

University of Colorado Hospital Policy and Procedure Transplant and Implant Tissue Storage and Issuance

Related Policies and Procedures:

Temperature Controlled Storage Unit Monitoring
Hospital Infection Control
Transfusion Services Policies on Product Inventory Management and
Dispense of Blood Products.
Patient Safety

Approved by: Provision of Care Policy Subcommittee
Infection Control Committee
Procedures and Sedation Committee
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Background: In 1997, the US Food and Drug Administration (FDA) announced a comprehensive regulatory oversight of tissue banking. The FDA has published guidance documents that were clarified as final rules. The most current rules were set forth in May 2005. American Association of Tissue Banks (AATB) and Eye Bank Association of America (EBAA) also have extensive standards related to Tissue Banking. In support of this process, the Joint Commission for Accreditation of Healthcare Organizations has adopted related standards that were effective July 1, 2005. These standards are applicable to hospitals, ambulatory care, and the laboratory accreditation program.

Description: This policy describes how transplant tissue and implant tissue will be acquired, received, stored, issued, and tracked. The goals are: 1) Standardization of the procedures for procurement, storage, tracking, and documentation of all stages of the tissue use process; 2) Provision of safe patient care through the efficient management and documentation of the tissue storage process; and 3) Identification of and response to adverse outcomes related to the tissue transplant or implant process.

The University of Colorado Hospital(UCH) has tissue banking (recovering tissue, packaging, storage, and distribution) in limited areas such as Reproductive Medicine, Blood Bank, stem cell transplant, and certain research areas. These areas are registered with the FDA and meet FDA standards for tissue banking. Solid –organ recovery and cadaveric allograft tissue recovery are handled by Donor Alliance, which is a tissue bank and organ procurement organization (OPO). Donor Alliance is designated by the Department of Health and Human Services to facilitate organ donation allocation and transplant in Colorado and Wyoming. Living donor transplantations have oversight by Perioperative Services and Transplant Services and meet established criteria for such procedures. With the exception of the tissue listed above, and autograft tissue, all tissue implanted at UCH is allograft tissue, obtained from an FDA approved source.

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Accountability: All UCH personnel are responsible for the proper documentation, handling, storage, and tracking of tissue obtained, stored, issued, or used within the organization.

Oversight for allograft use and living donor surgical procedures in the organization is the responsibility of the Director of Perioperative Services and the Transplant Administrator. Oversight of the organization's FDA approved tissue banking programs shall rest with the Directors of those programs (Blood Bank, Reproductive Medicine, Stem Cell Program.) Oversight of UCH participation with the Eye Banking program shall rest with appropriate Rocky Mountain Lions Eye Institute personnel and medical staff.

The Provision of Care Accreditation Readiness Team will, at least annually, review the program and associated standards and will be available as a resource to the areas involved. The Sedation and Procedures Committee will serve as an oversight committee as required.

Definitions:

Tissue: Cellular based material such as bone, cornea, skin, heart valves/conduits, tendons, fascia, dura, bone, tendons, bone marrow, veins, arteries, cartilage, sperm/semen, embryos, eggs, stem cells, cord blood, synthetic tissue (artificially prepared human, and non-human based) and other cellular and tissue-based tissue transplant or implant products. (Breast milk and secreted or extracted human products, such as collagen and blood factors are exempted by the FDA. Semen is considered an HCT/P.)

HCT/ Ps -Human cell, tissues, and cellular and tissue based products: Designation terminology used by the FDA to refer to "tissue".

Site of Use: Any department or clinical area within UCH which is involved with the procurement, reception, distribution, storage, use, or issuance of tissue.

Autograft Tissue: Tissue removed from a patient to be used in the future **for that patient only.** (Autologous)

Allograft Tissue: Tissue obtained from a separate donor and procured from an FDA-approved tissue bank or supplier.

Ambient room temperature: Storage for products that excludes refrigerated or frozen temperature ranges. Somewhat broader than "room temperature" and reflects temperature limits suggested by each tissue source for storage.

Policy and Procedure: To ensure a well-coordinated system for managing transplant and implant tissues, processes must be implemented to standardize tissue handling, provide a method to trace tissue from source to recipient, and investigate adverse outcomes.

A. Procurement of Tissue:

1. All tissue procured by the organization must be validated as supplied/distributed by FDA registered tissue establishments. This validation procedure will be performed annually by Materials Management to maintain a list of approved suppliers and distributors. This validation will be kept as part of the shared tracking file. Vendor Accreditation by AATB or EBAA means the tissue establishment voluntarily follows industry-set standards which are often more stringent than the FDA.
2. Tissue ordering will be coordinated between the department involved and Materials Management.

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3. The expectation that tissue will be transported and delivered in an acceptable condition, maintaining proper temperatures, will be presented to vendors and suppliers by Materials Management through a letter to the vendor.

B. Receipt and Delivery of Tissue:

Tissue may be delivered to Materials Management or preferably to the department, depending on content, supplier, and date and time.

1. Tissue must be transported, handled and stored according to source facilities' or manufacturer's directions. Temperature controls must be maintained during transport until it is accepted in the department.
2. Package integrity must be verified at receipt in the department as well as verification that the transport temperature range was controlled and acceptable.

C. Log-in and Tracking Documentation

1. All incoming tissue must be logged-in when received in the organization, and in the department. Tissue products ordered through Lawson and coming into Materials Management will be logged in when received into that system. When tissue is received in the department, it will be logged into an intranet-based spreadsheet, providing the basis for tracking documentation through implant.
2. The tracking information sheet will include order date, date and time received in the warehouse, purchase order number, date and time received in the department, staff who received the product, package integrity assessment, place stored, vendor, tissue type, lot and serial number, expiration date, date of implant, patient medical record number, patient encounter number, and whether implant card was issued.
3. FDA-approved tissue banking departments in the organization maintain their own departmental logs and records to meet the FDA and the Joint Commission standards and must comply with state/federal regulations when acting as a source facility supplying tissue.
4. Solid organ recovery and allograft retrieval documentation is maintained by Donor Alliance, the Eye Bank, and/or other FDA accredited recovery agencies.
5. Living donor transplant donors and recipients are assigned identifiers by UNOS post-surgery, and are tracked by the United Organ Sharing (UNOS) database. Living-donor specimens will be identified during the procedure by name and medical record number and by verification of blood type. Living-donor procedures will be tracked on the shared intranet file for tissue tracking.

D. Storage of Tissue-

In order to preserve the integrity of the tissue and prevent contamination and deterioration, tissue storage must be maintained at appropriate temperatures.

1. Tissue must be stored at temperatures required by the tissue source facility.
2. Continuous temperature monitoring must be maintained for storage refrigerators and freezers (mechanical and liquid nitrogen). Freezers and refrigerators are continuously monitored 24 / 7 by facilities. As emergency back-up, a departmental contingency plan maintained by Facilities for alternative storage or use of wet or dry ice, as well as transfer protocols, must be in place in the event of refrigeration failure in order to maintain required temperature.

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3. Daily records will be maintained by engineering services to verify that tissues are stored at required temperatures.
4. Temperature storage equipment has functional alarms and emergency back-up.
5. Tissues stored in 'ambient air' (room temperature) such as freeze-dried bone, require monitoring of the air temperature once daily, with records of that reading maintained. Ambient room temperature storage excludes tissue requiring refrigerated or freezer temperature ranges. Tissue product ambient temperatures are specified by the supplier.

E. Use and Implantation Documentation

Accurate record keeping permits the traceability of all tissues from the donor or source facility to all recipients or other final disposition.

1. Records must be maintained to permit tracing of any tissue from the donor or source facility to all recipients or other final disposition, including wastage of product or return to vendor.
2. Materials and instructions used to prepare or process tissues must be recorded. This includes the storage and lot number of any products used to reconstitute or process tissue. Instructions and vendor recommendations should be reviewed annually to verify current practice in preparation and storage.
3. Organizational records must include the identity of staff involved in preparing or issuing tissue and identity of staff who accepts the tissue, along with dates and times of those activities.
4. Tissue use and the unique identifier of the tissue must be recorded in the recipient's medical record.
5. Records of storage temperatures, superseded procedures, manuals, and publications, are retained for a minimum of 10 years.
6. Records documenting the source facility, original numeric or alphanumeric donor and lot identification, all recipients or other final dispositions of each tissue, and expiration date, are retained for a minimum of ten years beyond the date of distribution, transplantation, disposition, or expiration of tissue.
7. Tissue usage information cards will be returned to the source facility after implantation, and will be documented. The return of implant forms greatly enhances the ability to trace allografts and identify specific recipients in the event of a tissue recall.

F. Monitoring Outcomes

When a transplant program is informed that an organ recipient at that program is confirmed positive for or has died from a transmissible disease or medical condition for which there is substantial concern that it could be from donor origin, the transplant program must notify by phone and provide available documentation, as soon as possible and not to exceed one complete working day, to the procuring OPO. The overall intent is to transfer the knowledge/concern from one transplant center to all other transplant centers who have accepted organs from the same donor as quickly as possible. The transplant center originating the concern of transmissibility should not wait for all medical documentation that will eventually be available, but communicate that center's concerns through the OPO and OPTN to all other centers involved with that same donor as soon as possible so the other centers could use their medical judgment as to which, if any, investigations or actions need to be performed on their recipients.

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The procuring OPO shall be responsible for:

1. communication of the test results and diagnosis as soon as practicable to any transplant center and tissue bank that received an organ or tissue from the donor who is the subject of the investigation;
2. management of the investigation to determine whether the organ donor was diagnosed with a potentially transmissible disease or condition;
3. notification of the event to the OPTN as soon as possible; and
4. submission of a final written report to the OPTN within 45 days, which specifies the organizations and individuals who were notified, when the notifications occurred, and results of the investigation including test results of the organ recipients who are the subjects of the investigation.

The OPTN shall assist the procuring OPO in identifying all organ transplant programs and recipients who received an organ from the donor who is the subject of the investigation. The OPTN will monitor the notification process to verify that the procuring OPO and all recipient organ transplant programs have been notified of the disease or medical condition and will request that any additional diagnostic test results be submitted to the procuring OPO with a copy to the OPTN. The OPTN contractor will forward a copy of the OPO's final report to the recipient transplant centers and the Division of Organ Transplantation of the Health Resources and Services Administration. Note: The identities of the donor and any organ recipient who are the subjects of the investigation shall remain confidential and all correspondence will refer to the donor and recipients by their donor identification number and recipient social security numbers. Under no circumstances should a transplant program or OPO disclose this information in a manner that is contrary to applicable law.

All human tissue and tissue-related products have the potential to transmit communicable disease.

When adverse or suspected events occur, Professional Risk Management shall be notified. Infection events should also be relayed to Infection Control. Reports to regulatory agencies such as the FDA or Colorado Department of Public Health and Environment will be made as required.

References:

- CAMH, Joint Commission for Accreditation of Healthcare Organizations, 2006. (Level V)
Federal Drug Administration, Rule 21 CFR, Part 1271. (Level V)
AORN Online, Journal August 2005: Clinical Issues. (Level V)
AATB Bulletin, Proposed JCAHO Standards on Tissue Storage, September 15, 2004. (Level V)
AORN Online, July 2005: "Recommended Practices for Surgical Tissue Banking". (Level V)
FDA Consumer Magazine, May-June 2005."Keeping Human Tissue Transplants Safe". (Level V)
AATB: Useful Information Related to JCAHO Tissue Storage and Issuance Standards, 2006. (Level V)

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