

Title: Use of Cadavers and Recognizable Body Parts for Education and Research Purposes at the University of Pennsylvania

Effective Date:

Responsible Office: Vice Provost for Research

I. Policy Statement and Scope

The University is committed to the dignified and respectful treatment of cadavers and recognizable human body parts (“cadavers/parts”), including their use for educational and research activities at the University of Pennsylvania (“University”)¹. The procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers/parts used for education and research purposes must be conducted safely, respectfully, and in compliance with all legal, public health, and ethical standards. The purpose of this policy is to provide procedures and to assign responsibility for oversight of the appropriate management and use of all cadavers/parts used for educational and research activities at the University.²

II. Definitions

Anatomical Materials Database. The University-wide database managed by the Morgue of the School of Medicine (“SOM Morgue”) that contains a comprehensive inventory of all cadavers/parts used or stored at the University for educational and research activities, including teaching collections.³

Approved End User. An individual at the University, including a faculty member, staff member, post-doctoral fellow or student, who has been approved by the Operational Committee to conduct an Approved Project involving cadavers/parts.

Approved Project. Use of cadavers/parts for educational and research activities that has received formal, written approval by the Operational Committee as indicated on a Cadavers and Body Parts Request form.

Approved Source of Supply or Approved Supplier. A supplier of cadavers/parts that has been approved by the Policy Committee and is authorized in the BEN Buys system.

Cadavers and Recognizable Human Body Parts (“cadavers/parts”). Cadavers and any human body part, including whole bones, whole viscera and external parts that are commonly recognizable by the lay person. They do not include blood, urine, feces, semen, or other bodily fluids, small or microscopic quantities of tissue or sections of bones or viscera, 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).

¹ The University includes all academic schools and hospitals within the University of Pennsylvania Health System (“UPHS”).

² This policy does not address the use of cadavers/parts arising from the clinical activities of the UPHS. In addition, the treatment and disposition of Ancient Native American remains housed at the University are governed by federal and state statutes and are excluded from this policy.

³ The database includes the following for each cadaver/part: 1) unique identification number; 2) description; 3) location of activity and storage location; 4) use (e.g., research, education); 5) name and contact number of the Project Leader; 6) name and contact number of the departmental chair; 7) documentation and receipt of transfer; 8) tracking of subdivided specimens; 9) final disposition; and 10) Approved Source of Supply.

Cadavers and Body Parts Request (“CBP Request”). The institutional form that must be completed by the Project Leader and submitted to the Operational Committee for review and approval prior to initiating an educational or research activity involving cadavers/parts.

Commercial Trafficking in Cadavers/Parts. The sale or making of a profit in connection with the acquisition or transfer of cadavers/parts.

Final Disposition. Transfers of cadavers/parts out of the University to a third party for cremation, burial, or other purposes involving the extended use of the cadavers/parts.

External Individual and Entity. Any individual or entity not a part of the University, other than an Approved Source of Supply.

Humanity Gifts Registry of the Commonwealth of Pennsylvania (“HGR”). The state entity that receives donated or unclaimed cadavers and distributes them to medical schools based on requests and availability.⁴

Institutional Approval. Formal, written approval of a requested use of cadavers/parts by the Operational Committee and/or Policy Committee.

Morgues. The SOM Morgue responsible for cadavers/parts used only for educational and research activities and the UPHS Morgues that serve as holding areas for recently deceased patients pending transfer to funeral homes or for autopsy.⁵

Transfer. Change of control, possession and responsibility between members of the University workforce, or change of possession of cadavers/parts from the University to another entity.

Transport. The physical movement of cadavers/parts from one location to another within the University.

Workforce. Faculty, staff, students, trainees, volunteers and other persons whose conduct in the performance of work for the University is under the direct control of the University, whether or not they are paid by the University.

III. Responsibility for Compliance

It is the responsibility of the Provost, his or her designees, and the Deans of schools involved in educational and/or research activities using cadavers/parts to ensure compliance with this policy. Others who use cadavers/parts for research and education purposes and / or who are charged with responsibilities under this policy also must be familiar with this policy, including: Department Chairs / Division Chiefs, faculty, staff, students, postdoctoral fellows, and residents; and employees of the Department of Pathology and Laboratory Medicine, the SOM Morgue, the Division of Anatomic Pathology, and the Morgues of the Hospital of the University of Pennsylvania.

⁴ HGR was created by the Pennsylvania General Assembly through the Anatomical Law of 1883.

⁵ The UPHS Morgues are located at the Hospital of the University of Pennsylvania, Penn Presbyterian Medical Center, Pennsylvania Hospital and Penn Medicine at Rittenhouse Square (formerly, Graduate Hospital).

IV. General Requirements and Prohibitions

- All procurement of cadavers/parts must be from an Approved Supplier. All potential suppliers must meet all of the University's business requirements and must be approved by the Policy Committee.
- Cadavers/parts may only be used for Approved Projects, only for uses consistent with those indicated in the CBP Request, and only by Approved End-Users.
- All cadavers/parts used for Approved Projects must be kept intact as much as possible for the purpose of subsequent cremation and burial.

The following activities are prohibited:

- Acquisition of cadavers/parts from any source that is not an Approved Supplier.
- Use, storage, transfer or transport of cadavers/parts in a manner that has not been pre-approved in accordance with this policy.
- Any and all commercial trafficking in cadavers/parts. The University and its workforce will not sell or otherwise profit from the transfer of cadavers/parts.

V. Roles and Responsibilities

A. The **SOM Morgue** is responsible for the following:

1. Serves as the sole point of contact for acquisition, receipt and final disposition of all cadavers/parts procured through the HGR or from an Approved Supplier for educational or research activities at the University.
2. Tracks the location of all cadavers/parts and maintains appropriate supporting documentation. Initially records and subsequently monitors the location, movement, and use of cadavers/parts from the time of their arrival at the University until the time of their final disposition by the University, including internal transfer among investigators.
3. Oversees the movement of cadavers/parts between non-contiguous university locations for continued use.
4. Conducts at least annual site inspections of all University schools and centers that receive, use and store cadavers/parts.
5. Maintains official records of cadaver/parts for all Approved Projects.

B. The **Operational Committee** ("OC") serves as an advisory board to the Policy Committee, the Provost, and the Dean of the SOM, and is responsible for oversight of specific projects involving cadavers/parts used for educational and research activities, including:

1. Reviews and makes determinations regarding all CBP Requests submitted to the OC.
2. Oversees the activities involved in the procurement, use, storage, transfer, transport and final disposition of cadavers/parts.
3. Grants approvals for delegation of responsibility from the SOM Morgue to the Anatomical Specimens Coordinator.

The OC is chaired by the Responsible Executive Officer designated by the Provost in consultation with the Dean of the SOM. OC members are appointed by the Provost in

consultation with the Dean of the SOM. Membership shall include, at a minimum, the SOM Morgue's Director and Embalmer/Anatomy Technician. The OC shall meet at least 6 times per year or more frequently as needed and record minutes of each meeting.

C. The **Policy Committee** ("PC") serves as an advisory board to the OC, the Provost and to the Dean of the SOM, and is responsible for compliance oversight and the resolution of general policy issues involving cadavers/parts used for educational and research activities, including:

1. Approves the: a) criteria to qualify as an Approved Supplier; b) storage methods; c) determination of whether a specific use constitutes an educational or research use of cadavers/parts; d) transport and transfer methods; and e) final disposition methods.
2. Determines when a cost-recovery fee may be charged to the recipient of cadavers/parts.
3. Evaluates the adequacy of the separation of duties and controls within each school and center that uses and/or stores cadavers/parts.
4. Develops mandatory training and education programs for all individuals involved in Approved Projects.
5. Establishes minimum requirements for the role of Anatomical Specimens Coordinator and approves requests for exceptions.
6. Reviews instances of noncompliance with this policy and may recommend remedial actions and/or sanctions.
7. Determines whether database management and control responsibilities may be delegated by the SOM Morgue to an Approved End-User for a specific collection of cadavers/parts.
8. Reviews appeals of decisions from the OC and/or unresolved concerns and makes recommendations to the Provost or his/her designee, who in consultation with the Dean of the SOM, will have authority to make a final determination.

The PC is chaired by the Dean of the SOM or his/her designee. PC members are appointed by the Provost in consultation with the Dean of the SOM, and will serve three year terms. Membership shall include, at minimum, at least one representative from each of the following: the SOM Morgue, the Office of the Vice Provost for Research, the Institutional Compliance Officer or his/her designee, the SOM Office of Research Compliance and Integrity, Environmental Health and Radiation Safety, faculty involved in medical and dental gross anatomy courses, Approved End Users, the SOM Department of Pathology and Laboratory Medicine, the IRB and the Office of General Counsel. Membership shall also include a public member and an Ethicist.

The PC shall meet at least annually or more frequently if matters require immediate attention. The PC shall submit an annual report of its and the OC's activities to the Provost, to the Vice Provost for Research and to the Dean of the SOM that will also be distributed to the deans of schools whose faculty are responsible for compliance with this policy.

D. **Project Leader.** The Project Leader must be a faculty member and is responsible for the actual use of cadavers/parts during an Approved Project and assumes the lead role in directing and carrying out such activities as described in the CBP Request.⁶ The Project

⁶ The OC may grant an exception to the requirement that a Project Leader must be a faculty member provided that there is appropriate departmental oversight and that the department's chair or designee has approved the appointment of the Project Leader.

Leader's responsibilities may not be delegated to a student or post-doctoral trainee. The Project Leader:

1. Submits the CBP Request to the OC and commences use of cadavers/parts only after receipt of a CBP Request approved in writing by the OC.
2. Maintains records pursuant to Section VI. K.
3. Responsibilities listed in Section V.F. also apply to the Project Leader, unless assumed by the Anatomical Specimens Coordinator.

E. The **Department Chairperson or designee (i.e. Divisional Chief)** is responsible for the following:

1. Ensures that all departmental personnel comply with this policy, including cooperation with site inspections conducted by the SOM Morgue.
2. When deemed necessary (e.g. based on the volume of Approved Projects), designates a departmental employee(s) to serve as Anatomical Specimens Coordinator(s) and ensures that the Coordinator(s) receives proper training.
3. Ensures that the Anatomical Specimens Coordinator and Project Leader fulfill responsibilities assigned to them under this policy.

F. **Anatomical Specimens Coordinator.** This position will be appointed at the discretion of the Department Chairperson (See, E.2, above) and will only be delegated certain responsibilities by the SOM Morgue involving his/her department's Approved Projects, including:

1. Ensures that appropriate physical security controls are in place and that the Anatomical Materials Database is adequately updated with regard to the department's activities, including any change in the status (from clinical to educational/research use) of cadavers/parts.
2. Conducts quarterly inventories of cadavers/parts, including reconciliation of physical inventory with the Anatomical Materials Database, and reports any discrepancies or change in the status of cadavers/parts in writing to the SOM Morgue within three business days of discovering the discrepancy.
3. Participates in training and education programs as required.

The Anatomical Specimens Coordinator may not be a Project Leader, post-doctoral trainee or student, and may be subject to a criminal and financial background check.

VI. Procedures.

A. Identification of an Approved Supplier⁷

1. The Project Leader must indicate the Approved Supplier on the CBP Request.
 - For Cadavers, HGR⁸ or name of Approved Supplier
 - For Parts, Name of Approved Supplier or SOM Morgue's inventory.⁹

⁷ For cadavers/parts brought to the University by new faculty, staff or students, see VI H.

⁸ The annual request for cadavers by the University is coordinated through the SOM Morgue.

⁹ The Operational Committee can provide a list of Approved Suppliers.

2. Procurement or receipt of donated cadavers/parts from a source that is not currently an Approved Supplier must be approved by the PC in advance of procuring or accepting receipt.

B. Obtaining Approval of a Project by Submission of a Cadavers and Body Parts Request Form (“CBP Request”) to the OC.

1. The Project Leader is responsible for submitting to the OC a completed CBP Request form that may be obtained from the OC or SOM Morgue.
2. The OC shall determine whether to approve or deny a CBP Request. The OC will indicate its written approval on the CBP Request and return it to the Project Leader. If the CBP Request is denied, the OC shall return the request to the Project Leader indicating that the request is denied and the basis for the denial.
3. The research or educational project may not be initiated prior to obtaining written approval from the OC.
4. Changes in use subsequent to original approval require additional, written approval by the OC. An amended CBP Request must be submitted by the Project Leader to the OC and approved in writing prior to initiation or continuation of the project.

C. Commencement of an Approved Project / Receipt of Cadavers/Parts by the SOM Morgue.

1. Once written approval by the OC is received, procurement arrangements may be initiated.
2. The SOM Morgue may not accept receipt of cadavers/parts from an Approved Supplier prior to approval of the project. Cadavers received from HGR may be received without project approval.
3. All cadavers/parts used for educational and research activities must arrive at the University and leave its premises through the SOM Morgue in accordance with EHRS and HGR requirements, unless a different location is authorized by the OC. Transportation methods must be pre-approved by the PC in consultation with EHRS.¹⁰
4. The SOM Morgue shall enter the cadavers/parts information into the Anatomical Specimens Database where it will be assigned a unique identification number.

D. Transport of Cadavers/Parts to the Department.

The SOM Morgue will coordinate with the Project Leader to transport the cadavers/parts to the approved location of the Approved Project.

1. All cadavers/parts must be properly packaged and labeled prior to transport. The transporter is responsible for obtaining adequate training. Specific information about acceptable packaging may be obtained from the SOM Morgue.¹¹
2. All transport must be consistent with information contained in the CBP Request. Any proposed change related to transport requires submission of an amended CBP request and written approval by the OC prior to initiating the transport.

¹⁰ Transportation methods must be those approved by or equivalent to those required by HGR, as well as other applicable laws and regulations.

¹¹EHRS may also be contacted for requirements related to packaging, transporting, and permits.

3. Upon receipt by the department, the Anatomical Specimens Coordinator (if appointed) or Project Leader shall enter the cadavers/parts new location and any other changes in information into the Anatomical Materials Database.

E. Transfer between Approved Projects.

1. It is the responsibility of the transferring Project Leader and the receiving Project Leader to coordinate the transfer of cadavers/parts with the OC and SOM Morgue.
2. If the transfer between Approved Projects was not approved by the OC on the CBP Request, prior to the transfer, the receiving Project Leader must submit an amended CBP Request to the OC for approval.
3. Provided that it was not previously addressed in the approved CBP Request, the transferring Project Leader must amend the CBP Request to indicate that transfer to the receiving Project Leader's Approved Project is taking place. The OC must approve this amendment.
4. The transferring department's Project Leader or Anatomical Specimens Coordinator shall enter the transfer information into the Anatomical Materials Database and notify the SOM Morgue immediately following the approved transfer.

F. Transferring Cadavers/Parts out of the University for Continued Use.

A Material Transfer Agreement ("MTA") is required for the transfer of cadavers/parts from the University to other entities, other than to the Approved Supplier or for cremation. Contact the Office of Research Services ("ORS") for assistance.

G. Cremation.

1. Any cadaver provided from HGR must be cremated in accordance with HGR requirements. The transport and transfer of cadavers/parts for final disposition is the responsibility of the SOM Morgue.
2. When the department has completed use of the cadavers/parts, they shall be transported by an approved method to the SOM Morgue. Contact the SOM Morgue to arrange for transport.
3. The Project Leader or the Anatomical Specimens Coordinator shall update the Anatomical Materials Database and account for any portion of the cadavers/parts that is not returned to the SOM Morgue.
4. The SOM Morgue must acknowledge receipt of the cadavers/parts in and update the Anatomical Materials Database, and make arrangements for the disposal of cadavers/parts in a manner consistent with all legal requirements.

H. Cadavers/Parts Brought to the University by New Faculty, Staff or Students.

Transfer of cadavers/parts for new faculty, staff or students coming from another institution requires the submission of a CBP Request to, and written approval by, the OC. New faculty, staff, and students are encouraged to initiate consultation with the OC prior to arriving at the University.

I. Cadavers/Parts Used for Demonstration Purposes Only.

External Individuals and Entities may bring cadavers/parts to the University for demonstration purposes only if prior, written approval has been granted by the SOM Morgue and the OC as follows:

1. A Project Leader must take responsibility for the activity and submit a CBP Request and a completed Vendor Application Form obtained from the SOM Morgue to the OC for review and approval. The External Individual or Entity must complete the Vendor Application Form.
2. If the demonstration is approved, the External Individual or Entity must agree to retain custody of the cadavers/parts during the demonstration, and to remove the cadavers/parts following the demonstration.
3. The External Individual or Entity is prohibited from transferring or disposing of any cadavers/parts within the University in a manner not consistent with the CBP Request approved by the OC.

J. Tissue Culture – Parts Created from a Culture.

1. If recognizable cadavers/parts are created from tissues or cells, the individual responsible for the newly created cadavers/parts shall notify the OC by submission of a CBP Request and will be deemed the Project Leader for the continued use involving the part.
2. Upon notification by the Project Leader, the SOM Morgue will enter the information into the Anatomical Materials Database where it will be assigned a unique identification number.
3. After receiving the unique identification number, the Project Leader or Anatomical Specimens Coordinator is responsible for tracking the specimen in the Anatomical Materials Database.
4. A CBP Request must be approved prior to any new educational or research activity on the cadavers/parts.

K. Record Keeping and Retention.

1. Maintenance of accurate records is the responsibility of the SOM Morgue, Project Leaders, and Anatomical Specimens Coordinators (as applicable)¹².
2. Except as otherwise stated in this policy, the Project Leader who initially receives cadavers/parts is designated the party ultimately responsible for the maintenance of all records of cadavers/parts until their final disposition or approved transfer within the University.
3. Parts transferred to the SOM from the Morgue of the Hospital of the University of Pennsylvania for teaching purposes shall be inventoried within the database by the Project Leader.
4. Records will be maintained for the longest period specified by University or legal requirements.

L. Financial Aspects. All transactions related to costs involving the use of cadavers/parts for Approved Projects must be fully and accurately documented and flow through

¹² If there is both a Project Leader and Anatomical Specimens Coordinator in one department, the Project Leader must identify in writing those responsibilities that are being delegated to the Anatomical Specimens Coordinator, and such delegation must be in compliance with this policy.

established institutional channels. Financial records subject to this policy must be maintained and are subject to audit.

1. The SOM Morgue must be able to recover expenses incurred by obtaining and disposing of cadavers/parts for Approved Projects. The SOM will submit an invoice to the Project Leader's department which is responsible for reimbursing the SOM Morgue for the costs associated with disposition.
2. No department, investigator, staff, or other personnel is permitted to charge or receive remuneration related to the use of cadavers/parts covered by this policy, except as stated in this section. The University's Purchasing Card or personal credit cards may not be used for purchases of cadavers/parts.

VII. Noncompliance with this Policy

Consistent with the University's Principles of Responsible Conduct, the University strongly encourages staff and other members of the University community to report concerns of noncompliance with laws, regulations or University policy through normal lines of communication. Routine discussion with one's supervisor is the preferred method of resolution. If this is not satisfactory, alternatives for reporting such concerns are to contact the Department of Human Resources, unit management, or the appropriate university office such as EHRS, Audit, Compliance & Privacy, or the Office of General Counsel. The University's reporting line (215) P-COMPLY and reporting web page www.upenn.edu/215comply may be used for either direct or anonymous reporting.

VIII. Further Information/Contacts

For information or forms: SOM Morgue: Dwayne Hallman hallmanj@mail.med.upenn.edu.

Office of Purchasing Services, Ralph Maier – maierr@upenn.edu

Office of Research Services (for Material Transfer Agreements), Pamela Caudill – caudill@pobox.upenn.edu

Environmental Health & Radiation Safety, Matt Finucane – matt@ehrs.upenn.edu

Direct any general questions about this policy to the Office of the Vice Provost for Research.

IX. References and Related Policies

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

"Procedures Following Patient Death"

http://uphsxnet.uphs.upenn.edu/hupadmpl/1_6_11a.pdf