

Standard Operating Procedure

VUH Protocol for Surgical Bone Donation SOP

Date 4/30/2012

Applicable to: Vanderbilt Operating Room (VOR), Children's Hospital.

Team Members Performing: Perioperative OR personnel

I. Purpose:

To receive, store, and dispense autologous bone flaps and to maintain records of these services.

II. Procedure:

- A. Collection of autologous tissue should be done by aseptic technique to minimize the risk of microbial contamination, and is the responsibility of the attending physician.
- B. The procedure, "VUMC Protocol for Surgical Bone Donation" is attached to each bone flap collection kit.
- C. The responsibility for the coordination of the tissue dispensing service is the Neuro Manager who serves as the Tissue Coordinator or designee.

III. Intraop:

- A. Staff retrieves a bone collection kit from the core. It is going to be stored in Cabinet AO, on the top. It is not yet in PMM so the core staff cannot look it up. If you have any problems, there are extra kits at my desk in the manager's office.
- B. Assure there is a signed physician order for bone flap collection.
- C. The intra-op protocol remains exactly the same.
- D. Notify the Charge Nurse at the Board of intended bone flap collection
- E. OR circulator gives the bone flap to the Charge Nurse for storage/log into the bone freezer located in the MOR Core.

IV. Tissue Receipt – Charge Nurse:

- A. Check tissue container for damage.
- B. Inspect the tissue label for complete information: Name, MR#, Age, Sex, Date and Time of collection, Physician name, any infectious disease documentation, and physician signature.
- C. Notify the OR immediately if there is missing information or issues.
- D. Place the bone flap on the quarantine shelf of the bone freezer (third shelf from the top).

- E. Record the bone flap in the log book and place a patient sticker in the log book.

V. Tissue Receipt – Tissue Bank Coordinator or Designee:

- A. Confirm tissue in the log book.
- B. Make a folder for the patient with the following information on the folder tab: Pt.'s last, first name, MR#, and source.
- C. Assign bone flap a unique Vanderbilt donor number (V number).
- D. Enter the tissue information into the tissue tracking system.
- E. Print 3 copies one for the folder, one for the tissue and one for the patient record.
- F. Place folder in the Tissue Quarantine File.
- G. Check label on tissue for completeness.
- H. Write expiration date on label (Tissue expires 5 years from collection date).
- I. Secure the tissue, wrapping the container with surgical tape, once around and from top to bottom.
- J. Place copy of the tissue tracking form in Ziploc bag and secure to the bone flap container.
- K. 48 hours after original collection of tissue, check Star Panel for Microbiology culture results. Print results and place Vanderbilt donor number on the copies. Put these copies in the patient tissue folder.
- L. If the results are negative, complete the "Physician Review" form (per medical director-a negative culture does not require a signature) Place form in the patient tissue folder.
- M. Move the bone flap to the Autologous Bone shelf of freezer.
- N. Place patient tissue folder in the Tissue Dispensing File.
- O. If the cultures are positive, or no cultures were collected: Label the tissue with biohazard stickers, place bone flap back on the quarantine shelf of the bone freezer, complete the "Physician Review" form, Place form in the Bone Bank Medical Director's box for signature.
- P. When the folder is returned, file the folder in the Tissue Dispensing File.
- Q. The attending physician must be notified by sending a "Possible Contamination Release Request" via campus mail and confirmation email.
- R. The physician may elect to discard the tissue. If the release letter is returned signed by the physician, the tissue should be discarded in the biohazard trash and in the tissue tracking computer system for final disposition of the product.
- S. If the physician elects to use the tissue, the "Emergency Release" form must be signed by the physician.

VI. Dispensing (Issue) of Tissue:

- A. All bone flaps are dispensed to the O.R.
- B. The Clinic Surgery Scheduler will email the Tissue Coordinator when a surgical reservation is made to confirm bone flap status.

- C. The Tissue Coordinator will confirm bone flap status via email to the Surgery Scheduler, the Neurosurgery Charge Nurse and the attending physician.
- D. At issue, confirm with the O.R. staff, a visual inspection that the outer wrapper is intact.
- E. The Tissue Coordinator or designee will document dispensing in the log book.
- F. The O.R. staff is responsible for thawing the auto graft.

VII. Return of Tissue:

- A. An unused auto graft in the original, unopened, sterile package may be returned to the Bone Freezer if it is returned within 30 minutes, still frozen and the container is intake. It should be returned to tissue tracking inventory.
- B. Any tissue with an open container or one that has been out greater than 30 minutes must be discarded.

VIII. Storage:

- A. The Bone Freezer is set for -80 C.
- B. In the event the temperature reaches warmer than -40 C, the tissue should be moved to one of two plasma freezers that are maintained at -20 C or colder.
- C. Temporary storage is limited to a total of 6 months, and tissue stored at -20 C to -40 C must them be transferred to -40 C or colder, used or discarded.

IX. Tissue Inventory:

- A. Autologous tissue is kept for 6 months.
- B. Review autologous tissue inventory every 3 months.
- C. Autologous tissue older than 6 months: request approval for discard of tissue by sending an email to the attending physician for discard request.
- D. If tissue storage extension is requested: request date or time period for tissue expiration.

X. Tissue Disposal:

- A. Once appropriate approval has been received, discard tissue in biohazard container.
- B. Discard tissue if: The container is damaged, the patient expires, the tissue expiration date is reached, email from attending with approval for discard of tissue.
- C. Final disposition should be noted in the patient tissue folder and the tissue tracking system.

XI. Children's Hospital:

- A. Bone collection kits have been issued to VCH via Lori Graves
- B. VCH will obtain their own cooler for transport on wet ice
- C. All other steps in the process are the same.

XII. References:

- A. Standards for Tissue Banking, Current Edition, American Association of Tissue Banks, Bethesda, MD.