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Appropriate Usage of Human Anatomical Material Policy for Teaching & Training Purposes, iEXCEL

Contents

Purpose

The purpose of the Appropriate Use of Human Anatomical Material Policy is (1) to establish guidelines that account for the ethical management of human anatomical material from deceased individuals from initial procurement and use through final disposition; (2) to ensure that use of human anatomical material meets Uniform Anatomical Gift Act, OSHA Bloodborne Pathogen Standard, and other state and federal regulatory standards for the safe and ethical treatment of human anatomical material; (3) to ensure proper handling of human anatomical material; and (4) to protect individuals handling or transporting human anatomical material/specimens from potential exposure to blood and/or body fluids. The Compliance Officer of the University of Nebraska Medical Center (UNMC) shall be responsible for implementing and monitoring compliance with this policy.

Background

The Uniform Anatomical Gift Act regulates the donation of dead bodies or parts of bodies for transplantation, education and research. There are three types of anatomical gifts: tissue donation including blood, organ donation and whole body donation. The Nebraska State Anatomical Board, located at UNMC, is responsible for the Body Donation Program for the State of Nebraska. iEXCEL shall follow the guidelines set by the Nebraska State Anatomical Board for the use of human anatomical material. iEXCEL will obtain human anatomical material through vendors approved by the iEXCEL Human Anatomical Tissue Review Committee and have signed the iEXCEL Tissue Procurement Standards of Practice Agreement.

The Occupational Safety and Health Act (OSHA) Bloodborne Pathogen Standard (BBP) specifies precautions that shall be observed to prevent contact with blood or other potentially infectious materials. Precautions include use of personal protective equipment (PPE) and implementing engineering and work practice controls. Staff shall follow BBP standards when handling human anatomical material.

Definitions

Human Anatomical Material means the entire human body or human body segments that are grossly identifiable without the use of any specialized methods of identification.
Human body segment (part) means a portion of a whole body separated for the purposes of study, evaluation, education or research. Body segments consist of contiguous mixed tissues whose relationships have been altered only at the dissection boundaries.
Decedent identification number of origin means identification number which was assigned to donor at time of death, and which is ultimately traceable to a certified death certificate.

Procedures

Procurement of Human Anatomical Material

1. Faculty, researchers, staff and contracted vendors who require human anatomical material for educational or research purposes within the Davis Global Center shall work directly with the iEXCEL Manager, Advanced Surgical Simulation Operations to obtain the specimens. All other methods for obtaining anatomical material are strictly prohibited.

2. All Human Anatomical Tissue suppliers must be reviewed and approved by the iEXCEL Human Anatomical Tissue Review Committee and sign a Tissue Procurement Standards of Practice Agreement.

3. Human anatomical material from a living individual will never be used within the Davis Global Center for education or research purposes.

4. Requests for human anatomical material for teaching and training purposes ,within the Davis Global Center, will be made to iEXCEL through submission of the iEXCEL Anatomical Material Request Form to the iEXCEL Manager, Advanced Surgical Simulation Operations. A copy of an approved request signed by the iEXCEL Manager, Advanced Simulation Operations must accompany any requested human anatomical material.

5. The iEXCEL Manager, Advanced Surgical Simulation Operations shall assist in obtaining anatomical material from a source previously approved by the iEXCEL Human Anatomical Tissue Review Committee.

6. All human anatomical material will be scheduled and received by the iEXCEL Manager, Advanced Surgical Simulation Operations and follow a strict receiving process (iEXCEL Surgical Specimen Receipt Flow Process).

7. All human anatomical material shall be identified by the decedent identification number of origin. Identification tags should not be removed, unless temporary removal is necessary to conduct the test/procedure on the material. If identification tags must be temporarily removed, the user shall establish an alternative mechanism to account for the material (i.e. the container in which the material is maintained contains the identifier). Identification numbers shall be reaffixed to the material after the test or procedure is complete. If the recipient further subdivides human anatomical material, identification of parts must be maintained.

8. The iEXCEL Manager, Advanced Surgical Simulation Operations shall maintain a tracking system for human anatomical material, documenting the institutional source of the body or body part, fee schedules, charges of all third party providers, decedent identification number, department body or body part was provided to, purpose of use, storage facility, estimated and actual date of return, authorization for cremation, and plan for final disposition.

9. Inventory logs shall be retained in the department for three years after the return date of the last entry on each sheet.

10. Costs associated with the tissue request shall be paid by the requesting party. Costs may include but are not limited to procurement and disposition of body parts; development and maintenance of accounting systems; inspections and other oversight activities necessary to comply with this policy.

11. Anatomical material shall not be removed from approved campus facilities.

Transportation of Human Anatomical Material

I. Human anatomical material shall be transported to and from the Davis Global Center through an approved transportation company. All human anatomical material obtained from an approved outside source will be delivered directly to the Dr. Edwin G. & Dorothy Balbach Davis Global Center (iEXCEL Surgical Specimen Receipt Flow Process).

II. Anatomical material shall be placed in a primary container with a leak-proof seal that prevents leakage during collection, handling, processing, storage, transport or shipping. The primary container shall then be placed in a secondary leak resistant container that prevents leakage (i.e., a properly sealed, “zippable” plastic bag (like ZIPLOC®), a properly sealed body bag with a minimum 6 mil. thickness or a properly sealed plastic bucket with a screw-on lid, locking lid or a leak-proof lid, disaster bag). The secondary container shall contain absorbent material (i.e., cellulose packing, thick paper towel or cotton wool) which shall be placed around the top, bottom, and sides of the primary container. The secondary container shall have a biohazard label affixed to the container. Frozen specimens, once placed in their secondary container, shall be placed in a cooler with a latchable lid and transported immediately. If the specimen is transported on dry ice, a Styrofoam cooler with the lid securely strapped or taped in place, or other container approved by Environmental Health and Safety. The outside of the cooler shall be clearly labeled "For Specimens Only" and shall have the biohazard symbol displayed in a prominent place on the container.

III. Whole bodies and/or larger human anatomical material (limbs) shall be placed in a primary container which is tightly closed and prevents leakage during collection, handling, processing, storage, transport or shipping (i.e., large plastic drum with a seal or screw-top lid or a plastic body bag 6 mil. or thicker). Note

that if a plastic body bag is used, these bags are considered to be single-use devices. The primary container shall then be placed in a secondary container which shall prevent leakage (i.e. disaster bag, an air tray with a locking or secured lid). The secondary container shall also contain absorbent material (i.e., cellulose packing, thick paper towel or cotton wool) which shall be placed around the top, bottom and sides of the primary container. If an air tray is used for transport, it may be reused so long as no fluids from the body/anatomical material leak onto the box or the box is otherwise damaged. The secondary container shall have a biohazard label affixed to the container in a prominent place. Specimens shall be transported immediately.

IV. Transportation Documentation

a. Whole bodies. The delivery person shall hand-carry the iEXCEL Anatomical Material Request Form with the donor numbers listed. Upon delivery, the donor numbers shall be checked against the actual donor identification. Any discrepancies shall be reported immediately to the Nebraska State Anatomical Board or the iEXCEL Manager, Advanced Surgical Simulation Operations.

b. Human Anatomical Material Specimens. The iEXCEL Anatomical Material Request Form and an itemized list of package contents shall be placed in a watertight receptacle (i.e., a "zippable" plastic bag or plastic container). These documents shall be placed in the secondary container. Documentation for transportation of human anatomical material must not be separated from the specimen during the transport process.

V. Use of Human Anatomical Material

a. All requests for surgical training courses to be held within the Davis Global Center will need to start with an official request submitted through iEXCEL scheduling link (https://www.unmc.edu/iexcel/surgical-skills/schedule-training.html). All requests will follow the (iEXCEL Surgical Training Request Flow Process)

b. Research and educational activities using human bodies or human body parts may only be conducted in facilities with appropriate environmental safeguards. Use of fixed tissue requires proper ventilation.

c. Staff shall follow the UNMC bloodborne pathogen standards and utilize standard Universal Precautions when handling human anatomical materials. Staff shall maintain a clean and sanitary work environment. All personnel coming in contact with or being exposed to the anatomical material must be listed on the appropriate anatomical material request form. The anatomical material may not be distributed to or handled by anyone who is not listed on the form. All anatomical materials will have the serology results, including but not limited to HIV, hepatitis and NAT testing, sent to the department prior to shipping and accompany the anatomical material delivery. These serology results will be reported to the end-user prior to the use of any materials.

d. Human anatomical material shall be secured within the training facility when staff are not present. Material shall be stored in the primary leak-proof container when not in use.

VI. Disposition of Human Anatomical Material

a. All human anatomical material obtained from the Nebraska Anatomical Board shall be returned to the State Anatomical Board after use. All human anatomical material obtained by iEXCEL, from an outside source will be returned to the outside source directly or through an approved crematorium (iEXCEL Surgical Disposition Flow Process). An accounting of returned material will be conducted. Any irregularities will be reported to the iEXCEL leadership and the Compliance Officer.

b. Body parts may not be distributed to anyone who is not listed on an iEXCEL Anatomical Material Request Form.

VII. Program Inspection/Reporting Violations

a. Research laboratories and training centers using human anatomical material are subject to no-notice inspection by Environmental Health and Safety, Infection Control, and Compliance verify compliance with this policy.

b. Policy violations will be reported to the iEXCEL Leadership and the Compliance Officer. Corrective action plans will be developed to address policy violations. Anyone who knows of or suspects that a violation of this policy has occurred shall notify the Compliance Officer at 402-559-9576 or 402-559-6767 or the Compliance Hotline at 1-844-348-9584 or www.nebraska.ethicspoint.com so that an investigation can be conducted and corrective action taken as appropriate.

Additional information

- UNMC Guidelines for the Protection of Human Subjects in Research Studies
- iEXCEL Surgical Tissue Procedures