

The University of Pennsylvania recognizes the importance surrounding the use of cadavers and recognizable body parts for education and research purposes. Accordingly, the Office of the Vice Provost for Research, in collaboration with the Office of General Counsel, recently reviewed and updated the policy as included below. The main intent of this revision is to establish alternative procedures and oversight mechanisms for the approved use of cadavers/parts through an Excepted Program and to define the membership and respective responsibilities of committees responsible for compliance oversight and operations related to the use of cadavers/parts. This revised policy was reviewed and approved by the Provost, in consultation with the Dean of the Perelman School of Medicine and the Provost's Council on Research. This policy will become effective *April 1, 2019* and supersedes the prior version that was published Dec. 22, 2009 which was effective Jan. 1, 2010.

—Wendell Pritchett, Provost

—Dawn Bonnell, Vice Provost for Research

—J. Larry Jameson, Dean of the Perelman School of Medicine,
Executive Vice President for the University of Pennsylvania Health System

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

Effective April 1, 2019

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 Perelman School of Medicine ("PSOM Morgue") that contains an inventory of cadavers/parts used or stored at the University for educational and research activities, including teaching collections. As stated below, other schools/centers/programs (hereinafter referred to as "Excepted Programs") may be approved for an alternative review and compliance process; one such element of this may be the creation and management of a separate database containing an inventory of cadavers/parts used or stored by that school/center/program.

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 or an Excepted Program 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 or alternative process that has been approved as allowable by this policy.

Approved Supplier. A supplier of cadavers/parts that has been approved by the Oversight Committee, Purchasing Services and is authorized in the Penn Marketplace/BEN Buys system.

Cadavers and Recognizable Human Body Parts ("CBP or cadavers/parts"). Cadavers and any human body part, including whole bones, whole viscera and external parts that are commonly recognizable by the layperson. 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).

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

²This 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.

CBP Request or Cadavers and Body Parts Request. A request that must be completed and submitted to the Operational Committee or Excepted Program for review and approval prior to initiating an educational or research activity involving cadavers/parts. As addressed in Section V below, the information contained in the request may vary between the Operational Committee or an Excepted Program, as the Excepted Program may have an alternate review and approval process.

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

Excepted Program. A program that has been specifically authorized by the Oversight Committee to maintain an alternative review and compliance plan for activities that involve the procurement, inventory, use, storage, transfer, transportation, and disposition 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 Supplier.

HGR or Humanity Gifts Registry of the Commonwealth of Pennsylvania. The state entity that receives donated or unclaimed cadavers and distributes them to medical schools based on requests and availability.³

Institutional Approval. Formal, written approval of a requested use of cadavers/parts by the Operational Committee and/or appropriate alternative committee if an alternate process has been approved as part of an Excepted Program.

Morgues. The PSOM Morgue is 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.⁴

Operational Committee ("OpsC"). Committee responsible for training and educational programs, as well as oversight of all specific projects involving cadavers/parts used for educational and research activities, unless a program has applied for and received approval to function as an Excepted Program.

Oversight Committee ("OC"). Committee responsible for compliance oversight and the resolution of general policy issues involving cadavers/parts used for educational and research activities.

Penn Human Tissue Laboratory or HTL. A facility where medical students, residents, fellows, allied health personnel and attending physicians can perform advanced surgical training on fresh tissue.

³HGR was created by the Pennsylvania General Assembly through the Anatomical Law of 1883.

⁴The 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).

PSOM. Perelman School of Medicine, University of Pennsylvania.

Transfer. Change of control, possession and responsibility of cadavers/body parts 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

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

IV. General Requirements and Prohibitions

- Cadavers/parts may only be used for Approved Projects, only for uses consistent with those indicated in the CBP Request or by an approved Excepted Program and only by Approved End-Users.
- All cadavers/parts used for Approved Projects must be kept intact as much as possible for subsequent cremation and burial.
- All procurement of cadavers/parts must be from an Approved Supplier. All potential suppliers must meet University business requirements and must be approved by Purchasing Services after consultation with, and approval by, the OC.

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.
- All commercial trafficking of cadavers/parts. The University and its workforce are strictly prohibited from selling or otherwise profiting from the transfer of cadavers/parts.

V. Roles and Responsibilities

A. The PSOM Morgue is responsible for all cadavers/parts not used by an approved Excepted Program, unless otherwise indicated:

1. Serve 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. Document the location of all cadavers/parts at all times and maintain appropriate supporting documentation.
3. The morgue must allow for an annual audit, as well as any additional audits that may be requested by the OC. This includes providing access to all records and facilities, as well as assistance with accessing any recordkeeping systems.

B. The Oversight Committee ("OC") is responsible for compliance oversight and the resolution of general policy issues involving cadavers/parts used for educational and research activities, including:

1. Review instances of noncompliance with this policy and may recommend further investigation, programmatic audit, corrective actions and/or sanctions.

2. Review and approve exception requests to the general requirements and prohibitions, procedures, roles and responsibilities set forth in this policy.
3. Determine whether to authorize an Excepted Program after review of a compliance plan and supporting documentation.
4. Review all potential suppliers of cadavers and body parts with Purchasing Services and provide a recommendation to Purchasing Services regarding approval or disapproval of the potential supplier.
5. Review reports from the OpsC, approved Excepted Programs, audits and any other reports as needed. Make recommendations as necessary based on any report and/or finding.

The OC is chaired by the Dean of the PSOM or his/her designee. OC members are appointed by the Vice Provost for Research in consult with the Dean of the PSOM. At a minimum, members should include a representative from Environmental Health and Radiation Safety, Office of General Counsel, Institutional Compliance, either from the VPR's Office or Office of Audit, Compliance and Privacy and a Chaplain.

The OC shall meet at least annually or more frequently if matters require immediate attention. The OC shall submit an annual report of its activities, as well as those of the OpsC and approved Excepted Programs, to the Provost, to the Vice Provost for Research and to the Deans of the PSOM and Dental School. The report shall also be distributed to the deans of schools whose faculty are responsible for compliance with this policy.

C. The Operational Committee ("OpsC") serves as an advisory board to the OC, the Vice Provost for Research and the Dean of the PSOM. The OpsC is responsible for oversight of all specific projects involving cadavers/parts used for educational and research activities, unless a program has applied for and received approval to function as an Excepted Program. This committee is also responsible for training and educational programs for all individuals utilizing cadavers/parts, including approved Excepted Programs. Responsibilities include:

1. Review and make determinations regarding all CBP Requests submitted to the OpsC.
2. Oversee the activities involved in the procurement, use, storage, transfer, transport and final disposition of cadavers/parts.
3. As needed, develop training and education programs for all individuals involved with approved projects, including approved Excepted Programs except as set forth below in section V.D.1.c.
4. Submit an annual report of its activities to the OC, which will review and submit to the Provost, to the Vice Provost for Research and to the Dean of the PSOM. The annual report must be submitted no later than July 31 of each year and should include activities for the previous fiscal year.
5. Maintain documentation of all activities.

The OpsC is chaired by the responsible Executive Officer designated by the OC in consultation with the Vice Provost for Research and the Dean of the PSOM. OpsC members are appointed by the Vice Provost for Research in consultation with the Dean of the PSOM. Membership shall include, at a minimum, the PSOM Morgue's Director and Embalmer/Anatomy Technician. The OpsC shall meet in person at least annually or more frequently as needed. Meetings outside of the annual in-person meeting may be held via conference call or email exchange. Records and/or minutes will be maintained to document all discussions, including their outcomes.

D. Excepted Program. If a program wishes to function as an Excepted Program, it must first be approved by the OC through the submission and approval of a formal proposal.

1. A proposal to function as an Excepted Program must include a plan to manage all activities that would otherwise be the responsibility of the OpsC, including a plan to:
 - a. Review and make determinations regarding requests to perform an educational or research activity involving cadavers/parts.

- b. Oversee the activities involved in the procurement, use, storage, transfer, transport and final disposition of cadavers/parts.
 - c. Develop training and educational programs if there are any requirements or needs specific to the Excepted Program.
 - d. Submit an annual report of its activities to the OC as described below.
2. If a program is approved as an Excepted Program, it may be authorized by the OC to maintain an alternative review and compliance plan for activities that involve the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers/parts used for education use.
 3. All Excepted Programs must submit an annual report of its activities to the OC. The OC will review the report and submit it to the Provost, to the Vice Provost for Research and to the Dean of the PSOM. The annual report must be submitted no later than July 31 of each year and should include activities for the previous fiscal year.
 4. All Excepted Programs must allow for an annual audit, as well as any additional audits that may be requested by the OC. This includes providing access to all records and facilities, as well as assistance with accessing any recordkeeping systems.
 5. All Excepted Programs are responsible for maintaining compliance with all aspects of this policy.
 6. The approval to function as an Excepted Program may be revoked at any time by the OC, Vice Provost for Research, Provost or the Dean of the PSOM.

E. Project Leader. The Project Leader must be a faculty member and is responsible for the 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.⁵ The Project Leader's responsibilities may not be delegated to a student or post-doctoral trainee. The Project Leader:

1. Submits the CBP Request to the OpsC or approved Excepted Program and commences use of cadavers/parts only after receipt of a CBP Request approved in writing by the OpsC.
2. Maintains records pursuant to Section VI.L.
3. Ensures that appropriate physical security controls are in place and that the Anatomical Materials Database, or alternative database that may be approved as part of an Excepted Program, is adequately updated regarding the department's activities, including any change in the status (such as a change from clinical to educational/research use) of cadavers/parts.
4. Conducts quarterly inventories of cadavers/parts, including reconciliation of physical inventory with the Anatomical Materials Database, or alternative database that may be approved as part of an Excepted Program, and reports any discrepancies or change in the status of cadavers/parts in writing to the OC within three business days of discovering the discrepancy.
5. Participates in training and educational programs as required.

F. 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 PSOM Morgue or its designee.
2. Ensures the Project Leaders fulfill responsibilities assigned to them under this policy.

VI. Procedures

A. Obtaining Project Approval for Non-Excepted Program Projects

1. Prior to initiating a research or educational project, written approval of the project must be obtained from the OpsC.
2. The Project Leader is responsible for submitting to the OpsC a completed CBP Request form that may be obtained from the OpsC or PSOM Morgue.
3. The OpsC shall determine whether to approve or deny a CBP Request. The OpsC will indicate its written approval on the CBP Request and return it to the Project Leader. If the CBP Request is denied, the OpsC shall return the request to the Project Leader indicating that the request is denied and the basis for the denial.
4. If the CBP request is not approved, the Project Leader may appeal this decision with the OpsC. If the OpsC again does not approve the CBP request, the Project Leader may appeal the decision with the OC. If the CBP is denied by the OC, the Project Leader may request that the decision be forwarded by the OC to the Vice Provost for Research or his/her designee for a final determination. The VPR may consult with the Provost and/or Dean of the PSOM in making this determination.
5. Changes in use subsequent to the original approval require additional, written approval by the OpsC. An amended CBP Request must be submitted by the Project Leader to the OpsC and approved in writing prior to initiation or continuation of the project.

B. Obtaining Project Approval for Excepted Program Projects

1. Prior to initiating a project, written approval of the project must be obtained through the process that was approved by the OC for the Excepted Program.
2. If a project request is not approved by the Excepted Program process, the Project Leader may appeal the decision through the Excepted Program process. If the Excepted Program process again does not approve the project request, the Project Leader may appeal the decision with the OC. If the project is denied by the OC, the Project Leader may request that the decision be forwarded by the OC to the Vice Provost for Research or his/her designee for a final determination. The VPR may consult with the Provost and/or Dean of the PSOM in making this determination.
3. Changes in use subsequent to the original approval require additional, written approval. An amended request must be submitted by the Project Leader through the process approved by the OC for the Excepted Program and written approval received, prior to initiating any changes to the originally submitted project.

C. Approved Supplier

1. All procurement of cadavers/parts must be from a currently Approved Supplier.
2. All new suppliers must be designated as an Approved Supplier through approval by the OC and Purchasing Services in advance of procuring or accepting receipt of the cadavers/parts.

D. Commencement of an Approved Project/Receipt of Cadavers/Parts

All cadavers/parts used for educational and research activities must arrive at the University and leave its premises through the PSOM Morgue unless an alternative process has been approved through an Excepted Program application.

E. Inspection

1. Inspections of University Schools and Centers that receive, use and store cadaver/parts will be conducted at least annually.
 - a) As part of the inspection process, access to all records and facilities must be provided, as well as assistance necessary to access all record-keeping systems.

⁵The OpsC 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.

2. Inspections will be conducted by a party that has been designated by the OC to conduct such inspection(s).
3. Each inspection will include a review of the inventory to ensure consistency with records, storage areas for cadavers/parts to ensure appropriate security and access to cadavers/parts.
4. A summary of each inspection will be maintained by the party responsible for completing the inspection and forwarded to the OC.
5. Any issues identified during the inspection that are unable to be resolved by the Project Leader or Team will be brought by the party completing the inspection to the OC for review and potential implementation of corrective actions.

F. Transport of Cadavers/Parts to the Department

The PSOM Morgue will coordinate with the Project Leader to transport the cadavers/parts to the approved location of the Approved Project unless an alternative process has been approved through an Excepted Program application.

G. Transfer between Approved Projects

There shall be no transfer of cadavers/parts between Approved Projects unless approved in advance by the OpsC or through an approved Excepted Program process.

H. 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. Office of Research Services (“ORS”) may be contacted for assistance.

I. 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 OpsC, unless the new faculty, staff or student will be working within an approved Excepted Program, in which case written approval must be granted by the Excepted Program. New faculty, staff, and students are encouraged to initiate consultation with the OpsC or Excepted Program prior to arriving at the University.

J. 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 OpsC or approved Excepted Program process as follows:

1. Project Leader must take responsibility for the activity and submit a CBP Request and a completed Vendor Application Form obtained from the PSOM Morgue to the OpsC or approved Excepted Program 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 OpsC or approved Excepted Program.

K. 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 OpsC or approved Excepted Program by submission of a CBP Request and will be deemed the Project Leader for the continued use involving the part.
2. A CBP Request must be approved by the OpsC or approved Excepted Program prior to any new educational or research activity involving the cadavers/parts.

L. Record Keeping and Retention

1. Maintenance of accurate records is the responsibility of the PSOM Morgue, approved Excepted Programs and Project Leaders.
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. Upon a change in disposition of any cadaver/part, records should be updated to reflect this change.
4. Parts utilized for teaching purposes shall be inventoried within the database by the Project Leader at least annually and at the end of each project.
5. Records will be maintained for the maximum period specified by University or legal requirements.

M. 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 established institutional channels. Financial records subject to this policy must be maintained and are subject to audit. Industry supported training and education agreements should be documented using the University’s approved template. Any such funding shall be fair market value for the costs associated with staff time, space rental, food and any equipment/supplies purchased in connection with the Approved Project for purposes of conducting the training and educational session.

1. The PSOM Morgue must be able to recover expenses incurred by obtaining and disposing of cadavers/parts for Approved Projects. The PSOM will submit an invoice to the Project Leader’s department which is responsible for reimbursing the PSOM 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. Direct or anonymous reporting may occur through the University’s reporting line (215) P-COMPLY (215-726-6759) and reporting web page

<https://secure.ethicspoint.com/domain/media/en/gui/22868/index.html>

VIII. Further Information/Contacts

Any general questions about this policy may be directed to the Office of the Vice Provost for Research or the Chair of the OC.

IX. References and Related Policies

1. Native American Graves Protection and Repatriation Act, 25 U.S.C. 3001 et seq.
2. “Procedures Following Patient Death”
http://uphsxnet.uphs.upenn.edu/hupadmp/l_6_11a.pdf
3. CBP Request
<https://researchinventory.apps.upenn.edu/researchInventory/jsp/fast2.do?bhcp=1>