

TISSUE USE POLICY

Science Care sets the standard of excellence for the donation and responsible use of human tissues for medical research and training.

Accredited by the American Association of Tissue Banks.

Science Care distributes tissues to qualified Applicants who have been granted approval in accordance with the following provisions:

- 1) Completed an Anatomical Materials Transfer Agreement and remained in compliance with it's terms and conditions (each Legal Entity)
- 2) Completed a Tissue Request Form (each Tissue Request)
- 3) Demonstrated medical education, research or scientific merit

Anatomical Materials Transfer Agreement, Major Elements:

- All requests for human Tissue must be approved in writing.
- Tissue shall be transported and disposed of in accordance with state, federal and local laws and regulations.
- Unauthorized, multiple, immortalized or cloned use of tissues is prohibited unless otherwise approved by Science Care.
- Tissue is to be utilized for medical research and education and not for transplantation or therapy.
- Applicant will supply to Science Care upon request a complete accounting of tissue used by Applicant (by type and quantity) including documentation of final disposition.
- Applicant will pay reasonable fees to Science Care for its removal, processing, quality control, preservation, storage fees and the transportation of tissue.
- Tissue shall be obtained with the appropriate informed consent of the legal next of kin or the donor in compliance with federal, state and local laws.
- Tissues will be screened and serologically tested for HIV-1/2, Hepatitis B Surface Antigen and Hepatitis C Virus Antibody and tissues found confirmed reactive will not be released without the express prior written authorization of the Applicant.
- Tissues with a result of other than confirmed reactive may be released at Science Care's discretion.
- Tissues consisting, entirely or in part, of a human head and/or torso, must be cremated as human Tissue by a crematory licensed to accept human remains and not as medical, pathological or biohazardous waste unless otherwise approved by law.
- Approved Anatomical Materials Transfer Agreements must be signed by a Responsible Representative of the Applicant and authorized in writing by Science Care's Program Director or designated Administrator.
- Third party tissue transfers are prohibited without the prior express written consent of Science Care.

Tissue Request Form, Major Elements:

- Applicants are required to include supporting documentation as available. Such documentation shall include but is not limited to: copies of internal review approval, institutional review board approval and promotional materials for educational events.
- A detailed summary of use including information sufficient to allow for reasonable persons to make an informed determination of the ethicality and suitability of use.

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- Detailed description of requested tissues with shipping and receiving information to include emergency contacts.
- Name, date, location and proposed date of use.
- Description of the facility. (to exclude hotels, motels and facilities with general public access).
- Description of measures to prohibit general public access.
- Outline of security measures for maintaining the custody of human tissues before, during and after use.
- Confirmation that no change of venue may occur without prior written Science Care authorization.
- Description of the methods, date, location, responsible party and contact information providing tissue disposition.
- Authorization must be approved in writing by two Science Care Employees, with at least one signer as Science Care's Program Director, Medical Director or designated Administrator.
- All Tissue requests are subject to review by Science Care's Medical Director, Management Team and/or Science Care Advisors.
- Acknowledgement that human tissue should only be used and handled by trained and technically qualified individuals. Appropriate federal, state, and local authorities should be consulted concerning the safe handling and disposal of human tissue. In particular, special care and strict adherence to any and all governmental regulations and safe laboratory practices should be maintained when using human tissues.
- Universal precautions should be used when handling any human tissue as required by the Occupational Safety and Health Administration Blood borne Pathogens Final Standard, even human tissue tested for infectious diseases such as HIV, Hepatitis B or Hepatitis C. A negative or other than confirmed reactive test result is not an absolute assurance of safety and human tissues are not tested for all possible pathogens.

Other Consideration Prior to Tissue Release:

Competency of staff, adequacy of resources, reputation, ethical regard, and the responsibility and authority of the requestor will be considered.