HACKETTSTOWN MEDICAL CENTER
TISSUE STORAGE AND DOCUMENTATION

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Effective Date: 21 June 2013	**Policy No: 7420.112a**
Cross Referenced: 21 June 2013	**Origin: PATIENT CARE**
Reviewed Date: 12 June 2013	**Authority: Manager Surgical Services and CNO**
Revised Date: February 2016	**Page: 1of 4**

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SCOPE
All areas within the perioperative and operative process that store or handle human tissue.

PURPOSE
To provide guidance for Surgical Services as it relates to the storage and handling of selected human tissue**.** To ensure proper documentation of tissue storage, usage, and record keeping.

DEFINITIONS
Human tissue includes, but is not limited to, bone, cartilage, ligaments, tendons, fascia, dura mater, sclera, corneas, heart valves/conduits, bone marrow, vessels, skin, and fecal tissue management.

POLICY
It is the policy of HMC to ensure best practice tissue storage recommendations are implemented in clinical practice settings; main operating rooms, ambulatory surgery rooms, cardiac catheterization room, endoscopy suites, and all other areas where operative and other invasive procedures may be performed.

PROCEDURE
I. Materials Coordinator will order tissue.
   a. Maintain copies of FDA registration, if applicable
   b. Maintain copies of American Association of Tissue Bank (AATB) accreditation of outside vendors from whom tissue is obtained.

II. Materials Coordinator will receive delivery of tissue.

III. Freezer:
   a. Tissue will be logged into and placed in Lab Freezer by Materials Coordinator.
      i. Tissue Log Documentation:
         1. Date logging in tissue
         2. Time of Day for logging in tissue
         3. Person receiving and documenting tissue into refrigerator
         4. Vendor
         5. Catalog Number
         6. Serial Number
         7. Expiration Date
         8. Description
         9. Log if package is intact and log if temperature indicator is in proper temperature range

b. Lab

i. Tissue storage will be inspected daily by the Laboratory staff. A daily record log of temperature readings will be maintained a clipboard by the Laboratory staff.
ii. If temperature varies outside the normal range, the Laboratory staff will attempt an adjustment of the temperature dial.
iii. If unsuccessful, the Tissue Coordinator will call the Plant Operations department and put a work-order in to repair the freezer.
iv. In such a case, all tissue will be removed and stored elsewhere until repairs are completed. The nonfunctioning refrigerator/freezer will be clearly marked as needing repair and not to be used.
v. Materials Coordinator and Operating Room (OR)/Minors staff will also monitor temperatures when placing and removing items from the freezer. The tissue freezer has a continuous monitoring temperature gauge and alarm.
vi. In the event of variance from normal temperature range, the charge nurse at the OR Desk will be consulted immediately to determine the disposition of tissue and cells.
vii. Location of the tissue freezer or general storage area must be in a secured area, with limited access; main laboratory 1st floor.
viii. All tissue and cells will be stored according to the conditions stated on the label from the source facility/manufacturer.
ix. Tissue and cells exposed to temperatures warmer than the warmest labeled limit will be handled according to the source facility/manufacturer's instructions.
x. Suitable temperature recording devices include a calibrated continuous recording device or an NBS calibrated thermometer with alarms.
xi. Storage Temperatures:
1. Lyophilized or dehydrated musculoskeletal tissue should be stored at ambient or colder temperatures

- Frozen musculoskeletal and osteoarticular tissue: -40 degrees F or colder
- Frozen or cryopreserved skin: -40 degrees F or colder

xii. Tissue will be rotated in all storage areas to ensure timely use of the tissue. Expiration dates on all tissue packaging will be followed. Materials Coordinator checks once a week.

c. Retrieval for Usage by Operating Room (OR) or Minors staff
    i. Tissue Log (which is checked daily along with freezer stock by the Laboratory staff)
        1. Place patient sticker in Log Book
        2. Sign who is logging out
        3. Log out date documented
        4. Time that tissue is taken
        5. Doctor is documented

IV. Freeze Dried Stored in OR
a. Tissue will be logged into and placed in OR by Materials Coordinator.
    i. Tissue Log Documentation in Binder with product in OR:
        1. Date logging in tissue
        2. Time of Day for logging in tissue
        3. Person receiving and documenting tissue into refrigerator
        4. Vendor
        5. Catalog Number
        6. Serial Number
        7. Expiration Date
        8. Description
        9. Log if package is intact
b. Temperature of Storage Room monitored by Plant Operations.

V. OR Documentation
a. Electronic Health Record (EHR) documentation will include:
    i. Vendor
    ii. Catalog Number
    iii. Serial Number
    iv. Expiration Date
    v. Description
    vi. Reconstitution
b. Vendor paperwork for tissue is completed by circulator.
    i. One copy is to be mailed back to company.
    ii. One copy to be stapled into Ortho Implant Book.
    iii. Inserts on product kept for 10 years

VI. Records must be maintained for 10 years after tissue is dispensed or the tissue expiration date is reached, whichever is longer.

VII. Cases of post-transplant infections or adverse events will be documented in EHR and promptly reported to the source facility.

VIII. Tissue reported by the source facility as the cause of possible infection or tissue involved in an event that may have contaminated the product will be sequestered.

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REFERENCE:

AORN Standards, Recommended Practices and Guidelines, 2015 Edition

Approved at _____Meeting
month / year Committee Name