	Skin Biopsy Collection Protocol (Outside U of M)		SOP-1000
			Version: 002
	Approved By:	Approval Date:	Effective Date: 11/09/2011
			Managing Director: Lisa McLean

I. Purpose:

To identify the proper method of procedure, collection, and handling for completion of the skin punch biopsy.

II. Guideline:

Skin punch biopsies will be completed by means of the following procedure. Any deviation from procedure will be reported to the study PI.

III. Procedure:

A. Gather Supplies.


1. Sterile gloves
2. Tegaderm film
3. Gauze sponges
4. Small syringe (26 gauge or smaller)
5. 3mm Punch Biopsy
6. Vaseline Ointment Steri-Strips
7. Sterile scissors
8. Chloraprep
9. Lidocaine HCL 1% and Epinephrine 1:100,000 Solution

**Note: If you draw up the anesthetic before entering the room it needs to be properly labeled with date, time, initials, substance, and dose.*

B. Prepare Fresh tubes with Zamboni fixative (ready to use, no dilution necessary, Newcomer Supply Co. Catalog # 1459A. Fixative is 2% PFA and 0.3% picric acid in PBS).

1. Mix the fixative solution by repeated inversions.
2. Transfer 1.8 ml of the fixative into specimen vials (Nalgene cryogenic vials Cat. No. 5000-0020) with a plastic transfer pipette.
3. Label specimen vials with:
 - i. Patient identification number
 - ii. Date
 - iii. Source (ie. Ankle or Upper Thigh)
 - iv. Protocol Name Abbreviation (Ex. ObNeu)
 - v. Visit Number (1 or 2)
 - vi. Fix Time (time the sample first enters the fixative fluid)


C. Wash Hands and don sterile gloves.

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- D. Identify Skin Biopsy Sites listed in study protocol. If not specific to study, use the left side.
1. Distal leg (10 cm above the lateral malleolus, ankle)
 2. Upper lateral aspect of the thigh (20 cm below the anterior iliac spine)
- E. Clean Biopsy Sites.
1. Using Chloraprep applicator, scrub site back and forth for at least 10 seconds.
 2. Let Chloraprep solution dry on the skin before proceeding to the next step.
- F. Anesthetize Biopsy Sites.
1. Administer intradermally using a small syringe (26 gauge or smaller).
 2. Bevel of syringe should be facing upwards when it enters the skin.
 3. Use about 2-4 cc of the anesthetic; use enough that the area is properly numbed.
 4. During and after injection, a small bubble should raise in the skin.
- G. Biopsy Punch.
1. Ensure that the needle hole from the anesthetic is **outside** of the punch.
 2. Hold punch tool vertically over the skin and rotate downward using a twirling motion.
 3. Once the instrument reaches the hub, remove it.
 4. Have gauze sponges nearby to catch any bleeding.
 5. Cut off the bottom of the biopsy sample with sterile scissors, if necessary, while securing the sample in the forceps with the other hand.
- H. Transfer Sample to Fixative Fluid.
1. Using metal forceps, grab hold of the biopsy sample by the dermis, taking care **NOT** to pinch the upper, epidermis layer which could crush important nerve endings in the epidermis layer of the skin.

**Skin biopsy specimens with an excessive amount of blood can be rinsed briefly in PBS buffer (Nalgene cryogenic vials labeled Rinse PBS) to wash off the blood.*
 2. As each sample is transferred from the body to the tube of fixative fluid, verbalize the location of the sample to the appropriate tube. Example: "The ankle specimen is going into the ankle tube."

**Rationale: This acts as a double check for the nurse and utilizes the patient to double check that the right sample is going into the right tube.*
 3. The "Fix time" should be recorded as the time the sample first enters the fixative fluid.
 4. Store sample refrigerated at 4⁰C.

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I. Bandage Biopsy Wound.

1. Apply pressure to wound with a gauze sponge to stop bleeding.
2. May squirt extra anesthetic into wound to further decrease bleeding.
3. Apply Steri-Strips across wound.
4. Apply a small amount of Vaseline ointment over the Steri-Strips.
5. Place gauze sponge over the Steri-Strips.
6. Cover with a large Tegaderm.

J. Teaching.

1. Provide verbal biopsy care instructions to pt.
2. Provide biopsy care written instructions to pt.

K. Specimen Handling and Transport.

1. All specimen tubes will be labeled with:
 - i. Patient identification number
 - ii. Date
 - iii. Source (ie. Ankle or Upper Thigh)
 - iv. Protocol Name Abbreviation
 - v. Visit Number (1 or 2)
 - vi. Fix Time (time the sample first enters the fixative fluid)
2. Double check that each tube has a specimen in it and the specimen is totally submersed in fixative before placing it in the 4°C refrigerator.

**** IMPORTANT** Biopsies must be removed from fixative and placed in 30% sucrose within 12-24 hours to avoid over fixation. If your specimens will not be delivered to the CIC prior to this time point, please make arrangements in advance for the transfer from fixative to sucrose to insure over fixation does not occur which could render the biopsies unusable.**

U of M researchers: Contact the Study Coordinator when skin biopsies are available for pick-up.

Outside of U of M researchers: Within 12 – 24 hours of collection, transfer biopsies from fixative to sucrose then refer to SOP-1005 for delivery to the CIC.

L. Deliver skin biopsies:

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