|  |  |
| --- | --- |
| **Application Received** |  |
| **Reviewed & Approved** |  |

Core **Services**

**TITLE OF STUDY:**

**APPLICATION PROCESS**:

1. Complete sections 1–10, sign and date
2. Submit to Dr. Richard Kew at richard.kew@stonybrookmedicine.edu
3. Review by [BioBank Advisory Committee](http://medicine.stonybrookmedicine.edu/pathology/biobank/about) (BAC) ***or*** Digestive Diseases Review Committee
4. Database query for availability of biospecimens and data
5. Approval by BAC
6. Submission of IRB protocol (or exempt method)
7. Completion of MTA
8. Agreement of terms and conditions
9. Arrangements for biospecimen delivery

**1. INVESTIGATOR DATA**

**Project PI:**

**Institution: Department:**

**Email:**

**Phone:**

**2. EXPLANATION OF PROPOSED STUDY (please use page 2)**

**Request biological material from: General Biobank­­­ \_\_\_\_ Digestive Diseases Biobank \_\_\_\_**

**Please provide the following information for the scientific review of the request:**

* 1. **Research hypothesis/objective**
  2. **Study design**
  3. **Materials requested**
  4. **Sample size/statistics**
  5. **Completion of study timeline**
  6. **Funding source**
  7. **IRB Authorization**

**EXPLANATION OF PROPOSED STUDY (continued – Use additional page if necessary)**

**3. TISSUE REQUEST**

(\*These request types will be forwarded to SBUM Pathology Research Histology Core and you will receive a separate bill for those)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Benign** |  | **Malignant** |  |
|  | **Tissue Type** | **Quantity** | **Tissue Type** | **Quantity** |
| Live cells |  |  |  |  |
| Fresh tissue |  |  |  |  |
| Snap-frozen tissue |  |  |  |  |
| OCT tissue blocks |  |  |  |  |
| \*FFPE blocks TMA slides |  |  |  |  |
| \*TMA slides |  |  |  |  |
| \*FFPE cores |  |  |  |  |
| \*FFPE unstained slides |  |  |  |  |
| \*H&E slides |  |  |  |  |
| \*Other (please specify) |  |  |  |  |

**4**. **BLOOD REQUEST**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Quantity** | **(μl)** | **Quantity** | **(μl)** |
| Serum |  |  |  |  |
| Plasma (EDTA) |  |  |  |  |
| Plasma (Heparin) |  |  |  |  |
| Whole blood |  |  |  |  |
| Buffycoat |  |  |  |  |
| Cryopreserved cells |  |  |  |  |
| Other (please specify) |  |  |  |  |

**5. DATA REQUEST**

Please describe in detail (use separate sheet) the use of data requested and check appropriate data request:

* Disease type – Details: (e.g Late stage breast cancer)
* Gender and age in years
* Pathology results

D A

**6. FUNDING INFORMATION**

Tissues will be provided to investigators based on review by the BioBank Advisory Committee (BAC). The information on pertinent funding to conduct the research described in this application should be provided to the review committee. Pilot studies do not require funding information. Shipment of specimens will occur upon confirmation of payment source.

* Pilot Study
* Regular Study. Funding Source:

**Budget number for BioBank charges:**

**Grant Sponsor:**

* + 1. **Principal Investigator:**
    2. **Date of award:**
    3. **Award Period:**

**7. BILLING AND SHIPPING INFORMATION**

There is a handling and processing fee for each specimen (please see fee structure on website). If the specimens are to be sent outside Stony Brook University Campus, you will receive an invoice with the shipment of the specimens. The invoice is payable within 60 days.

Is a purchase order (P.O.) required for shipment of specimens to your institution?

* Yes
* No
* If yes, please list name of contact for P.O.

Name:

Phone:

Currently, invoices are included with the tissue shipment to the shipping address listed above. If you would like the original invoice to be mailed to another location (e.g., your billing department), please enter that address below. A copy of the invoice will also be included with your shipment.

**SHIPPING ADDRESS**(if different from above):

Department:

Street:

Building: Room:

City: State:

**ZIP:**

(Shipping charges will be added to your invoice unless you provide a FedEx or UPS number.)

**FedEx/UPS number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**TERMS AND CONDITIONS**

**SPECIMEN USE BY GROUP(S) OTHER THAN PI APPLICANT**

This application is limited to samples that will be utilized by the laboratory and/or personnel under the supervision of the PI listed in the application. If the research described above contemplates the transfer of samples or aliquots to personnel or laboratories that are not under the direct supervision of the PI applicant, the following information must be provided:

a. An explanation of the need to transfer the materials and how this will benefit the investigator’s research.

b. The name and institution of any collaborator and a description of their scope of work for the research, including any preliminary results.

c. A signed copy of the **Terms and Conditions** section below, from each collaborator, and IRB approval or satisfactory evidence that the collaborator’s research is covered under the IRB approval granted for the principal research project described in this application.

**SCIENTIFIC REVIEW AND PRIORITIZATION PROCESS**

Requests will first undergo a scientific review by the BAC. A report will be issued that includes the priority score. The scientific review and availability of biospecimens will be considered in the final decision by the BAC. Please allow one to two weeks for the review process.

**Determination of Scientific Merit:**

* Scientific merit, including potential clinical/scientific impact
* Potential impact on other ongoing studies (does not limit access to specimens for other ongoing research)
* Justification for requests for frozen tissue versus fixed tissue
* Basis for the number of specimens requested
* Availability of specimens and the absence of restrictions on their use for research (as noted in the informed consent)
* Experience of the requesting investigator
* Need to support currently funded projects or to generate pilot data for external grant applications
* Ranked priority is to support active NCI awards, followed by other active federal or national grants, Stony Brook University-funded research projects, industry-sponsored grants, and unfunded projects

**MATERIAL TRANSFER AGREEMENT**

1. The material (as specified in the SBUM BioBank Tissue Request Form) is not allowed to be sent or transported to any location other than the recipient’s laboratory without the express written permission of the SBUM BioBank Advisory Committee (BAC). The recipient shall refer any request by third parties for the material to the SBUM BioBank Review Committee.

2. The investigator must contact the clinical chief of the division that provided the specimens to invite participation by the chief or another member of their division as a co-author of any publications that result from the use of the specimens. This should be contingent on the clinical collaborator qualifying for authorship based on ICMJE criteria (http://www.icmje.org/about-icmje/faqs/icmje-recommendations):

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

2. Drafting the work or revising it critically for important intellectual content; AND

3. Final approval of the version to be published; AND

4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

3. Any additional research not included in the original proposal requires the express written permission of the SBUM BioBank Committee. Violation constitutes a breach of contract.

4. Specimens must be stored appropriately and to professionally accepted standards while in care of the recipient researcher. Use, maintenance and disposition of the material will be conducted in strict accordance with all appropriate local, national and international laws, guidelines and regulations.

5. Any unused material should be returned to the SBUM BioBank. Specimens being returned should be carefully packaged in the same manner as which they were sent. Specimens shipped insured must be returned insured for the same value. Furthermore, any remaining biological (cell lines) and/or molecular derivatives (RNA, DNA) must be returned to the SBUM BioBank.

6. Tissue request applications must include a timeframe for completion of the proposed research. Time extensions should be requested in writing before the grant expiration date. Typically, the researcher will not receive a 'due' notice. However, it is the recipient's responsibility to fulfill the terms of the request by complying with any conditions placed upon the recipient by the signed copy of the specimens invoice.

8. The recipient is required to acknowledge the SBUM BioBank in all presentations or written publications that used data generated from any sample obtained from the SBUM BioBank. In any event, the borrower is required to provide 2 copies of any publications resulting in part or whole from this request, and/or 2 copies of assay results.

* Publishing the name of the SBUM BioBank
* The correct name to use in publication for the SBUM BioBank is: The Stony Brook Medicine BioBank.
* Acknowledging the SBUM BioBank
* I/We would like to acknowledge the Stony Brook Medicine BioBank, a Department of Pathology and Cancer Center core facility at the Stony Brook University School of Medicine, NY, for their support in my/our research.

9. The SBUM BioBank requires to be informed of all electronic database submissions (such as GenBank accession numbers) associated with the analytical procedures resulting from the specimens granted. This additional specimen data should be submitted electronically (spreadsheet) to the SBUM BioBank.

10. The recipient is asked to return a copy of this MTA with the SBUM BioBank Tissue Request Form.

By reading the above conditions and returning the signed copy of this request form to the BioBank, the recipient agrees to abide by the policies outlined above and any additional written stipulations for any material from the SBUM BioBank.

**Name of Recipient (typed or printed) Recipient Agency or Institution**

**Signature of Recipient Date**