

System Policy
Code: S: PC-2013

Entity: Fairview Health Services
Manual: Policy and Procedure

Category:	Provision of Care, Treatment and Services
Subject:	Safety Protocol for Invasive and/or High Risk Procedures (Site Marking and Verification)
Purpose:	To assure the correct patient receives the intended procedure on the correct site of his/her body.
Policy:	Prior to all invasive and/or high-risk procedures, clinicians will verify the correct procedure, patient, site, and (as necessary) laterality, levels, and multiples. This includes procedures done in the operating room as well as settings such as the bedside, a special procedures unit, endoscopy unit, interventional radiology suite, clinic, etc. The person performing the procedure is accountable for assuring the correct patient receives the intended procedure on the correct site of his / her body. All members of the care team, including the patient (as able), participate in the process.
Definitions:	<p>A. HIGH-RISK PROCEDURE: Any procedure that is known to expose a patient to the possibility of permanent loss or injury. Generally, this includes procedures requiring a signed consent. (See Appendix A)</p> <p>B. INVASIVE PROCEDURE: Any procedure involving puncture or incision of the skin, or insertion of an instrument or foreign material into the body, including but not limited to percutaneous aspiration, biopsies, cardiac and vascular catheterization, endoscopies, angioplasties, and implantation, excluding venipuncture and intravenous therapy. (See Appendix A)</p> <p>C. LATERALITY: The side of the patient’s body (i.e. left, right or bilateral). (See also POSITION.)</p> <p>D. LEVEL: The specific level of a body part that has multiple levels (e.g. level of the spine).</p> <p>E. MULTIPLE STRUCTURES: Body parts that there are more than one of (e.g. fingers, toes). For hands use thumb, index, long, ring and small. For toes use great toe, 2nd, 3rd, etc.</p> <p>F. POSITION: Refers to the placement or angle of the patient for the procedure (e.g., supine or prone). Reference to position is important when determining laterality.</p>

	<p>G. SITE: The specific anatomic location as indicated by 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.)</p> <p>H. VERIFICATION: The process of checking consistency between the informed consent documentation, diagnostic studies and the verbal response of the patient / guardian to assure the correct patient, correct procedure, the correct procedure site.</p>
<p>Procedure:</p>	<p>Assuring correct site procedures involves the following processes: scheduling, informed consent, site marking and verification.</p> <p>A. SCHEDULING:</p> <p>The physician or his/her designee notifies the procedure area with:</p> <ol style="list-style-type: none"> 1. Patient name and medical record number (when available) or birth date 2. If minor, name of parent or legal guardian 3. Patient date of birth 4. Surgeon or practitioner name 5. Date of procedure 6. Name of procedure(s) – minimize use of abbreviations 7. Site of procedure(s) – laterality, level, and/or multiples 8. Diagnosis 9. Any special needs – e.g. precautions, specialized equipment, interpreter. <p>B. INFORMED CONSENT:</p> <p>Informed consent is obtained per entity policy (FLHS, FNRHC, FRH, FSH, UMMC, Metro Clinics) for all planned and possible invasive or high risk procedures. To assure correct site procedure, informed consent documentation includes:</p> <ol style="list-style-type: none"> 1. Patient name (and medical record number, if available) 2. Date 3. Treatment / procedure recommended 4. Site of procedure – including laterality, level, and/or multiples <p>C. SITE MARKING:</p> <ol style="list-style-type: none"> 1. Applies only to procedures considered high-risk or invasive that involve laterality, level, and/or multiples 2. Any controversy related to site marking (including procedure, level, laterality, or documentation) is resolved prior to site marking. 3. The clinicians involved in the care of the patient prior to and during the procedure (e.g., pre-op nurse, other nurse teams, radiology personnel, and/or anesthesia care providers) separately verify the: <ol style="list-style-type: none"> a. Patient’s identity (using two identifiers)

- b. Procedure to be performed
- c. Site of the procedure by comparing relevant documentation, diagnostic studies and the verbal response of the patient / legal guardian
- 4. Procedures to be marked include those considered [high-risk or invasive](#) that involve laterality, level, and/or multiples.
- 5. For bilateral procedures, both sides will be marked.
- 6. In cases where the approach is midline but the internal approach involves laterality, the physician/clinician will mark the exterior of the body at the incision site with the laterality of the intended side.
- 7. Procedure involving levels will have:
 - a. A second verification and marking using intra-operative/procedure imaging
 - b. The site marked indicating position (anterior/posterior), laterality, and general level (cervical, thoracic, or lumbar).
- 8. Multiple sites/digits in the same anatomical location are to be labeled on the informed consent documentation and marked on the patient in the same manner.
- 9. Procedures not requiring marking:
 - a. Single organ procedures where laterality is not a factor (e.g. Cesarean section, cardiac surgery, endoscopies, rectal/vaginal procedures)
 - b. Interventional cases for which the catheter/instrument insertion site is not predetermined (e.g. cardiac catheterization)
 - c. Teeth – but, do indicate tooth names on informed consent documentation or mark the operative tooth (teeth) on the dental radiographs or dental diagram
 - d. Premature infants for whom the mark may cause a permanent tattoo. All infants under the corrected gestational age of 38 weeks should not be marked.
 - e. Situations where marking the site would cause the patient harm (e.g., emergency procedures and unstable back fractures); the site should not be marked and the rationale documented in the patient record.
 - f. Minor procedures not requiring signed consent (See [Appendix A](#)).
 - g. Procedure sites that cannot be marked due to physical location (e.g., rectal or vaginal procedures) or do not involve an incision or injection (e.g., cvstoscopy, bronchoscopy).

laryngoscopy).

- h. Procedures that enter through an orifice where the target organ is not associated with laterality (e.g., cystoscopy, bronchoscopy, laryngoscopy).

10. Special Considerations related to marking:

- a. Site sensitive areas may be marked above or lateral to the procedure site (e.g., scrotal surgery sites will be marked on the groin area on the appropriate part of the body, breast sites will be marked on or above the breast on the upper chest area)
 - b. For facial procedures where site marking may cause an obvious temporary but lasting tattoo effect, the physician may discuss the use of an alternative process (e.g. a drawing) and document method used in the medical record.
 - c. If a patient refuses to have a site marked, an alternative process (e.g. a drawing) is used and the patient's wishes are documented in the record.
11. The credentialed/privileged clinician or a physician in training (i.e. resident or fellow) who is part of the team performing the procedure marks the procedure site.
12. Marking is done in consultation with the patient, if possible. If the patient wishes, he/she may do the marking with the person performing the procedure present.
13. The site is marked using a marker that is sufficiently permanent to remain visible after completion of the skin prep, and whenever possible, the mark is placed so that it is visible in the operative field after the site is prepped and draped.
14. The clinician performing the procedure uses his/her initials to mark the site. Do not mark non-operative sites. Do not use stick-on labels.
15. The site is marked prior to the patient moving to the room where the procedure will be performed and while the patient is alert enough to participate in the process, if possible. Pre-op sedation will be administered based on the patient's needs as determined by anesthesia and may be administered prior to site marking. If the procedure is performed in the same room the patient is in, the site is marked prior to commencement of the procedure.
16. For spine surgery:
- a. Pre-operative skin marking of the spinal/other incision site, anterior or posterior, laterality, and general level with the initials of the person marking the site (i.e. the credentialed/privileged clinician performing the procedure).

- b. The preoperative imaging will be present during the procedure in the operating room or procedure area.
- c. Intraoperative imaging with opaque instruments marking the specific boney landmarks will be done and compared with the preoperative imaging as part of the correct site verification procedure.
- d. Final verification is the comparison of the pre- and intraoperative imaging by the surgeon or other physician performing the procedure.

- 17. For regional anesthesia: Prior to the administration of regional anesthesia the credentialed/privileged anesthesia provider verifies the correct site and laterality through review of informed consent documentation, the patient record, pre-op note and/or the marked surgical site, and through discussions with the patient/family, if possible. The anesthesia personnel will conduct a “pause for the cause” immediately prior to performing the procedure. All clinicians present will participate in the “pause for the cause”. The responsibility for marking the site rests with the credentialed / privileged clinician performing the procedure and may be done following the block in cases where processes do not allow the site to be marked prior to the block being administered.
- 18. In the event of a life-threatening emergency, the site need not be marked prior to transporting the patient to the OR; however, the surgical team must affirm the operative site in the OR.
- 19. In cases in which the credentialed/privileged clinician performing the procedure is in continuous physical attendance with the patient from the time it is determined to do the procedure and consent from the patient through the conduct of the procedure, site marking is not required. All other parts of the policy apply.

D. VERIFICATION:

- 1. The clinicians involved in the care of the patient prior to and during the procedure (e.g., pre-op nurse, other nurse teams, radiology personnel, and/or anesthesia care providers) **separately** verify the:
 - a. Patient’s identity (using two identifiers)
 - b. Procedure to be performed
 - c. Site of the procedure by comparing relevant documentation, diagnostic studies, and the verbal response (when able) of the patient/legal guardian
- 2. This will be documented by each person, at each point of the verification process, and recorded in the patient record.
- 3. Just before the actual procedure begins, a final verification (“pause for the cause”) is performed by all clinicians present (e.g. in the OR:

surgeon, anesthesia care provider, surgical technician, and RN circulator). Using active verbal participation, members of the team verbally verify the following:

- a. Patient identity
- b. Procedure to be performed
- c. Site of the procedure, noting the position of the patient
- d. Presence of images (properly labeled and displayed)
- e. Presence of required implants and any special equipment.

The clinician identified as accountable for recording verifies the information with the record and documents the “pause for the cause” in the patient record.

4. During the procedure, all members of the care team will actively participate in the intra-procedure pause. An intra-procedure pause will occur:
 - a. If an implant is used final verification prior to implant should include:
 - 1) Implant specification/type
 - 2) Size
 - 3) Laterality
 - b. In cases where the approach is midline but the internal approach involves laterality, the physician/clinician will actively verbalize the lateral approach (e.g., right urethra, left bronchial)
 - c. In cases where multiple unrelated procedures are to be performed, the “pause for the cause” (pause and verification) is repeated prior to each incision or injection.
5. In cases where the procedure is exploratory or unexpected findings occur during the procedure that results in a change in the procedure or original site (e.g. cancer is identified while doing an exploratory), the following applies:
 - a. The change in procedure or site must be within the parameters of the signed consent form and verified.
 - b. All personnel involved in the procedure must stop to perform an additional verification, noting the change in procedure and/or site.
6. The verification process is performed whenever a clinician leaves the room and/or the patient is moved into a new area.
7. **If, at any point in the process, a discrepancy is discovered in the site marking or verification process, the clinicians involved in performing the procedure are notified. The procedure is stopped and does not continue until the discrepancy is reconciled.**

E. REPORTING:

	<p>Any episode of wrong patient, wrong site, or wrong procedure is immediately reported in accordance with the Fairview Organizational Response to a Sentinel Event/Near Miss policy and Minnesota state law.</p>
<p>External Ref:</p>	<p>American Academy of Orthopedic Surgeons: Report of the Task Force on Wrong-Site Surgery; September 1997 (www.aaos.org)</p> <p>American Academy of Orthopedic Surgeons: Recommendations for Eliminating Wrong-Site Surgery; Academy News. March 2000. (http://www.aaos.org/wordhtml/papers/advistmt/1015.htm)</p> <p>American Health Consultants: Surgeons urged to sign patients to avoid surgery on the wrong site; Health Risk Management, March 1999. (Accessed June 28, 2004 at http://www.ahcpub.com/ahc_online/hrm.html)</p> <p>American College of Surgeons: Statement on ensuring correct patient, correct site, and correct procedure surgery: December 2002. (Accessed June 28, 2004 at http://www.facs.org/fellows_info/statements/st-41.html)</p> <p>Association of Perioperative Nurses (AORN): 1999 Standards, Recommended Practices, and Guidelines, pg. 151.</p> <p>Association of Perioperative Nurses (AORN): Identifying Surgical Sites, AORN Journal, March 1999, Vol. 69, No. 3, pg. 652.</p> <p>Association of Perioperative Nurses (AORN): AORN Position Statement on Correct Site Surgery; February 2003.</p> <p>Institute for Clinical systems Improvement. Health Care Protocol: Safe Site Protocol for All Invasive, High-Risk or Surgical Procedures. Third Edition, January 2007</p> <p>Joint Commission on Accreditation of Healthcare Organization (JCAHO): Lessons Learned: Wrong Site Surgery, Sentinel Event Alert, Issue Six, August 28, 1999. (Accessed June 28, 2004 at http://www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_6.htm)</p> <p>Joint Commission on Accreditation of Healthcare Organization (JCAHO): National Patient Safety Goals for 2005 and 2004.</p> <p>Joint Commission on Accreditation of Healthcare Organization (JCAHO): Universal Protocol approved by JCAHO's Board of Commissioners at the July 2003 meeting.</p>

	<p>Kaiser Permanente: Assuring the Correct Spinal Level, Four Key Mandatory Processes; May 2004</p> <p>Midwest Medical Insurance Company: Partners in Prevention: Wrong Site Surgery: Preventable and Indefensible. March 2003.</p> <p>North American Spine Society: Prevention of Wrong-Site Surgery. Sign, Mark, & X-ray SmaX); 2001. (Accessed June 28, 2004 at http://www.spine.org/smax.cfm)</p> <p>Safe Site Surgery Event Summary Report; October 2004.</p>
Internal Ref:	Entity policies on informed consent (<u>FLRHC</u> , <u>FNRHC</u> , <u>FRH</u> , <u>FSH</u> , <u>UMMC</u> , <u>Metro Clinics</u>)
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Date Reviewed:	7/06, 6/07

Appendix A – Definition of Surgical, High-risk, or Other Invasive Procedures

A. Procedures considered surgical, high-risk, or invasive include:

- Any procedures involving skin incision;
- Any procedures involving general or regional anesthesia, monitored anesthesia care, or conscious sedation.
- Injections of any substance into a joint space or body cavity;
- Percutaneous aspiration of body fluids through the skin (e.g., arthrocentesis, bone marrow aspiration, lumbar puncture, paracentesis, thoracentesis, suprapubic catheterization, chest tube);
- Biopsy (e.g., breast, liver, muscle, kidney, genitourinary, prostate, bladder, skin);
- Cardiac procedures (e.g., cardiac catheterization, cardiac pacemaker implantation, angioplasty, stent implantation, intra-aortic balloon catheter insertion, elective cardioversion);
- Electrocautery of lesion;
- Endoscopy (e.g., colonoscopy, bronchoscopy, esophagogastric endoscopy, cystoscopy, Percutaneous Endoscopic Gastrostomy (PEG), J-tube placements, nephrostomy tube placements);
- Laparoscopic surgical procedures (e.g., laparoscopic cholecystectomy, laparoscopic nephrectomy);
- Invasive radiological procedures (e.g., angiography, angioplasty, percutaneous biopsy);
- Dermatology Procedures (biopsy, excision and deep cryotherapy for malignant lesions – excluding cryotherapy for benign lesions);
- Invasive ophthalmic procedures, including miscellaneous procedures involving implants;
- Oral surgical procedures including tooth extraction and gingival biopsy.
- Podiatric invasive procedures (removal of ingrown toe nail, etc.);
- Skin or wound debridement performed in an operating room;
- Chemotherapy/oncology procedures;
- Electroconvulsive treatment (ECT)
- Radiation oncology procedures, and
- Central line placement
- Kidney stone lithotripsy
- Colposcopy, endometrial biopsy
- Manipulations and reductions

B. Procedures not considered surgical, high-risk, or invasive

- Venipuncture
- Intravenous therapy
- NG tube insertion
- Foley catheter insertion
- Flexible sigmoidoscopy
- Vaginal examinations (Pap smears)

* This list is not meant to be comprehensive. Adapted from the Veteran's Association