INTERNATIONAL INSTITUTE FOR THE ADVANCEMENT OF MEDICINE
NON-DISTRIBUTOR APPLICATION AND AGREEMENT FOR HUMAN BIOLOGICAL MATERIALS
FOR RESEARCH USE

International Institute for the Advancement of Medicine (IIAM)
Research Biomaterials Policy

I. PURPOSE
To provide non-transplantable, human biomaterials for medical research, education and development, and other uses demonstrating scientific merit.

II. AVAILABILITY
All requests for biomaterials will be considered. Availability will be contingent on donor referrals and criteria.

III. PROCEDURE
All applicants must complete and submit the IIAM Application/Biomaterials Transfer Agreement (BMTA), and Exhibits A-C.

IV. BIOMATERIALS USE
Biomaterials shall be used only for the purposes cited in the Application, and may not be transferred to a 3rd party without prior written authorization from IIAM.

V. RESEARCH PRECAUTIONS
IIAM will provide documentation of serological test results, and other donor demographic information. Researcher is responsible for using appropriate precautions in handling human biomaterials.

VI. RECORD KEEPING
Applicant agrees to maintain and provide upon request by IIAM a timely and complete accounting of biomaterials received. This information shall be used in part to ensure adequate tracking of biomaterials, and can be made available for inspection by any regulatory agency. Upon approval of IIAM’s Application Review Committee, an executed copy of the BMTA will be returned to the applicant/researcher, and biomaterial placement will commence.

VII. ACKNOWLEDGEMENT
All researchers must acknowledge IIAM in any presentations or publications. A copy of any published material should be forwarded to IIAM.
I. APPLICANT DATA

RESEARCHER INFORMATION

Name of Researcher: ________________________________  Phone (day): ________________________________
Institution Name or Corporation Name: ____________________________  (Nights/weekends): ________________________________
Is institution a non-profit organization?  □ Yes  □ No
Name and mailing address: ________________________________  Fax: ________________________________
E-mail address: ________________________________  Add'l contact: ________________________________
Phone (day): ________________________________  (Nights/weekends): ________________________________

II. HUMAN BIOMATERIALS

Description of Biomaterials requested: ________________________________
Specimen size or weight: ________________________________
Number of samples, frequency & duration, proposed start date: ________________________________

Source of Specimens and Condition of Biomaterials Requested:

□  Organ donor: non-transplantable organs recovered under sterile conditions within 0-60 minutes of cessation of cardiovascular circulation, and typically delivered to researcher within 12-48 hours from aortic cross-clamp. Please indicate acceptable time from cross-clamp to delivery; up to ____ hours

Disease Screening:

IIAM requires that all biomaterials provided for research are obtained from donors after receiving appropriate authorization for donation, a detailed medical/social history screening and serological testing. Serological testing is included as part of IIAM’s service, and is administered for: Anti-HIV I-II, HBsAg, HBcAb, Anti-HCV, Syphilis, Anti-CMV and EBV
These test results can be provided to Applicant if desired but should never be considered conclusive. Biomaterials from a donor testing positive for any of the infectious diseases (e.g. Anti-HCV) in the standard panel will not be shipped unless specific written authorization is obtained from the Applicant at that time. Please check all that apply:

- Standard infectious disease screening panel (listed above)
- Please include the following tests in addition to the standard panel (extra charge): __________________________
- Biomaterials from donors testing positive for the presence of one or more infectious agents are acceptable because:

III. PRESERVATION METHODS

- Fresh; stored in preservation solution and shipped on wet ice. (UW and HTK are considered industry-standard for preservation and are the primary preservation solutions used in IIAM's Organ Division.)
- Other media: Please list below. Researcher may be required to supply any non-standard preservation media or fixatives:

IV. RESEARCH PROJECT

Title:

Use of biomaterials (complete attached Exhibit A for detailed summary):

Funding Source (and identification number, if applicable):

Institutional Review Board (IRB) approval: If required by APPLICANT'S institution, please attach letter of approval or exemption from your IRB.

IRB Alternative: If IRB approval is not required by APPLICANT’S institution, it is incumbent on the researcher to obtain approval from his/her supervisor or the authority designated to undertake and review the proposed research, whose signature is required on page 6 of the Biological Materials Transfer Agreement.
MASTER AGREEMENT

This BIOLOGICAL MATERIALS TRANSFER AGREEMENT (the Agreement) is made this ___ day of ___________ (Year) __________ by and between __________________________, hereinafter referred to as “APPLICANT”, and the Musculoskeletal Transplant Foundation, a District of Columbia non-profit organization (“MTF”) acting by and through the International Institute for the Advancement of Medicine, an unincorporated division of MTF (“IIAM”).

WHEREAS MTF, acting by and through IIAM, acquires or procures and distributes non-transplantable human biomaterials (hereinafter “biomaterials”) for the advancement of medical research, education, and development, and other approved uses;

WHEREAS, APPLICANT desires IIAM’s services in obtaining such biomaterials; and

WHEREAS, the parties desire to cooperate for the purposes of providing APPLICANT with such biomaterials,

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements hereinafter set forth and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereby agree as follows:

1) **a)** APPLICANT agrees to pay service fees (“Service Fees”) to IIAM for its biomaterials acquisition, processing, preservation, storage and delivery charges as set forth on Exhibit C attached hereto, and which may be amended by IIAM from time to time, provided that any such changes in the Service Fees shall only be effective on 30 day written notice.

2) **a)** APPLICANT agrees to pay service fees (“Service Fees”) to IIAM for its biomaterials acquisition, processing, preservation, storage and delivery charges as set forth on Exhibit C attached hereto, and which may be amended by IIAM from time to time, provided that any such changes in the Service Fees shall only be effective on 30 day written notice.

b) Payment terms are net thirty (30) days.

c) APPLICANT will receive a 100% credit for the Service Fee of IIAM biomaterials if the biomaterials fall outside of the APPLICANT’S approved protocol, provided that the Applicant notify IIAM within 24 hours of receiving the biomaterials. In the event that IIAM is not notified within 24 hours of biomaterial receipt, the credit may be reduced by at least 50% subject to IIAM’s sole judgment. APPLICANT shall either destroy the biomaterials at its facility in accordance with local, state and federal regulations or, if APPLICANT is unable
to destroy the biomaterials, APPLICANT may return the biomaterials to IIAM, with prior permission from IIAM, within five business days of delivery to APPLICANT. IIAM is responsible for the costs of transportation and tissue destruction in such cases.

3) IIAM represents and warrants that it has reviewed consent or authorization for research from the donor or authorizing party which was obtained, to the best of IIAM's knowledge, in accordance with all applicable state and federal laws and regulations prior to recovery and distribution. IIAM will maintain approved protocols, consent or authorization forms for biomaterial acquisition for research.

4) APPLICANT hereby makes the following representations and warranties to IIAM:

   a) APPLICANT will not transfer any biomaterials or biomaterial progeny (as defined in Section 1 of the Agreement) received from IIAM to any third party without prior written authorization from IIAM.

   b) APPLICANT agrees to maintain and provide upon request by IIAM a timely and complete accounting of biomaterials being used. This information shall be used in part to ensure adequate tracking of biomaterials, and may be made available for inspection by any regulatory agency.

   c) APPLICANT or anyone on its behalf will not intentionally contact or acquire human biomaterials from IIAM's sources, which are available upon request, during the term of the Agreement or any extension thereof and for a period of two (2) years thereafter. This restriction does not apply to those IIAM sources with whom the APPLICANT previously had a biomaterials acquisition or procurement agreement prior to the execution date of this Agreement. Furthermore, this restriction shall not apply if during such period IIAM ceases to exist or ceases to engage in the supply of human biomaterials.

   d) APPLICANT'S employees, representatives, and agents shall handle human biomaterials obtained under this Agreement using universal precautions, as mandated by the U.S. Occupational Safety and Health Administration Bloodborne Pathogens Final Standard (OSHA). APPLICANT and its employees, representatives and agents shall use, handle, store and dispose of all human biomaterials supplied to APPLICANT pursuant to this Agreement in compliance with all applicable local, state, and federal statutes, laws, rules and regulations including but not limited to OSHA.

   e) During the term of this Agreement, APPLICANT will utilize the services of an entity authorized under applicable law to dispose of the biological materials provided by IIAM. APPLICANT agrees to use the entity listed on the attached Biomaterials Request Form to dispose of all biological materials provided by IIAM to APPLICANT pursuant to this Agreement.

   f) APPLICANT shall not use or store any biological materials in any facility other than one primarily used as a medical facility or laboratory (a "Medical Facility"), unless prior to utilizing such biological materials: (i) APPLICANT requests in writing that IIAM permit the use of such biological materials in a facility other than a Medical Facility (a "Non-Medical Facility"), and indicates the proposed use of such biological materials as well as how they will be disposed, and (ii) the owner or operator of said Non-Medical Facility provides to IIAM a written certification that (X) such owner or operator is aware of the proposed use of such biological materials in said Non-Medical Facility, (Y) such owner or operator consents to such use in the Non-Medical Facility, and (Z) the proposed use of such biological materials in said Non-Medical Facility is permitted under applicable law.

   g) APPLICANT may request that IIAM and IIAM, at its sole discretion, may agree to dispose of biological material provided by IIAM to APPLICANT pursuant to this Agreement. In the event IIAM agrees to dispose of any such biological materials, APPLICANT shall arrange for the shipment of such biological materials to IIAM or an IIAM designated facility (as directed by IIAM) in accordance with all applicable laws, including proper wrapping and containment of all such biological materials to ensure their safe shipment.
APPLICANT agrees to pay all shipping costs and IIAM’s fees related to the disposal of any such biological materials.

h) APPLICANT shall not identify or attempt to identify the donor of any biomaterials provided by IIAM.

i) All statements in the Application are complete and correct.

5) All shipments of biomaterials shall be made on the following terms:

   a) Shipments will be made in the best possible manner so as to preserve the quality of the biomaterials. The parties hereto understand that the fragility of human biomaterials is such that damage may occur during shipment; nevertheless, IIAM shall use its best efforts to comply with the handling and shipping protocols provided by APPLICANT.

   b) Except as otherwise expressly stated herein, all biomaterials are provided by IIAM “as is” and without additional warranty. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ARE DISCLAIMED.

6) APPLICANT will acknowledge IIAM as a provider of human biomaterials and agrees to provide IIAM with a copy of any non-confidential publication that makes reference to IIAM.

7) a) APPLICANT will indemnify and save harmless IIAM and their respective officers, directors, agents, employees, consultants and/or IIAM’s human biomaterials sources from any actual loss or damage resulting from the use by APPLICANT of human biomaterials specimens provided by IIAM or IIAM’s human biomaterials sources, except for loss or damage resulting from any breach of warranties or representations made by IIAM in this Agreement or as a result of IIAM’s gross negligence or willful misconduct in performing its obligations hereunder.

   b) IIAM will indemnify and save harmless APPLICANT and its respective officers, directors, agents, employees, and/or consultants from any actual loss or damage arising from IIAM’s performance of this Agreement except for loss or damage resulting from any breach of warranties or representations made by APPLICANT in this Agreement or as a result of APPLICANT’S gross negligence or willful misconduct in performing its obligations hereunder.

8) a) All medical or other information relating to a donor shall be treated as Confidential Information of each party, and notwithstanding any provision to the contrary continued herein, shall not be disclosed except to the extent otherwise required or permitted by law. Both parties to this Agreement shall act, and shall take reasonable measures to cause their respective agents, contractors, employees, officers and directors to act, in accordance with all applicable laws, rules and regulations regarding the confidentiality of donor specific medical information. This obligation shall expressly survive termination of this Agreement.

   b) Each party understands that the other party and its agents, contractors, employees, officers and directors will or may be provided valuable technical and non-technical information and trade secrets relating to, among other things, the referral, recovery and use of biomaterials and/or medical or other information relating to donors (“Confidential Information”) that is proprietary and valuable to the disclosing party (the “Disclosing Party”) and that to protect the Disclosing Party’s legitimate interests, the Disclosing Party must protect such Confidential Information. Therefore, the receiving party (the “Receiving Party”) will hold in confidence and not disclose to third parties or use any such Confidential Information except in connection with the performance of its obligations hereunder, and will take reasonable steps to cause its agents, contractors, employees, officers and directors to hold in confidence and not disclose to third parties or use any Confidential Information except in connection with the performance of the Receiving Party’s obligations.
The Receiving Party agrees that the Disclosing Party's failure to mark any such information as "Confidential Information" shall not relieve the Receiving Party of its obligation to treat such information as Confidential Information.

c) The Receiving Party shall cause each of its agents, contractors, employees and officers who have access to Confidential Information to enter into a confidentiality agreement containing confidentiality provisions comparable to those set forth herein. The provisions of this paragraph shall not apply to any information that is in the public domain, is known to the Receiving Party at the time of its disclosure, is acquired or developed by the Receiving Party following disclosure without violation of this Agreement or is disclosed by the Disclosing Party to any third party without similar non-disclosure restrictions.

d) The Receiving Party shall promptly notify the Disclosing Party if the Receiving Party receives a subpoena seeking any Confidential Information so that the Disclosing Party has an opportunity to take appropriate action with the entity issuing the subpoena before any such Confidential Information is released. The parties agree that the terms and conditions of this Agreement will be considered Confidential Information.

9) The term of this Agreement shall be one (1) year beginning on the date of execution and automatically continuing for further successive terms of one (1) year thereafter, unless either of the parties hereto shall have given to the other thirty (30) days prior written notice (by certified mail at their respective addresses listed at the end hereof, return receipt requested) of its intention to terminate this Agreement, whereupon this Agreement shall terminate thirty (30) days after receipt of such notice. Termination shall not relieve the parties hereto of any of their obligations by the nature thereof extending past such termination.

10) a) This Agreement may not be amended without the prior written consent of both parties hereto.

b) This Agreement and the Application attached hereto constitutes the entire agreement between the parties hereto relating to the subject matter hereof, and supersedes any prior agreements, written or oral, regarding the subject matter hereof.

c) This Agreement will be binding upon and inure to the benefit of the parties hereto and their respective heirs, successors and assignees; provided, however, that neither party shall transfer or assign this Agreement or their rights and obligations hereunder, including by merger or operation of law, with a change of control of APPLICANT constituting an assignment for purposes of this Agreement, without the prior written consent of the other party.

d) This Agreement shall be construed and interpreted in accordance with the laws of the State of New Jersey.

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement.

RESEARCHER:
Print name/title: ____________________________ Date: ____________________________
Signature: ____________________________

RESPONSIBLE DEPARTMENT HEAD:
Print name/title: ____________________________ Date: ____________________________
Signature: ____________________________

MUSCULOSKELETAL TRANSPLANT FOUNDATION:
Print name/title: ____________________________ Date: ____________________________
Signature: ____________________________
Reseacher __________________________ Date of Request ______________ Application Request ID # ______________

Approved by IIAM Application Review Committee:

By: ____________________________ Date: __________________________
   Responsible Department Head

By: ____________________________ Date: __________________________
   Medical Director

By: ____________________________ Date: __________________________
   IIAM

By: ____________________________ Date: __________________________
   (Ad Hoc External Review Committee)

By: ____________________________ Date: __________________________
   (Ethics Committee Review - Optional)
**Exhibit A - Synopsis of Research**

to be completed by the Researcher/Applicant

**SPECIFIC AIM:**

**LONG TERM OBJECTIVE:**

**SUMMARY:** (Please describe this in laymen's terms to be shared with our donor families).
IIAM Biomaterials Request Form-Exhibit B

Date of Request ________ Requested by ________________ Application # (IIAM Use Only) ______

SHIP TO:

Name of Institute & Address:
____________________________________________________________________________
____________________________________________________________________________
City: _______________ State: _______________ Zip: _______________
Attention: ___________________________ Phone Number: (_____) _______________________

Do you have an account with Sterling Courier (IIAM’s preferred courier): Yes ___ No ___
If “yes,” please provide the Sterling Courier Account Number:
____________________________________________________________________________

Accept Weekend Deliveries? Yes ___ No ___
Accept Sunday referral for Monday delivery? Yes ___ No ___

ACCOUNTS PAYABLE:

Name of Institute:
____________________________________________________________________________
Billing Address:
____________________________________________________________________________
City: ___________________________ State: ___________________ Zip: ___________________
Contact: ___________________________ Phone Number: (_____) _______________________
Fax Number: (_____) ___________________________
Email: ___________________________

Purchase Order Number:
____________________________________________________________________________
(Please verify with your accounting department; if P.O. is not required, please indicate “N/A”)

DISPOSAL OF MEDICAL WASTE: Disposed of by Applicant’s Designated Medical Waste Agent:
Exhibit C –2013 Fee Schedule

Organ: 

Service Fee: $75/ per shipment (to cover costs for shipping materials & follow-up information including the Donor Demographic Form with all pertinent medical information)

Shipping: Shipping costs vary depending on weight, courier and destination. Estimates available upon request.

Fee Acknowledgement: Please initial and return to IIAM ______

IIAM Payment Information

IIAM does not accept credit cards as a form of payment. To discuss other payment options, please contact Annemarie Graci at 800-946-9008 ext. 2208.

Payment Remittance Address

International Institute for the Advancement of Medicine (IIAM)
P.O. Box 415911
Boston, MA 02241

Electronic Funds Transfer Information

Bank Name: Bank of America, NA
Account Type: Checking
Currency: USD
Bank Identifier
FOR WIRE TRANSFERS: (ABA#) 026009593
FOR ACH: 021200339

Account Name: Musculoskeletal Transplant Foundation Operating Account
Account Number: 0977707245

Bank Address:
3670 Route 9 South
Freehold, NJ 07728
Swift Code: BofAUS3N