Chapter 220, Research—General
Section 03, Anatomical Specimens
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Responsible Department: Office of Research
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I. Purpose

This section establishes standards and procedures for the procurement, inventory, use, management, transfer, transportation, and disposition of human anatomical specimens to support the appropriate educational and research use of anatomical materials by faculty, staff, students, and residents.

II. Definitions

Additional definitions are available in the UC Policy on Anatomical Donation/Materials Programs.

B. Anatomical Materials Registry—a database accessible by the Body Donation Program (BDP) staff that contains a comprehensive inventory of all anatomical specimens used or stored at UC Davis (except teaching collections).

C. Disposition—cremation and scattering or another legal means of final disposal of an anatomical specimen.

F. Transfer--change of control, possession, or ownership of an anatomical specimen from one person or entity to another, including (1) transfer between UC Davis employees or students; or (2) transfer from UC Davis to another University of California campus or non-UC entity or researcher.

G. Written/electronic inventory--comprehensive inventory of anatomical specimens that minimally includes the following:

1. Unique identification number.
2. Description.
3. Location.
4. Use (e.g., research, education).
5. Name and contact number of person with day-to-day responsibility.
6. Documentation and receipt of transfer.
7. Tracking of subdivided specimens.
8. Date and manner of disposition.

III. Policy

A. Anatomical specimens are used by the University or transferred to an approved end-user for research or teaching purposes only.

B. The transfer of anatomical specimens to third-party brokers or intermediaries is prohibited.

C. The procurement, inventory, use, management, transfer, transportation, and disposition of anatomical specimens used for research and teaching must be conducted safely and respectfully (see http://ehs.ucdavis.edu/snfn/safetynets/snml).

D. The University may not profit from the transfer of anatomical specimens; however recipients may be charged a cost-recovery fee.

E. The following activities are prohibited:

1. Acquisition of an anatomical specimen acquired from an unapproved source.
2. Use of an anatomical specimen in a manner that has not been pre-approved by the Human Anatomical Specimen and Tissue Oversight Committee (HASTOC) or the Anatomical Materials Review Committee (AMRC).
3. Use of a method of storage or transport that has not been pre-approved by HASTOC or the AMRC.
4. Transfer of an anatomical specimen without prior approval by HASTOC or the AMRC.

F. Ancient Native American remains are excluded from this policy. The treatment and disposition of such remains housed at UC Davis are governed by federal and state statutes, by UC systemwide policy, and by the Office of the President, which has charged a standing advisory committee with primary responsibility for dealing with Native American remains housed at all UC campuses (see VIII, below).

IV. Roles and Responsibilities

A. BDP; also known as Anatomical Materials Program or Willed Body Program

1. Unless otherwise noted in B-C, below, the BDP is the point of contact for acquisition, receipt, transfer, transport, or disposition of all anatomical specimens procured through the BDP, another UC program, or an approved, alternate source for educational or research use at UC Davis.
2. The BDP is responsible for tracking and documenting anatomical specimens originally intended for immediate therapeutic use but that become subject to this policy when made available for educational or research use.
3. At least annually, the BDP will conduct site inspections of all University departments that receive anatomical specimens through the program.

B. The Department of Pathology is responsible for receipt and disposition of anatomical specimens obtained during surgery or autopsy at UCDMC or its affiliated clinics.

C. AMRC

1. The AMRC is responsible for reviewing and recommending action on requests to use anatomical specimens for those that can be obtained directly from the BDP or from an approved, alternate source.
2. The committee is chaired by the responsible Executive Officer as designated by the Dean--School of Medicine, and is composed of the following members:
   a. faculty advisor to the BDP.
   b. BDP Director.
   c. any other members designated by the Dean--School of Medicine.
3. The AMRC meets monthly or at least ten times per year.
4. The AMRC may serve as the subcommittee for HASTOC.

D. HASTOC

1. HASTOC serves as the UC Davis anatomical advisory board.
   a. The committee must meet at least annually.
   b. A subcommittee will be convened for matters requiring immediate attention.
2. HASTOC is responsible for the following:

a. Approves the following with respect to anatomical specimens:

1) Procurement sources (subject to UC systemwide approval).
2) Storage methods.
3) General uses.
4) Transport methods.
5) Disposition methods.
6) Extensions of holding periods.

b. Determines when a cost-recovery fee may be charged to the recipient of an anatomical specimen.

c. Evaluates the adequacy of the separation of duties and controls within each department that uses or stores anatomical specimens.

d. Develops a mandatory training and education program for users.

e. Establishes minimum requirements for employees filling the role of Anatomical Specimens Coordinator and approving requests for exceptions.

f. Recommends remedial actions in the event of a policy violation.

g. Determines whether database management and control responsibilities may be delegated from the BDP to an end user for a specific collection.

h. Reviews and recommends action on requests to use anatomical specimens for those that cannot be obtained directly from the BDP and that are obtained from an outside source.

3. Committee members are appointed by the Dean--School of Medicine and serve three-year terms. Membership includes, at minimum, the following:

a. Dean--School of Medicine.

b. Responsible Executive Officer to the BDP.

c. Research Compliance Officer.

d. UC Davis Pathology department representative.

e. Campus or UCDHS Counsel.

f. BDP Director.

g. Representatives of users of anatomical specimens from Davis campus and UCDHS.

h. Representative from Environmental Health and Safety.

i. IRB Director.

j. Public member.

k. Ethicist.

4. The committee must submit an annual report of its activities to the Vice Chancellor--Research and to the Office of the President.

E. The Department of Pathology is responsible for receipt and disposition of anatomical specimens obtained during surgery or autopsy at UCDMC or its affiliated clinics.

F. Project leader

1. The principal investigator, faculty member, or other employee who has day-to-day responsibility for the conduct of the project or educational activity in which the anatomical

specimens are used.

2. Responsible for compliance with this policy and the safe handling of the anatomical specimens.

3. This responsibility may not be delegated to a student.

G. Department head

1. The department head (e.g., center director, department chair) to whom the project leader reports is responsible for the inventory of all anatomical specimens held by the department.

2. The department head is responsible for ensuring that quarterly inventories of anatomical specimens are performed and that the physical inventory is reconciled with the written or electronic inventories. Any discrepancies must be reported to the BDP Director within three business days.

3. Ensures that all departmental personnel cooperate with inspections conducted by the BDP.

4. Ensures that any change in the status (from therapeutic to educational/research use) of an anatomical specimen that requires an entry in the Anatomical Materials Registry be reported to the BDP within three business days.

5. Designates a departmental employee (or employees) to serve as Anatomical Specimens Coordinator(s) and ensure that the Coordinator(s) receives proper training.

H. Anatomical Specimens Coordinator(s)

1. The Anatomical Specimens Coordinator(s) are responsible for ensuing appropriate physical security controls and anatomical specimen tracking systems are in place and adequately maintained by the department.

2. The Anatomical Specimens Coordinator must be a Staff Research Associate, Management Services Officer, member of the Academic Senate or Academic Federation, or a Staff Physician with an MSP designation, and is subject to a criminal and financial background check.

3. The individual with day-to-day responsibility for anatomical specimens may not be the Anatomical Specimens Coordinator.

4. All Anatomical Specimens Coordinators must participate in mandatory training and education at specified intervals.

5. If the designated employee does not meet the requirements established in G.2, above, the department must submit a written exception request for approval by HASTOC before assigning duties.

I. The Health System Compliance Department and Audit & Management Advisory Services are responsible for disseminating information regarding this policy.

V. Procedures

A. Approval for acquisition and use

1. Requests to acquire or use anatomical specimens must be submitted to the BDP or Pathology Department and approved in writing by the AMRC. (Contact the BDP at 916-734-9562 for relevant forms)

a. The BDP or a HASTOC approved biorepository for research may fulfill requests for non-surgically obtained anatomical specimens. If the BDP is unable to fulfill a

request based on current inventory, it must order the necessary specimen from a pre-approved source of human anatomical materials.

b. The Pathology Department fulfills requests for surgical anatomical specimens obtained at UCDMC or its affiliated clinics.

2. Arrangements for the procurement or donation of anatomical specimens from a source other than the BDP or Pathology Department must be approved by the AMRC prior to receipt.

3. External entities may bring anatomical specimens to the University for demonstration purposes only.

a. The external entity must register with the DBP prior to the demonstration by completing a Vendor Application Form. (Contact the BDP at 916-734-9562 for relevant forms)

b. The external entity must agree to retrain custody of the anatomical specimen during the demonstration, and to remove the specimen following the demonstration.

c. The external entity must agree that no transfer or disposition of any part of the specimen will take place.

B. Recording acquisition

1. Anatomical specimens received from the BDP.

a. The BDP enters the anatomical specimen information into the Anatomical Materials Registry where it will be assigned a unique identification number.

b. Upon receipt, the department's Anatomical Specimens Coordinator enters the anatomical specimen into the department's written or electronic inventory and completes and returns the tracking form to the BDP.

2. Anatomical specimens brought to the University upon new hire or appointment.

a. An Anatomical Material Review Application (AMRA) must be approved in writing prior to the transfer of specimens.

b. The Anatomical Specimens Coordinator enters the anatomical specimen information into the department's written/electronic inventory after it has been assigned a unique identification number by the BDP.

c. If HASTOC has delegated control and database management for a collection of anatomical specimens to the department, the Anatomical Specimens Coordinator follows the procedure described in the delegation.

3. Anatomical specimens collected at UC Davis clinical locations.

a. An anatomical specimen may not be removed from an operating room/clinic until the responsible physician completes the Pathology Requisition form. Copies of the form must be sent to the Pathology Department and BDP.

b. The Pathology Department will provide the BDP with a unique identification number for the specimen.

c. Upon receipt of the specimen, the Anatomical Specimens Coordinator enters the information into the written/electronic inventory.

4. Anatomical specimens created from a culture.

a. If a commonly recognizable anatomical specimen is grown, the Anatomical Specimens Coordinator notifies the BDP.

b. Upon notification, the BDP will enter the information into the Anatomical Materials Registry where it will be assigned a unique identification number.

c. After receiving the identification number, the Anatomical Specimens Coordinator is responsible for tracking the specimen in the written/electronic inventory.

d. An AMRA must be approved in writing prior to any further research on the anatomical specimen.

C. Transporting anatomical specimens

1. HASTOC must pre-approve general methods of transportation. The specific method of transportation to be used on any specific project must be approved in writing by the AMRC.

2. All specimens must be properly packaged and labeled prior to transport.

3. The transporter is responsible for obtaining adequate training, and for properly classifying, packing, labeling, documenting, or obtaining permits for import/export.

4. The shipper consults one or more of the following to determine proper transportation and shipping guidelines for the type of specimen transported.

a. Biosafety in Microbiological and Biomedical Laboratories (BMBL), Appendix C.

b. Title 49 CFR, Parts 173-178.

c. Title 42 CFR, Part 72.

d. The International Air Transport Association (IATA)/The International Civil Aviation Association (ICAO), Dangerous Goods Regulations.

5. Anatomical specimens must not be transported in personal vehicles or the passenger compartment of University vehicles.

D. Transfers

1. The transfer of an anatomical specimen must be approved in writing by the AMRC via amendment to the AMRA prior to the physical transfer.

2. The approved recipient must sign the AMRA and agree to all terms.

3. The transferring department's Anatomical Specimens Coordinator enters the transfer information into the written/physical inventory immediately following the approved transfer.

4. Upon receipt, the receiving department's Anatomical Specimens Coordinator must notify the BDP of the transfer and update the written/electronic inventory.

E. Disposition

1. When the department has completed use of an anatomical specimen, it must be transported by a preapproved method to the BDP or Pathology Department with the Anatomical Material Return Tracking form.

2. The Anatomical Specimens Coordinator updates the written/electronic inventory and account for any portion of the specimen that is not returned.

3. The receiving department completes disposition as follows:

a. The BDP:

1) Acknowledges receipt of the specimen.
2) Updates the Anatomical Materials Registry.

3) Disposes of the specimen in a manner consistent with State law;

or

If the original source of the specimen requires that the specimen be returned for disposition, transports the specimen by an approved method back to the source.

3) The department is responsible for reimbursing the BDP for the costs associated with disposition.

b. The Pathology Department:

1) Updates the electronic/written inventory.
2) Disposes of the specimen in accordance with department protocol and State law.

4. Alternative arrangements for disposition must be preapproved by HASTOC.

F. Duration of use

1. The department is responsible for identifying the duration of use in the initial application.
2. Any use that will last for more than 12 months requires annual update of the status to the BDP.
3. Use for a period longer than indicated on the initial application requires written approval from the BDP.

G. Prioritization of specimen allocation.

1. UC Davis
   a. Education
   b. Research
2. UC System
   a. Education
   b. Research
3. Not-for-profit research or educational entities
   a. UC Davis affiliates
   b. Other not-for-profit entities
4. For-profit research or educational entities

VI. Violations

Suspected violations of this policy must be reported to the campus hotline (877-384-4272), the Research Compliance Officer, or the Health System Compliance Office for investigation.

VII. Further Information

A. For information or forms, contact the BDP, (916) 743-9560, BDPinfo@ucdavis.edu.

B. The UCDHS Department of Pathology Handling Procedure No. 10310 is available from the Department of Pathology, (916) 734-2525.

VIII. References and Related Policies

A. UC Office of the President:

1. Policy on Anatomical Materials Programs.
2. Policy and Procedures on Curation and Repatriation of Human Remains and Cultural Items.

B. Native American Graves Protection and Repatriation Act, 25 U.S.C. 3001 et seq.

C. California Native American Graves Protection and Repatriation Act, California Health and Safety Code Sections 8010-8030.

D. UCD Policy and Procedure Manual Section 290-55, Biological Safety.

E. Personnel Policies for Staff Members UCD Procedure 21, Exhibit D, Background Checks.

F. UC Davis Biosafety Manual.

G. UC Davis Body Donation Program Materials Request Flow Diagram