STANDARDIZED PROCEDURE
VULVAR OR PERINEAL/PERIANAL BIOPSY (Adult, Peds)

These procedures are intended to describe procedures performed by Nurse Practitioners and/or Certified Nurse Midwives (depending on the clinical privileges granted to the individual practitioner) at UC San Diego Health.

I. Definition
Vulvar/perineal/perianal biopsy is an office procedure performed using local anesthesia for obtaining a small sample of vulvar/perineal/perianal epithelium for histologic examination. Methods used for vulvar biopsy in the Ob/Gyn setting are (1) excisional biopsy performed with a cervical biopsy forcep instrument (such as Baby Tischler) or (2) a Keyes punch biopsy.

II. Background Information
A. Setting:
The setting (inpatient vs outpatient) and population (adults vs pediatrics) for the Advanced Health Practitioner (AHP) is determined by the approval of the privileges requested on the AHP Privilege Request Form. If the procedure is being done on a Pediatric patient, make sure Child Life Services is involved and use age appropriate language and age appropriate developmental needs with care of children, as appropriate to the situation.

B. Supervision: The necessity of this protocol will be determined by the AHP in collaboration with the supervising physician or his/her designee. Designee is defined as another attending physician who works directly with the supervising physician and is authorized to supervise the AHP.

Direct supervision will not be necessary once competency is determined, as provided for in the protocol. The AHP will notify the physician immediately upon being involved in any emergency or resuscitative events or under the following circumstances:

1. Patient decompensation or intolerance to the procedure
2. Bleeding that is not resolved
3. Outcome of the procedure other than expected

C. Indications
Vulvar biopsies may be indicated in the following situations: (1) lesions with thickened skin or color changes; (2) raised, red or pigmented lesions; (3) lesions presumed to be genital warts, particularly those which are not responding to conventional office or home treatment; (4) chronic dermatoses that do not respond to medical therapy; (5) any lesion suspicious for neoplasia, and (6) any lesion with equivocal changes that cannot be reliably diagnosed by visual inspection alone.

Vulvar biopsy may be necessary to differentiate benign from malignant conditions or to establish the diagnosis and proper treatment of acute or chronic vulvar conditions. The decision to biopsy may be instigated by patient symptomatology, such as persistent pain or pruritus, or by the findings of visual or colposcopic lesions. Vulvar lesions that do not spontaneously or therapeutically disappear
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within several weeks or tend to have a chronic course should be followed closely and may need histologic diagnosis.

D. Precautions/Contraindications
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Determine if the patient is allergic to Chlorhexadine or either topical or local anesthetic agents.

III. Materials
1. Mayo stand
2. Chorhexadine or other topical cleanser
3. Topical anesthetic such as lidocaine gel
4. Local anesthetic such as 1-2% lidocaine drawn up in a 1-3ml syringe with a 27-30 gauge needle
5. Kevorkian or Baby Tischler biopsy forceps or Keyes biopsy punches (2-6mm – size determined by size of lesion)
6. Pick-up forceps
7. Iris scissors
8. Gauze sponges
9. Monsel’s solution or silver nitrate sticks
10. Formalin specimen bottle labeled with patient’s name and MRN number, date, and biopsy site

IV. Vulvar Biopsy
A. Pre-treatment evaluation
   Identify the area to be biopsied.

B. Set up (if applicable)
   See above

C. Patient Preparation
   Counsel patient about the procedure: reason for biopsy, determination of any topical allergies, expectations about topical and local anesthesia, care of wound afterward. Answer questions, obtain informed consent, perform time-out.

D. Procedure
1. Clip vulvar hair, if necessary.
2. Apply 5% topical anesthetic, if using.
3. Prepare area with antiseptic solution.
4. Inject tissue with 1-2% lidocaine or similar local anesthetic to create a small wheal.
5. (Excisional biopsy) Use biopsy forceps to obtain a small segment of tissue.
6. (Keyes Punch biopsy) Using the biopsy punch, fix the skin with the nondominant hand and direct the dermatologic punch through the skin into the subcutaneous tissue. The punch is circled in a clockwise fashion until there is release of resistance, indicating that the punch blade is in the subcutaneous tissue. Lift the tissue with the pick-up forceps and use scissors to clip the circular piece of tissue from the subcutaneous area.
7. Cauterize any defect with Monsel’s or silver nitrate.
8. Place specimen in labeled formalin container.
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E. Post-procedure
Though unlikely, patient can apply an ice pack if secondary edema occurs. There is generally over the counter analgesics that may be used.

F. Follow-up treatment
Schedule appointment to discuss pathology results and/or future treatment.

V. Documentation

A. Documentation is in the electronic medical record
   1. Documentation of the pretreatment evaluation and any abnormal physical findings.
   2. Record the time-out, indication for the procedure, procedure, EBL, the outcome, how the patient tolerated the procedure, medications (drug, dose, route, & time) given, complications, and the plan in the note, as well as any teaching and discharge instructions.

B. All abnormal or unexpected findings are reviewed with the supervising physician.

VI. Competency Assessment

A. Initial Competence
   1. The AHP will be instructed on the efficacy and the indications of this therapy and demonstrate understanding of such.
   2. The AHP will demonstrate knowledge of the following:
      a. Medical indication and contraindications of vulvar or perineal/perianal biopsy
      b. Risks and benefits of the procedure
      c. Related anatomy and physiology
      d. Consent process (if applicable)
      e. Steps in performing the procedure
      f. Documentation of the procedure
      g. Ability to interpret results and implications in management.
   3. AHP will observe the supervising physician perform each procedure three times and perform the procedure three times under direct supervision.
   4. Supervising physician will document AHP’s competency prior to performing procedure without direct supervision.
   5. The AHP will ensure the completion of competency sign-off documents and provide a copy for filing in their personnel file and a copy to the medical staff office for their credentialing file.
B. Continued proficiency

1. The AHP will demonstrate competence by successful completion of the initial competency.

2. Each candidate will be initially proctored and signed off by an attending physician. AHP must perform this procedure at least three times per year. In cases where this minimum is not met, the attending, must again sign off the procedure for the AHP. The AHP will be signed off after demonstrating 100% accuracy in completing the procedure.

3. Demonstration of continued proficiency shall be monitored through the annual evaluation.

4. A clinical practice outcomes log is to be submitted with each renewal of credentials. It will include the number of procedures performed per year and any adverse outcomes. If an adverse outcome occurred, a copy of the procedure note will be submitted.

VII. RESPONSIBILITY
Questions about this procedure should be directed to the Chief Nursing and Patient Care Services Officer at 353-4380.

VIII. HISTORY OF POLICY
Revised by the Committee of Interdisciplinary Practices: 2/26/2014, 9/28/2016
Reviewed by the Medical Staff Credentials Committee: 3/5/2014, 10/6/2016
Approved by the Medical Staff Executive Committee: 3/20/2014, 10/7/2016