# Section: Virginia Department of Health

**Effective Date: 1-1-2013 Revision Date:**

**Title: Requests for the Importation of Anatomical Material**

**Purpose:** As required by the Code of Virginia *§ 32.1-302 The Commissioner may, in his/her discretion, on the application of any person, empower such person to import into this Commonwealth and traffic in such anatomical material and pathological specimens as the Commissioner may designate.* The purpose of this policy is to provide guidelines for the submission of an application for the importation of anatomical materials. This policy also defines what constitutes anatomical material and identifies the proper and accepted uses thereof. Proper and accepted usage of anatomical materials is identified as those for educational and research activities only and conducted in facilities that are designated for such use. This policy also contains items specific to vendors/suppliers of the anatomical material to ascertain that the proper disclosures and authorizations were granted at the time of the initial body donation. This policy has been implemented to allow the Virginia Department of Health (VDH) to properly monitor and document the source, importation, distribution, usage, and final disposition of anatomical material imported into the Commonwealth of Virginia.

## Applies To: These policies apply to all public and private persons who import anatomical material into the Commonwealth of Virginia for the purpose of education, research or other approved activities.

**Definitions:**

***Anatomical Material:*** Shall be defined as a whole dead body; or, any segment or part of a human body, any human organ, or identifiable body tissue from a deceased individual.

***Identifiable Body Tissue***: Shall be defined as tissue that can be readily identified as having originated from a human body. This includes organs, segmented body parts, and/or individual body tissues.

***Cadaver*** : Whole body a dead human, either fully intact or disassociated

**POLICY:**

All requests for the Importation of Anatomical Material must be submitted to the State Health Commissioner for notification and approval to insure proper acquisition, transportation, handling, usage, custody, and disposition. This includes the identification of the purpose of the request and disclosure of the facility in which the activity will occur. All activities utilizing anatomical material shall be conducted in a manner and at a location that ensures that the public and participants are protected from misuse and potential exposure from biohazardous and chemical materials.

**Procedure for Submitting Requests:**

1. The **Application for the Request for Importation of Anatomical Material into the Commonwealth of Virginia** can be obtained by contacting the Virginia State Anatomical Program (VSAP) or the Office of the Chief Medical Examiner (OCME). (see attachment to policy)
2. Applications are required for each shipment of Anatomical Material being imported. (Applications are not necessary for each individual use or time utilized).
	1. If the Anatomical Material is being designated for use on multiple occasions this must be noted in Section 3 – question 2 of the Application.
		1. If the material will be utilized for research multiple times, a proposed time frame for use must be provided.
		2. If the material is being stored for future projects or uses, this must be noted in Section 3 – question 2 and include an explanation of plans for storage and custody.
	2. If Anatomical Material received in one shipment is being used for separate uses, each use must be described in Section 3 – question 2.
3. Completed applications can be submitted via mail, fax, or email to the Operational Director of VSAP:

Operational Director

Virginia State Anatomical Program

400 East Jackson St.

Richmond, VA 23219

(804) 786-2479 – main line

(804) 225-2766 – fax

Email: ocme.anatomical@vdh.virginia.gov

1. Faxed and emailed applications will be processed but an original application, complete with signature, must be sent to the Operational Director prior to final approval.
2. Applications must be submitted at least 45 days prior to expected import of the material into the Commonwealth.
3. Applicants shall provide the name and contact information for a minimum of one primary contact person.
4. The Operational Director of VSAP will review the application and contact the applicant if any additional information is necessary to process the application.
5. If the Operational Director recommends the application for approval, it will then be forwarded to the Chief Medical Examiner for review and recommendation.
6. If the Chief Medical Examiner recommends the application for approval, the application will be forwarded to the Deputy Commissioner of Public Health and Preparedness for review and recommendation.
7. If all recommendations are complete and in support of the application, the application is forwarded to the State Health Commissioner for final approval.
8. After approval by the State Health Commissioner, the Operational Director of VSAP will then notify the applicant of the approval.
9. Once notified by the Operational Director of the approval the applicant can then make arrangements for receipt of the anatomical material.
10. Once the application, complete with signatures, is returned to the Operational Director of VSAP a copy will be made for VDH, VSAP records and the original will be sent to the applicant for their records.

**Policies and Procedures Specific to the Importation and Usage of Anatomical Material.**

Acquisition:

1. The provider of anatomical material shall be a reputable supplier and licensed or authorized to provide such material.
2. The provider of anatomical material shall, upon request, provide documentation of donor acquisition, medical history of donor, and a traceable identification process for the anatomical material.
3. All anatomical material shall be obtained with consent of the legal next of kin or other legal representative or designee (is it always next of kin?). Proof of disclosure of intended uses shall be available for review.
4. All documentation pertaining to acquisition of the anatomical material by the provider should be maintained by the applicant.
5. Applicants shall maintain all documentation with regards to anatomical material acquisition, identification, use, and disposition.

Maintenance and Use:

1. Applicants shall maintain the identification and origin of tissue while it remains in their possession.
	1. Identification tags shall not be removed from anatomical material.
	2. If identification tags are temporarily removed, mechanisms must be in place to maintain the identity of the material and its source, and to re-join identification tags with anatomical materials.
	3. If any tissues or anatomical materials are disassociated with or if a whole body donor is subdivided, mechanisms must be in place to maintain the identity of all such parts and their sources, and to re-join identification tags with anatomical materials.
2. The anatomical material identified in the application may be utilized only for educational and research purposes only.
3. The anatomical material identified in the application may not be sold to other users.
4. Anatomical material shall be used by the applicant only for those uses stated within the application.
	1. If the anatomical material is to be utilized, loaned, or transferred to other entities, the State Health Commissioner shall be notified in writing at least 30 days in advance of such transfer.
	2. If the anatomical material is to be utilized for purposes other than those stated in the original application, the State Health Commissioner shall be notified in writing at least 30 days in advance of such use.
	3. All written notifications shall be submitted to the Operational Director of VSAP for initial review.
5. Use of anatomical material shall occur only in a licensed healthcare facility, educational facility or designated research center. The following minimum requirements must be satisfied:
	1. Facility must have provisions for the disposal of biohazardous waste.
	2. Facility must have written policies and procedures in place to minimize exposure of employees, participants, students, and the public to biohazardous and chemical material.
	3. Facility must have adequate and secure storage for anatomical material while in possession of such material.
	4. Facility must have adequate and functional refrigeration available for the maintenance of anatomical material that has not been preserved or fixed by alternative processes or chemical means.

Disposition:

1. Disposition of anatomical material shall be done in a dignified manner that is acceptable by law.
2. Disposition by Cremation requires appropriate cremation authorization for Cadavers.
	1. If the person died in Virginia and has donated their body to an out-of-state anatomic material vendor Virginia cremation authorization is required.
	2. If the cadaver died in a state other than Virginia, the appropriate cremation authorization procedure for that state must be followed and documented.
		1. Importation of cadavers must be authorized by the Commissioner and that authorization includes attestation that appropriate cremation procedures for the state of origin have been followed.
		2. Some out-of-state vendors retrieve cadavers after use for cremation in their own state.
		3. Those vendors that request cremation by the user in Virginia must provide appropriate documentation that cremation has been properly authorized in the state of origin as well as a traceable identification process for the anatomical material.
3. Detached body parts may be cremated without further authorization.
	1. Surgical specimens do not require authorization for cremation.
	2. Detached body parts used for education or scientific study do not require additional authorization for cremation.
		1. If the parts are from Virginia donors, cremation of the cadaver has already been authorized.
		2. If the parts are from out-of-state vendors and the Commissioner has authorized importation, no additional authorization is required since the vendor has attested that proper cremation procedures have been followed for the state or origin.
4. Disposition by cremation can only be done at a crematory facility that is licensed by the Commonwealth of Virginia or licensed in the state where cremation is to occur.
	1. User shall maintain a copy of crematory licenses and contracts for such services.
	2. User shall not use or contract with crematories that dispose of biohazardous waste or animal remains.
	3. In cases where anatomical material is being returned to the supplier, documentation of the return of remains shall be maintained by user.
5. Disposition of cremated human remains shall be made in a designated area reserved for such use.
6. Applicants shall adhere to the *Code of Virginia* 32.1-301 as it pertains to the return of cremated remains, if so requested by next of kin.

Records:

All documentation listed above must be maintained and available for a period of 2 years after receipt of anatomical material for review by the Virginia State Health Commissioner or individuals designated by Commissioner.