

UC Davis Policy and Procedure Manual

Chapter 220, Research—General Section 03, Anatomical Specimens

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Responsible Department: Office of Research

Source Document: UC Policy on Anatomical Materials Programs

I. Purpose

This policy 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

- A. Anatomical specimen--any human body part that is commonly recognizable. It does not include blood, urine, feces, semen, or other bodily fluids, microscopic tissue samples, human cells, hair, teeth, nails, paraffin blocks, or tissue slides; or any body part designated for immediate therapeutic or clinical use (e.g., anatomical or surgical pathological analysis or organ transplantation). Contact the UC Davis Donated Body Program Director at (916)743-9560 for further guidance.
- B. Anatomical Materials Registry--database accessible by the Donated Body Program staff that contains a comprehensive inventory of all anatomical specimens used or stored at UC Davis (except teaching collections).
- C. Disposition--cremation or final disposal of an anatomical specimen.
- D. 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.
- E. 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 shall be 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/sftynet/index.cfm>).

- D. The University shall 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 from an unapproved source.
 - 2. Use of an anatomical specimen in a manner that has not been pre-approved.
 - 3. Use of a method of storage or transport that has not been pre-approved.
 - 4. Transfer of an anatomical specimen without prior approval.
- 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. Donated Body Program (DBP); also known as Anatomical Materials Program or Willed Body Program
 - 1. The DBP shall be the sole point of contact for acquisition, receipt, transfer, transport, or disposition of all anatomical specimens procured through the DBP or an outside source for educational or research use at UC Davis.
 - 2. The DBP 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 DBP will conduct site inspections of all University departments that receive anatomical specimens through the program.
- B. Anatomical Material Review Committee (AMRC)
 - 1. The AMRC is responsible for reviewing and recommending action on requests to use anatomical specimens.
 - 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 DBP
 - b. the DBP Director
 - c. any other members designated by the Dean--School of Medicine.
 - 3. The AMRC shall meet monthly or at least ten times per year.
- C. Human Anatomical Specimen and Tissue Oversight Committee (HASTOC)
 - 1. HASTOC serves as the UC Davis anatomical advisory board.
 - a. The committee shall meet at least annually.
 - b. A subcommittee shall be convened for matters requiring immediate attention.
 - 2. HASTOC is responsible for the following:
 - a. Approving 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. Determining when a cost-recovery fee may be charged to the recipient of an anatomical specimen.
 - c. Evaluating the adequacy of the separation of duties and controls within each department that uses or stores anatomical specimens.
 - d. Developing a mandatory training and education program for users.
 - e. Establishing minimum requirements for employees filling the role of Anatomical Specimens Coordinator and approving requests for exceptions.
 - f. Recommending remedial actions in the event of a policy violation.
 - g. Determining whether database management and control responsibilities may be delegated from the DBP to an end user for a specific collection.
3. Committee members are appointed by the Dean--School of Medicine and serve three-year terms. Membership shall include, at minimum, the following:
 - a. Dean--School of Medicine
 - b. Responsible Executive Officer to the DBP
 - c. Research Compliance Officer
 - d. UC Davis Pathology department representative
 - e. Campus or UCDHS Counsel
 - f. DBP 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 shall submit an annual report of its activities to the Vice Chancellor--Research and to the Office of the President.
- D. The Department of Pathology is responsible for receipt and disposition of anatomical specimens obtained during surgery or autopsy at UCDCMC or its affiliated clinics.
- E. 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 is responsible for compliance with this policy and the safe handling of the anatomical specimens.
 2. This responsibility may not be delegated to a student.
- F. 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 DBP Director within three business days.
 3. The department head is responsible for ensuring that all departmental personnel cooperate with inspections conducted by the DBP.
 4. The department head shall ensure 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 DBP within three business days.
 5. The department head shall designate a departmental employee (or employees) to serve as Anatomical Specimens Coordinator(s) and ensure that the Coordinator(s) receives proper training.
- G. Anatomical Specimens Coordinator(s)
1. The Anatomical Specimens Coordinator(s) are responsible for ensuring appropriate physical security controls and anatomical specimen tracking systems are in place and adequately maintained by the department.
 2. The Anatomical Specimens Coordinator shall 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 person 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.
- H. The Health System Compliance Department and Internal Audit 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 DBP or Pathology Department and approved by the AMRC.
 - a. The DBP fulfills requests for non-surgically obtained anatomical specimens. If the DBP is unable to fulfill a request based on current inventory, it will 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 UCDCM or its affiliated clinics.
 2. Arrangements for the procurement or donation of anatomical specimens from a source other than the DBP 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.
 - b. The external entity must agree to retain 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 DBP.
 - a. The DBP shall enter 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 shall enter the anatomical specimen into the department's written or electronic inventory and shall complete and return the tracking form to the DBP.
 2. Anatomical specimens brought to the University upon new hire or appointment.
 - a. An Anatomical Material Review Application (AMRA) must be approved prior to the transfer of specimens.
 - b. The Anatomical Specimens Coordinator shall enter the anatomical specimen information into the department's written/electronic inventory after it has been assigned a unique identification number by the DBP.
 - c. If HASTOC has delegated control and database management of a collection anatomical specimens to the department, the Anatomical Specimens Coordinator shall follow 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 shall be sent to the Pathology Department and DBP.
 - b. The Pathology Department will provide the DBP with a unique identification number for the specimen.
 - c. Upon receipt of the specimen, the Anatomical Specimens Coordinator shall enter 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 shall notify the DBP.
 - b. Upon notification, the DBP 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 prior to any further research on the anatomical specimen.
- C. Transporting anatomical specimens
1. HASTOC will pre-approve general methods of transportation. The specific method of transportation to be used on any specific project must be approved by the AMRC.

2. All specimens shall 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 shall consult 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 shall 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 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 shall enter 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 DBP of the transfer and update the written/electronic inventory.

E. Disposition

1. When the department has completed use of an anatomical specimen, it shall be transported by an approved method to the DBP or Pathology Department with the Anatomical Material Return Tracking form.
 2. The Anatomical Specimens Coordinator shall update the written/electronic inventory and account for any portion of the specimen that is not returned.
 3. The receiving department shall complete disposition as follows:
 - a. The DBP:
 - 1) Acknowledges receipt of the specimen.
 - 2) Updates the Anatomical Materials Registry.
 - 3) Disposes with 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.
 - 3) The department is responsible for reimbursing the DBP 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 disclosing the duration of use in the initial application.
 - 2. Use that will last for more than 12 months requires annual update of the status to the DBP.
 - 3. Use for a period longer than indicated on the initial application requires written approval from the DBP.
- 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 shall 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 DBP, (916) 743-9560, DBPinfo@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.