

MUSCULOSKELETAL TRANSPLANT FOUNDATION

Research Tissue Policy

I. PURPOSE

To provide human tissue for research, with priority given to allograft-related research.

II. ELIGIBILITY

All requests for tissue will be considered. Preference will be given to requests originating in MTF member institutions.

III. AVAILABILITY

Availability will be contingent on MTF inventory. If multiple requests are in progress, tissue researchers will be advised and a schedule of delivery estimated.

IV. POLICY

All researchers must give credit to the Musculoskeletal Transplant Foundation in any presentations or publications. A copy of any abstract or publication should be forwarded to MTF. Progress reports on research projects may be requested by MTF. The researcher is responsible for using appropriate precautions in handling human tissue. MTF will provide the reason for rejection of the tissue or donor if rejected tissue is supplied, and the researcher assumes responsibility for the safe handling of it.

V. PROCEDURE

All researchers must complete and submit the Request for Tissue Form, the Tissue Acceptance Form and a 1- 2 page description of the research project. Upon approval of the VP Scientific Affairs and/or Research Committee, a signed copy of the requests will be returned to the researcher, and shipment of tissues will commence. Shipping charges will be paid by MTF for researchers at member institutions. Other researchers will be responsible for their own shipping charges. (Include Federal Express account number.)



MUSCULOSKELETAL TRANSPLANT FOUNDATION
TISSUE REQUEST FORM
Form-483 Rev. 2

Date _____ E-mail Address: _____

Project
Title _____

Principal Investigator _____

Institution Name & Address _____

City _____ State _____ Zip _____

Office Telephone # _____ Fax # _____

Type of Tissue Requested _____ Total # Requested _____

MTF Product # (if applicable) _____

Donor Criteria/Donor Age Requirements: _____

Special Considerations: (ie: paired tissues) _____

Other: _____

Start Date: _____ Completion Date: _____

How Will Tissue be Disposed of? _____

Federal Express Account # _____ (for billing of shipping charges, if necessary)

***Please attach a 1-2 page description of the proposed research. Include significance, objectives, materials and methods and plans for publication.**

If approved, researchers will receive complete donor information and the reason for the rejection of the tissue with each tissue specimen sent when non-transplantable tissue is supplied. The researcher is responsible for all safety precautions appropriate to handling human tissue. *Please fill out a separate form for each tissue type requested.*

Researcher's Signature _____ Date _____

MTF EVP Donor Services _____ Date _____

Medical Director _____ Date _____

Responsible Department Head _____ Date _____

Musculoskeletal Transplant Foundation
Tissue Acceptance Waiver

_____ [Insert Name of Research Institution] ("Recipient) has been informed by the Musculoskeletal Transplant Foundation (MTF), that the human tissue to be shipped to Recipient ("Tissue") for the research purpose indicated in this application was rejected for transplant purposes due to the Tissue's failure to satisfy the current testing procedures employed by MTF.

Recipient represents and warrants that the Primary Investigator has read the current OSHA recommendation for Universal Precautions, a copy of which was provided by MTF to Recipient. Recipient recognize that the handling of the Tissue may represent a potential health hazard for any individual who may handle, test or otherwise use such Tissue, and agrees to be responsible for all safety precautions, which are appropriate for the safe handling and disposal of the Tissue. Recipient will clause the Primary Investigator to comply with his or her obligations hereunder.

Recipient and Primary Investigator agree to use the Tissue only for research purposes set forth in this application. Furthermore, Recipient and Primary Investigator agree not to transfer the Tissue to any third party without the prior written consent of MTF.

Recipient hereby assume all legal responsibilities arising out of or relating to the use and handling of the Tissue for the research purpose set forth in this application. Furthermore, Recipient hereby agree to indemnify, defend and hold MTF harmless from and against any and all liability, damages, loss or expense (including reasonable fees of attorneys and other professionals) arising from any claim, demand, action or proceedings based, arising out of or related to the use or handling of the Tissue by it or any employees, agent or contractors or the employees, agents or contractors of the laboratory or facility at which the research will be conducted.

Recipient and Primary Investigator hereby agree to comply with the terms of the MTF Research Policy, a copy of which is attached hereto.

Primary Investigator or his/her designee will accept Tissue that has been rejected in any of the categories as indicated with a "Y" or "Yes," from the list below. All rejection categories from which Recipient **does not** wish to receive Tissue are indicated with an "N" or "No."

The Primary Investigator or his/her designee will be contacted for approval prior to any shipment of Tissues to Recipient's laboratory or facility, and will have the right to refuse any Tissue that I feel is not within the best interests of the project to accept.

The following is a current list of reasons for rejection of Tissue for failure to satisfy MTF standards, which may be relevant to your work. Please mark "Y" or "N" to indicate your wishes regarding acceptance of Tissue appropriate for the research as stated within your application.

Rejection Reason	Yes/No
Disease Found at Autopsy (i.e., pneumonia, myocarditis, carcinoma, etc.)	
Microbial	
Social Risk	

A copy of the current OSHA recommendations for Universal Precautions is attached. An additional reference is: Federal Register, OSHA Regulations on Occupational Exposure to Blood Borne Pathogens, Vol. 56, No. 235, December 6, 1991. A summary of the OSHA regulations is also available through the American Association of Orthopaedic Surgeons' Office of the General Counsel.

Primary Investigator Signature _____ Date _____

MTF EVP Donor Services _____ Date _____

The current OSHA recommendations for Universal Precautions are listed below:

1. *All health-care workers should routinely use appropriate barrier precautions to prevent mucous membrane exposure when contact with blood or bodily fluid is anticipated. Gloves should be worn for touching blood and body fluids, mucous membranes, or intact skin, for handling items or surfaces soiled with blood or body fluids, and for performing venipuncture and other vascular access procedures. Gloves should be changed after contact with each patient or donor. Masks and protective eyewear or face shields should be worn during procedures that are likely to generate droplets of blood or other body fluids to prevent exposure of mucous membranes of the mouth, nose and eyes. Gowns or aprons should be worn during procedures that are likely to generate splashes of blood or other body fluids.*
2. *Hands and skin surfaces should be washed immediately and thoroughly if contaminated with blood and other body fluids. Hands should be washed immediately after gloves are removed.*
3. *All health-care workers should take precautions to prevent injuries caused by needles, scalpel, and other sharp instruments or devices during procedures; when cleaning used instruments after procedures, during disposal of used needles; and when handling sharp instruments after procedures. To prevent needlestick removed from disposable syringes and needles, scalpel blades, and other sharp items should be placed in a puncture-resistant container for transportation to the processing area.*
4. *Although saliva has not been implicated in HIV transmission, to minimize the need for emergency mouth-to-mouth resuscitation, mouthpieces, resuscitation bags, or other ventilation devices should be available for use in areas in which resuscitation is predictable.*
5. *Health-care workers who have exudative lesions or weeping dermatitis would refrain from all direct patient care and from handling patient care equipment until the condition is resolved.*
6. *Pregnant health-care workers are not known to be at greater risk for contracting HIV infections than health-care workers who are not pregnant; however, if a health-care worker develops HIV infections during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health-care workers should especially be familiar with and strictly adhere to precautions to minimize the risk of HIV transmission.*