



Biosample Request Form
Female Tissue Acquisition Core

Contact:

Purnima Ghose, Post doc.

Office: (615) 327-6698

Lab Hours: 8:00 am – 4:30 pm

Save form then fill out (* **required**). Email as attachment to pghose@mmc.edu

- I. DIRECTIONS** -This application is intended for the use and processing of samples utilized by the laboratory and/or personnel that fall under the supervision of the PI listed in the application. Any transfer of samples or aliquots to personnel or laboratories that are not under the supervision of the indicated PI requires the following:
- An explanation of the need to transfer the materials and benefit to the investigator’s research
 - A copy of the enclosed Meharry Medical College-Female Tissue Acquisition Core (MMC-FTAC) agreement page signed by the collaborator
 - A copy of the collaborator’s IRB approval unless the collaborator is covered under the IRB approval granted for the project proposed in this application

The MMC-FTAC does not supply samples to banks solely for distribution to third party researchers; those researchers should be encouraged to apply to the MMC-FTAC directly.

The information requested in these forms is necessary in order to document correctly your request for tissue and other services and to ensure that the MMC-FTAC operates within the guidelines of the NIH/NIHMD.

When submitting a written request for services:

- A. Please print neatly or type.
- B. Please be specific about your requirements for handling tissue samples from the time the specimen is collected until it is delivered to your lab (i.e., need for sterility, transport media, refrigeration status, etc.).
- C. Patient identity is confidential. Samples will be coded and delivered at a processing fee of \$30/sample for researchers at academic institutions and \$70/sample for researchers at non-academic institutions, plus shipping costs. Additional charges may be assessed for special preparation.
- D. **Investigators must have human use approval to receive tissue from the MMC- FTAC. Either full or expedited approval can be obtained from your Institutional Review Board (Human Use Committee). A COPY OF THE HUMAN SUBJECTS APPROVAL SHOULD BE ATTACHED TO THIS FORM.** A human subject’s review is required and must be forwarded to the MMC-FTAC in order to maintain your eligibility to receive tissue.

II. INVESTIGATOR DATA

A. Principal Investigator:

Last Name: First Name: Middle Initial:

Investigator's Title:

Primary Mailing Address:

Street/Bldg./Room: Department:

Institution/Company:

City: State: Zip:

Phone (Day): (Nights/Weekends):

FAX Number at which you may be notified:

Contact Person Lab/Phone or e-mail:

B. Shipping Address (if different from above):

Name:

Street/Bldg./Room: Department:

Institution/Company:

City: State: Zip:

C. Billing Information:

Is purchase order (PO) /VR # (VICTR) required for shipment of specimens to your institution?

No Yes if yes, please list name of contact for P.O. /VR:

Name:

Phone:

**Currently invoices are included with the tissue shipment to the shipping address listed above.
Please complete the address below for original invoice to be mailed to another location (e.g. your billing department).
A copy of the invoice will also be included with your shipment.**

Billing Address (if different from the shipping address):

Street/Bldg./Room:

Department:

Institution/Company:

City:

State:

Zip:

(Shipping charges will be added to your invoice unless you provide a Federal Express number.)

Federal Express Number:

III. FUNDING INFORMATION

Tissues will be provided to investigators in the following priority order:

1. Peer reviewed funded investigators (including Federal and National laboratories)
2. New investigators and academic investigators developing new research projects.
3. Other investigators

A. To help determine your priority, please include your major research grant. Institutional and other funding sources may also be listed. If you are currently unfunded, please indicate below:

Funding Source and Period of Support:

- | | |
|----|----|
| 1. | 3. |
| 2. | 4. |

B. Please provide the title and a short research summary of the proposed research on the tissues you are requesting from the MMC- FTAC (use separate page if required).

IV. TISSUE SPECIFICS (Please copy this page as needed for multiple requests):

A. Human Tissue Specimen Request Criteria

1. Anatomic Site or Tissue Type:

Malignant; specify:

Benign

Normal

Diseased

Other Specify:

2. Is matched normal tissue from the same patient a must?

3. Accept tissues from patients previously treated with:

4. Must specimen be sterile?

5. Tissue Source: Surgical: Must be frozen within _____ hours of surgery or
time constraint not applicable
Autopsy: Must be collected within _____ hours after death

6. Tissue Details_ Age range:

Race:

Other limiting characteristics:

7. Amount of tissue required (minimum to maximum size or dimension):

8. Frequency tissue is needed:

9. Total number of samples needed:

10. Requested starting date to receive tissue:

B. **Preparation and Preservation of Samples :**

(Check those that apply, all media should be supplied by the requestor)

Fresh: Indicate Transport Media :

Shipping Requirements (dry ice, ice, etc) :

Frozen: Indicate freezing requirements (fresh-frozen, OCT, etc.):

Fixed: Indicate fixative requirements (10% NBF, etc.):

Will you accept Saturday deliveries, if notified? Yes; No; Sometimes.

C. Required Sample Information: (*Anatomic site of tissue, provisional diagnosis, final diagnosis, quality control diagnosis and patient age, sex and race [if available] will be provided for all samples.*) Request for **additional information must be made at the time of application submission. Requests for additional information cannot be accepted after the application has been processed. (NOTE: please notify your division coordinator ASAP if your needs change).**

AGREEMENT and ACKNOWLEDGEMENT FOR USE OF TISSUE

The recipient/investigator agrees that the tissues provided by the Meharry Medical College- Female Tissue Acquisition Core (MMC-FTAC) will be used only for the purposes specified in this application. The recipient agrees not to attempt to obtain information identifying the individuals providing tissues to the MMC-FTAC. The recipient agrees that it shall not sell any portion of the tissues provided by the MMC-FTAC, or products directly extracted from these tissues (e.g. protein, mRNA or DNA). The recipient agrees that it shall not transfer tissue (or any portion thereof) supplied by the MMC-FTAC to third parties without the prior written permission of the MMC-FTAC.

The recipient understands that while the MMC-FTAC attempts to avoid providing tissues that are contaminated with highly infectious agents such as hepatitis and HIV, all tissues should be handled as if potentially infectious. The individuals who have supplied tissue to the MMC-FTAC have not agreed to have clinical tests performed on this tissue (e.g. for the presence of infective agents such as hepatitis), therefore, the recipient agrees not to perform such tests on the tissues supplied by the MMC-FTAC. The recipient acknowledges that the institution where the tissue will be used follows OSHA regulations for handling human specimens and will instruct their staff to abide by those rules. The recipient further agrees to assume all responsibility for informing and training personnel in the dangers and procedures for safe handling of human tissues.

Tissues are provided as a service to the research community without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied. The MMC-FTAC accepts no responsibility for any injury (including death) damages or loss that may arise either directly or indirectly from their use.

The recipient agrees to acknowledge the contributions of the Meharry Medical College- Female Tissue Acquisition Core in all publications resulting from the use of these tissues. Recommended wording to the methods or acknowledgement section is as follows: "Tissue Samples / all histology / immunohistochemistry services were provided by the Meharry Medical College Female Tissue Acquisition Core which is funded by the RCMI Grant (5G12 MD007586-29NIH / NIMHD)"

When tissue is to be used at State Institutions: The institution agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage or loss that may arise solely from the receipt, handling, storage and use of tissues received from the MMC-FTAC to the extent permitted under the laws of this State. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.

When tissue is to be used at U.S. Government Agencies: The US government assumes all risks and responsibilities in connection with the receipt, handling, storage and use of tissues received from the Meharry Medical College- Female Tissue Acquisition Core. The United States assumes liability for any claims, damages, injury or expense arising from the use of the material or any derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chap. 171).

When tissue is to be used by all other institutions: The institution agrees to assume all risks and responsibility in connection with the receipt, handling, storage and use of tissues from the Meharry Medical College- Female Tissue Acquisition Core. It further agrees to indemnify and hold harmless the Meharry Medical College- Female Tissue Acquisition Core and the United States Government from any claims costs, damages or expenses resulting from the use of the tissues provided by the MMC-FTAC. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.

BY MY SIGNATURE I AGREE TO THE TERMS SET FORTH IN THE ABOVE AGREEMENT

Typed Name of Recipient:

Digital Signature Required as well as written

* Recipient Date:

Division or Department:

UPON RECEIPT OF THESE SIGNED UNDERSTANDINGS AND THE INFORMATION REQUESTED ABOVE, MEHARRY MEDICAL COLLEGE - FEMALE TISSUE ACQUISITION SHARED RESOURCE WILL CONSIDER THIS REQUEST AND ALL FUTURE REQUESTS FOR TISSUE. Specific questions about your application should be directed to your regional coordinator. Other questions may be directed to the Dr. Billy R. Ballard, DDS, MD, Program Director at (615)327-6663 or Dr. Purnima Ghose at (615)327-6898

DATA USE AGREEMENT BETWEEN MEHARRY MEDICAL COLLEGE- FEMALE TISSUE ACQUISITION CORE (MMC-FTAC) INSTITUTIONS PROVIDING A LIMITED DATA SET AND LIMITED DATA SET RECIPIENTS

This Data Use Agreement (“Agreement”) is designed to permit the use of a Limited Data Set for research pursuant to the Standards for Privacy of Individually Identifiable Health Information, (Privacy Rule) 45 CFR Parts 160 and 164. All terms used in this agreement are as defined in the Privacy Rule.

This Agreement is made and entered into as of _____ by Meharry Medical College_Female Tissue Acquisition Core and _____ "Data Recipient".

1. This Agreement sets forth the terms and conditions pursuant to which the Covered Entities will Disclose certain Protected Health Information (PHI) to the Data Recipient. PHI may include associated histopathology, demographic, and clinical data that have been rendered a Limited Data set in compliance with 45 CFR 164.514(e) (1).
2. Except as otherwise specified herein, the Data Recipient may make Uses and Disclosures of the Limited Data Set consistent with the purpose of the research as described within their research application to the MMC-FTAC.
3. The individuals, or classes of individuals, who are permitted to Use or receive the Limited Data Set include the Data Recipient and other researchers or individuals directly involved with the research project described within their research application to the MMC-FTAC.
4. The Data Recipient agrees to not Use or Disclose the Limited Data Set for any purpose other than the Research Project or as Required by Law.
5. The Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement.
6. The Data Recipient agrees to report to the Covered Entities any Use or Disclosure of the Limited Data Set not provided for by this Agreement, of which it becomes aware, including without limitation, any Disclosure of PHI to an unauthorized subcontractor.
7. The Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set, agrees to the same restrictions and conditions that apply through this Agreement to the Data Recipient with respect to such information.
8. The Data Recipient agrees not to attempt to identify or contact the individual(s) to whom the Limited Data Set applies.
9. This agreement may be terminated by the Covered Entities upon five (5) days written notice to the Data Recipient if the Data Recipient materially breaches any provision contained in this Agreement and such breach is not cured within the five (5) day period. The Data Recipient acknowledges that if efforts to cure the breach are unsuccessful, the Covered Entities may discontinue disclosure of Protected Health Information and report the problem to the Secretary of the Department of Health and Human Services.
10. The terms of this agreement can be changed only by written modification signed by both parties.

Initials of Data Recipient:

Signature of Data Recipient:

Name of Principal Investigator (Typed or Printed)

Date:

Core Use:

MMC-FTAC APPLICATION

This page should accompany this application for your request. Once reviewed, you will be notified by email whether your application was approved or denied.

Application Received By:

Date:

IRB for Human Subjects Use received: Yes or No

Human Subjects Agreement received and signed: Yes or No

Data Us Agreement received and signed: Yes or No

Application approved:

Approved By:

Date:

Application denied:

Denied By:

Date:

Please give brief detail to explain why the application was denied.