

IIAM
INTERNATIONAL INSTITUTE FOR THE ADVANCEMENT OF MEDICINE
APPLICATION AND AGREEMENT FOR HUMAN BIOLOGICAL MATERIALS FOR RESEARCH USE

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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; such third party end-user shall have clearly demonstrated scientific, medical, or educational use for the biomaterials through written or electronic documentation. Notwithstanding the foregoing, IIAM consents to Applicant's use of biomaterials as described in and pursuant to Exhibit A attached hereto. This information shall be used in part to ensure adequate tracking of biomaterials, and can be made available for inspection by any regulatory agency.

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

Fax: _____

Name and mailing address: _____

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: _____

Preferred Source(s) of Specimens and Condition of Biomaterials Requested:

- Organ donor (**from IIAM's Organ Division only**): 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
- Deceased donor (**from IIAM's Anatomical Division only**): biomaterials are typically recovered under clean, non-sterile conditions within 24-96 hours post-mortem. Please indicate acceptable period of post-mortem time; up to ____ hours

Disease Screening:

IIAM requires that all biomaterials provided for research are obtained from donors after receiving appropriate consent or 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:

Organ Division: Anti-HIV I-II, HBsAg, HBcAb, Anti-HCV, Anti-HTLV I-II, RPR, Anti-CMV and EBV

Anatomical Division: Anti-HIV I-II, HBsAg, Anti-HCV, RPR, and HB core Antibody IgM

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.)
- Passive freezing at -20° C and shipped on dry ice (the primary mode of preservation used in IIAM's Anatomical Division).
***Fixative, Medium, or Other Requirements** (if other than those listed above. * 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): IIAM consents to Applicant's use of biomaterials as described in and pursuant to the Synopsis of Research attached hereto as Exhibit A, subject to the conditions therein.

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 7 of the Biological Materials Transfer Agreement.

**IIAM, INTERNATIONAL INSTITUTE FOR THE ADVANCEMENT OF MEDICINE
DISTRIBUTOR APPLICATION AND AGREEMENT FOR HUMAN BIOLOGICAL MATERIALS
FOR RESEARCH USE**

BIOLOGICAL MATERIALS TRANSFER 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) During the term of this Agreement, IIAM will use reasonable efforts to provide biomaterials suitable, in its sole judgment, and that meet criteria provided by the APPLICANT in the Biomaterials Request Form, which is attached hereto as Exhibit B, for APPLICANT’s requirements and in the amounts requested. IIAM acknowledges that APPLICANT’s needs are subject to change; such changes will be communicated via an updated Exhibit B. This Agreement and any transfer of biomaterials made pursuant hereto constitutes a limited and conditional license to APPLICANT for use of the biomaterials or biomaterial progeny (cells, cell lines, subcellular fractions, isolates, or recombinant materials, DNA, RNA, or any derivatives thereof), and use thereof shall be limited to the specific use set forth in APPLICANT’s Application and Agreement for Human Biological Materials for Research Use to which this Agreement is attached. Uses of immortalized or cloned material are prohibited unless prior written consent is obtained from IIAM. Use of human biomaterials as a therapy is strictly prohibited without prior written authorization from IIAM. In addition, except as set forth in Exhibit A attached hereto, the APPLICANT’s use of biomaterials shall not be subject to any licensing, contractual, or consulting obligation to another party without IIAM’s prior written consent, which may be withheld in IIAM’s sole discretion, except that APPLICANT may share the data and results with third parties. Notwithstanding the foregoing, IIAM consents to Applicant’s use of biomaterials as described in and pursuant to Exhibit A attached hereto.
- 2) 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 next-of-kin 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 except in accordance with and subject to the conditions set forth in Exhibit A.

- 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 three (3) 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 and this Agreement including as contemplated by Exhibit A. 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 hereunder. 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 Confidential Information to enter into a confidentiality agreement that contain 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. The Agreement may also be terminated by either party before the end of an annual term by giving the other thirty (30) days prior written notice 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: _____
Signature: _____ Date: _____

MUSCULOSKELETAL TRANSPLANT FOUNDATION:

Print name/title: _____
Signature: _____ Date: _____

RESPONSIBLE DEPARTMENT HEAD:

Print name/title: _____
Signature: _____ Date: _____

IIAM Internal Use ONLY

Researcher _____ Date of Request _____ Research 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 Researcher/Applicant)

SUMMARY:

... IIAM approves of this research and the distribution of IIAM materials provided, however, that no such IIAM supplied biomaterials including, without limitation, unprocessed human biomaterials or any processed biomaterial constituents (cells, cell lines, subcellular fractions, isolates, or recombinant materials, DNA, RNA, or any derivatives thereof), shall be made available or provided by APPLICANT to any third party other than pursuant to a written contract obligating the counter-party thereto to use any such biomaterials and any product or other derivative therefrom (i) for research purposes only, (ii) in compliance with any applicable foreign, federal, provincial or state law, rule or regulation and (iii) in compliance with any rule or regulation disseminated by a non-governmental regulatory body that is applicable to such third party and its use of such biomaterials or product or derivative therefrom, and provided, further, that upon request from IIAM, APPLICANT will provide evidence reasonably satisfactory to IIAM that APPLICANT has complied with such requirements with respect to provision of such biomaterials to third parties.

SPECIFIC AIM:

LONG TERM OBJECTIVE: