invasive Procedures List & Exceptions Attachment B – Salem Health Medical Group Invasive Procedure Examples
Expert Consultants Position
Accreditation/Patient Safety Manager.
References – Required for Clinical Documents – Insert N/A for Administrative Policies
Joint Commission National Patient Safety Goal and related FAQs; World Health Organization Surgical Safety Checklist
Policy, Procedure or Protocol Cross Reference Information – Insert N/A if not applicable
Patient Identification Policy & Procedure Transfer of Care Communication (Hand-off) Policy Informed Consent Policy
Definitions – Insert N/A if not applicable
• **Providers**- synonymous with all physicians, providers and Licensed Independent Practitioners (PA, APRN, etc.) who practice at Salem Health. • **Special Equipment/Devices** - any equipment or supplies that are not available in floor stock; in the case of implants, they must be available for use in the procedure room • **Proceduralist** – synonymous with Surgeon and Independent Licensed Practitioner; the provider who is privileged and permitted to perform the intended procedure • **One person time-out**- time out conducted between the provider and the patient during simple procedures that only require the provider and the patient present. One person timeout includes provider verifying the patient, the site and the procedure prior to starting of the procedure. • **Orange armband**- Armband used to indicate laterality when site marking is not practical, or patient refuses skin marking
Computer Search Words
time out, site marking, universal protocol
Is there a Regulatory Requirement? Yes or No – Insert N/A if not applicable
Yes, Joint Commission UP.01.01.01, UP.01.02.01, UP.01.03.01

Attachment A
Invasive Procedures List & Exceptions

All Surgical Procedures

Biopsy
All internal organs and structures including, but not limited to:
- Breast
- Lung
- Liver
- Bone
- Kidney
- Pancreas
- Nodes

Aspiration
All internal organs, joints and bone marrow including, but not limited to:
- Paracentesis
- Pericardiocentesis
- Thoracentesis

Other diagnostic or therapeutic procedures
Where there are issues of laterality, and/or significant physiological effect including, but not limited to:
- Myelogram
- Cardiac Catheterizations, with or without interventional therapies, e.g. PTCA, Stent
- Vascular Catheterization/Angiography, with or without interventional therapies
- ERCP
- Bronchoscopy
- Gastroscopy
- Colonoscopy, including flexible sigmoidoscopy
- Laryngoscopy
- TEE
- Joint injection
- PEG placement
- Implantation of arterial and/or venous device

Site Marking Exceptions:
1. Interventional procedure cases, for which the catheter or instrument insertion site is not predetermined, e.g., cardiac catheterizations, imaging guided biopsies or aspirations—note: if laterality is involved, (breasts, lungs, kidneys, etc.), a mark must be made in the general area;
2. Procedures with a midline approach intended to treat a single, midline organ, e.g., caesarean section, CABG, cholecystectomy;
3. Dental procedures—indicate the operative tooth name(s) and number(s) on the dental radiograph or dental diagram;
4. Premature infants, for whom the mark may cause a permanent tattoo;
5. Peripheral venous or arterial puncture for phlebotomy, or insertion of an intravascular devise;
6. Venipuncture for peripheral including PICC lines, arterial lines, and hemodynamic monitoring catheters, and intravenous therapy;

7. Nasogastric or nasojejunal tube placement;
8. Incision and drainage of obvious external lesions, unless wounds exist bilaterally and only one is to be treated.
9. Closed reduction;
10. Dialysis;
11. Radiation therapy;
12. Pelvic exam and vaginal, or cervical tissue biopsy
13. Operative gynecological procedures on internal organs, either via laparoscopic or laparotomy approach.

Attachment B: Salem Health Medical Group Clinic Invasive Procedures include, but are not limited to:

Aspirations
Biopsy skin
Circumcision
Cyst removal
Drain abscess
Drain joint
Endometrial biopsy
Excise skin lesion
Inject joint
Inject tendon/sheath
Inject trigger point
Insert implanted contraception devices
IUD Insertion
IUD Removal
Nail plate removal
Removal of foreign body
Remove implanted contraception devices
Shave skin lesion
Skin tag removal
Vasectomy