

SECTION 8: SPECIAL COMMODITY PROCEDURES

SUBJECT: CADAVERS, ORGANS, AND HUMAN TISSUE

POLICY:The University of Washington is committed to the respectful procurement, transportation and treatment of all cadavers and recognizable human body parts for education or research. All purchases of cadavers or recognizable human body parts must be completed in accordance with this policy to ensure compliance with all relevant laws, regulations and policies.

The purchase of human remains for research requires certain special procedures to ensure purchases are only made from legal sources, compliance with all public health and safety regulations, and transportation and disposal are handled appropriately.

The University of Washington Willed Body Program¹ should be the first source for purchase of human remains for research. If the Willed Body Program cannot meet the present need, additional sources may be consulted.

Human remains should not be purchased via Non-PO invoice or P-Card. All purchases of human remains should be made via a purchase order, contract, or memorandum of understanding with another University or commercial supplier.

PROCEDURE:

Prior to procuring a cadaver or other part, the employee must complete a Biological Use Authorization Application,² which must be approved by the Institutional Biosafety Committee, and/or Environmental Health and Safety Research and Occupational Safety, as required by the National Institute of Health.

Generally, researchers will not need Institutional Review Board (IRB) approval prior to purchasing or performing research with cadavers, unless it will involve personal identifiers or information about the cadaver's living relatives will be collected.

Before contacting an outside source, determine whether the University of Washington Willed Body Program can provide the required cadavers, organs or other human tissue. If the Willed Body Program cannot provide the necessary parts, contact one of the institutions listed by the University of Florida State Anatomical Board's list of body donation programs in the United States.³ If none of these programs can provide the necessary parts, consider contacting another third party organization.

The primary law that governs the transfer and sale of cadavers and human remains is the Revised Uniform Anatomical Gift Act (UAGA).⁴ The UAGA governs how a gift may be made, how it must be documented, and how transfer may occur. Under the UAGA, "a part for transplantation or therapy" may not be sold for "valuable consideration" if it is to be removed

¹ Available at: <http://wbp.biostr.washington.edu/>

² Available at: <http://www.ehs.washington.edu/rbsresplan/bua.shtm>

³ Available at: <http://old.med.ufl.edu/anatbd/usprograms.html>

⁴ Adopted and Codified in Washington as Chapter 68.64 RCW, available at: <http://apps.leg.wa.gov/rcw/default.aspx?cite=68.64&full=true>

“after the individual’s death.” RCW 68.64.150(1). Sale of whole cadavers, and partial cadavers used for research, rather than transplant or therapy, is not prohibited.

Once an appropriate supplier has been identified and the University has determined that the supplier is in compliance with all applicable laws and regulations, issue a purchase order or contract, if one does not currently exist.

All cadavers must be properly packaged and labeled for transportation. All transportation of human remains shall be in accordance with WAC 246-500-040.⁵ Transportation should be conducted in accordance with the Universal Anatomical Gift Act, and the American Association of Tissue Banks non-transplant tissue banks or whole body donation regulations.

Contracts for transportation of cadavers or human remains should indicate the above requirements for transportation, but place the ultimate responsibility for ensuring compliance on the supplier.

If required by the party from whom the cadaver is obtained or necessary for the particular research use of the part, negotiate and sign a Material Transfer Agreement with the provider of the cadaver or other part. Material Transfer Agreements govern the transfer of tangible research materials and will define the intellectual property and other rights each party has with regard to any research findings or derivatives. Ensure that the University has the right to the results of any research conducted on the cadaver or other part.

The cadaver or other part should be examined and stored in accordance with WAC 308-48-030⁶ and Chapter 246-500 WAC⁷, in a properly ventilated area in compliance with all relevant laws, regulations and University policies. If it will be transported within a building or between buildings at the University, it must be transported in accordance with the University’s policy on Transporting and Shipping Biohazardous Agents.⁸

Upon the completion of research or other use, the cadaver or other part must be disposed of in a manner that meets all applicable laws, regulations and University of Washington policies, including the University’s Policy on Biohazardous Waste.⁹

⁵ Available at: <http://apps.leg.wa.gov/wac/default.aspx?cite=246-500-040>

⁶ Available at: <http://apps.leg.wa.gov/wac/default.aspx?cite=308-48-030>

⁷ Available at: <http://apps.leg.wa.gov/wac/default.aspx?cite=246-500&full=true>

⁸ Available at: http://www.ehs.washington.edu/rbsbiosafe/BSM_AppC.pdf

⁹ Available at: <http://www.ehs.washington.edu/ohsreslab/biowaste.shtm>

Transportation

Contracts that include transportation or shipment of cadavers, organs and human tissue must be in writing. Transportation of cadavers, organs and human tissue must be in compliance with WAC 246-500-040, which requires that:

1. Prior to transporting human remains by common carrier,¹⁰ the supplier must:
 - a. Enclose the cadavers, organs, or human tissue in a leak-resistant container placed inside another leak-resistant, securely constructed shipping container to prevent the release of all body fluids;
 - b. Obtain and enclose the burial-transit permit in a sturdy envelope; and
 - c. Attach the burial-transit permit to the shipping container
2. The party transporting such cadavers, organs or human tissue:
 - a. Use effective hygienic measures consistent with handling potentially infectious material
 - b. Obtain a burial-transit permit from the local health officer or local registrar of vital statistics or file a notice of removal according to requirements of RCW 70.58.230

All shipments of non-infectious human remains should be in compliance with the International Air Transport Association regulations on shipping human remains, and relevant United States Postal Service (USPS) regulations and publications. USPS Publication 52 provides more specific mailing and shipment requirements for hazardous materials. Prior to authorizing shipment, UW should confirm that the firm used for shipment is aware of compliance obligations in shipping human remains and has adequate compliance measures in place.

If remains contain an infectious disease, all transportation services should be in compliance with any applicable regulations. 49 CFR 172.101 contains a hazardous material table to determine if additional procedures are necessary to comply with hazardous material regulations. If the cadaver, organ or human tissue comes from a person who died of a communicable disease, determine whether it requires approval of the Director of the Center for Disease Control, as required by 42 CFR 71.55.

Liability for proper shipment of a cadaver, organ, or human tissue should be placed on the supplier and party performing transportation whenever possible. As a matter of practice, those parties are in a superior position to ensure compliance with the provisions of the RUAGA and WAC 246-500-040. These statutes reflect this by placing the burden, by default, on the party performing transportation or preparing the cadaver, organ, or human tissue for transportation.

¹⁰ Common Carrier generally means a transportation organization that is in the business of shipping people and/or freight. Typically, common carriers are responsible for the loss of freight during transport.