UNIVERSITY of VIRGINIA HEALTH SYSTEM

UVA Biorepository & Tissue Research Facility (BTRF)
Application for Biospecimens

IMPORTANT INFORMATION REGARDING TERMS OF BTRF SERVICES

1) Samples will be provided in one of three formats with regard to subject identity:

Anonymous: The sample is stripped of all identifying information. Only basic demographic data available at the time of collection is provided. **No other clinical or pathologic data can be provided.** The University of Virginia Institutional Review Board for Health Sciences Research (IRB-HSR) has determined that samples provided in this manner are exempt from Institutional Review Board (IRB) oversight.

Coded-linked: The sample is stripped of all identifying information, and is given a code number that is linked to subject identity in Biorepository files. **You will not be given the subject's identity for *any* reason**, but de-identified clinicopathologic data and clinical follow-up may be provided by the Biorepository. While such studies may qualify for IRB exemption, the IRB-HSR will make this determination. **A copy of IRB-HSR exemption or approval must accompany this application.**

Identified: The sample is given to you with subject identifying information or you are provided the linking information to a code number. **This requires IRB-HSR review, and a copy of the approval must accompany this application.** You are responsible for complying with the subject informed consent procedures stipulated by the IRB-HSR-approved protocol.

The investigator must agree not to seek to obtain subject identity for specimens received as anonymous or coded-linked, and to follow all University of Virginia policies and procedures regarding human subjects research by signing the Investigator agreement at the end of the application.

2) Infectious biohazards

The Biorepository does not screen samples or subjects for any type of infections, and therefore the researchers and all laboratory personnel should observe universal precautions. **You must understand that in receiving anonymous or coded-linked samples, subject identity cannot or will not be disclosed even in the event of exposure of laboratory personnel to potentially infectious material.** It is assumed the investigator adheres to all University of Virginia policies and procedures regulations regarding biohazardous materials, including the appropriate training of, and notification of risk to, all personnel exposed to these materials.

3) Material transfer

All University of Virginia policies and procedures regarding transfer of material to a third party apply to these biospecimens. **The transfer of coded-linked and/or identified human materials to individuals or entities not authorized by the IRB-HSR is a violation of Federal Law.**

4) Biorepository Fees

The current fee structure may be obtained from the Biorepository manager at crumpel@virginia.edu

5) Publications

To justify the investment by UVA in this facility, you must agree to acknowledge the contribution of the Biorepository and Tissue Research Facility in any publications arising from the use of these samples. We also request that a copy of the manuscript(s) be sent to us upon publication.

By completing the following application, you agree to the terms above.

Initialed by principal investigator: _____ **Date:** _____

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UVA Biorepository & Tissue Research Facility (BTRF)

Application for Biospecimens

Please print neatly in pen or type. Please indicate funding type and Cancer Center membership.

Direct questions to: Craig Rumpel, Biorepository Manager, 2-6453, PIC#6551, crumpel@virginia.edu

Principal Investigator Name: _____

Department: _____ Messenger Mailbox #: _____

Phone #: _____ PIC/pager #: _____ E-mail: _____

Lab Building and Room Number: _____

Contact Name (if different): _____

Phone #: _____ PIC/pager #: _____ E-mail: _____

Is the Principal Investigator a member of the School of Medicine? ☐ Yes ☐ No

Is the Principal Investigator a Cancer Center member? ☐ Yes ☐ No

UVA Institutional Biosafety Committee (IBC) Approval # (required for unfixed tissue): _____

Account number to be billed (PTAEO, local funds preferred): _____

Funding source:

Extramural: ☐ NCI ☐ Other NIH ☐ ACS ☐ Other: _____

Internal: ☐ Cancer Center Pilot Project ☐ Other: _____

Brief description of study

Specimen Criteria:

Please be specific about special handling needed (carefully consider your needs; the more strict the specifications, the fewer specimens you may receive).

Subject identity:

☐ **Anonymous** (no specific clinicopathologic information to be obtained)

☐ **Coded-linked** IRB-HSR#: _____ ***Please attach IRB-HSR approval page.***

☐ **Identified** IRB-HSR#: _____ ***Please attach IRB-HSR approval page.***

Collection type: (mark all that apply):

☐ Prospective procurement of remnant tissue and/or fluid after examination for pathology diagnosis

☐ with histologic quality control (QC)(default); ☐ without histologic QC

☐ Biorepository banked specimens (note: these are all coded-linked specimens and have histologic QC)

☐ Direct collection of tissue from operating room prior to pathologic examination (requires documented informed consent of risks from the subjects)

☐ Tissue and/or fluid specifically collected for the study (not obtained for routine clinical care - requires documented informed consent of risks from the subjects)

☐ Retrieval from Pathology archives (only histologic sections from formalin-fixed paraffin embedded blocks available, subject to review and approval by Pathology staff; supplemental form used to specify materials needed)

Application for Biospecimens

(For each anatomic site or distinct neoplasm make additional copies of these 2 pages.)

Tissue type or subject status (check all that apply):

☐ Neoplasm/tumor; ☐ Non-neoplastic/normal; ☐ Non-neoplastic/diseased; ☐ Other

Anatomic site:_____

Type of neoplasm or disease:_____

Is normal/uninvolved matching tissue required? ☐ Yes; ☐ No; ☐ If available

If a neoplasm is desired, are metastatic tumors acceptable? ☐ Yes; ☐ No; ☐ Metastatic tumors only

Restrictions/limitations:

Subject gender: ☐ Male; ☐ Female; ☐ Either

Age restrictions: ☐ No; ☐ Yes: _____ Race restrictions: ☐ No; ☐ Yes: _____

Prior Therapy restrictions (e.g. chemotherapy, radiation): ☐ No; ☐ Yes:_____

_____

Other restrictions:_____

Tissue Source(s):

☐ Surgical specimens

☐ Autopsy specimens

Minimum amount of tissue required (mg). If requesting multiple preps, specify for each type:

_____

_____

Fluid source(s):

☐ Blood

☐ Serum; ☐ plasma; ☐ whole blood

☐ Ascites

☐ Urine

☐ Other:_____

Minimum amount of fluid required (µL or mL):

_____

Preservation Method (Form in which sample needs to be provided to your laboratory. Mark all that apply):

☐ Fresh tissue: ☐ Dry (no fluid added); ☐ In saline; ☐ In standard transport media*; ☐ In RNAlater

(*Standard transport media is RPMI w/o serum + 1x penicillin, streptomycin, fungizone)

☐ Other media (include supplements): _____

☐ Quick-frozen (non-viable) tissue

☐ OCT-embedded quick-frozen (non-viable) tissue

☐ Cryo-preserved fresh viable cell suspension in FBS/DMSO $5X10^6$ cells or greater

☐ Fixed tissue - standard formalin-fixed, paraffin embedded (FFPE) block

☐ Fixed tissue - other (non-standard fixative, free floating, etc.) Specify: _____

☐ Other _____

Additional Instructions: _____

_____

Specimen Information Required:

Standard information provided with coded-linked specimens consists of anatomic site, pathologic and/or clinical diagnosis, age, sex and race, if available. A de-identified copy of the final pathology report is provided with neoplastic specimens. Standard information for anonymous specimens is age, sex, and anatomic site of tissue only. There is no additional charge for this standard information.

☐ Standard Information Only

Requests for additional clinical information are subject to review and approval of the BTRF director. Requests must be justified by the applicant prior to acceptance of the request, should be limited in scope to readily accessible clinical/history data and lab results, and fall within the guidelines of the Principal Investigator's IRB-HSR protocol. The BTRF will attempt to obtain the requested health information and provide it in abstracted, de-identified form. We do not review or provide health information from outside healthcare providers, except where such information is included in records resident at the University of Virginia. The BTRF will not contact specimen donors or their caregivers to obtain information under any circumstances, and the BTRF does not guarantee that the requested information will be available for a particular specimen. Time spent retrieving additional information beyond the standard information will be billed to the investigator at an hourly rate.

☐ Standard Information and additional clinical information indicated below:

Estimated number of specimens to collect (total, or per year): _____

Requested starting date to begin receiving samples: _____

Note: The BTRF does not routinely deliver specimens to the end-user except by special arrangement for fresh specimens or sensitive protocols. Specimens may be held in the BTRF facility pending pickup. However, specimens on-hand for more than 30 days will incur a storage charge in addition to the procurement fee.

I understand that, unless otherwise specifically stated, the Biorepository and Tissue Research Facility (BTRF) has not performed any such test of observation to indicate the presence or absence of extraneous agents or deleterious properties, including but not limited to Human Immunodeficiency Virus, Hepatitis Viruses, and other microbial infections in the biospecimens (tissue, blood products, etc.) that it provides. I also understand that even in such cases where tests or observations have been performed, the BTRF accepts no responsibility for any injury (including injury resulting in death), damage or loss that may arise from the use of the biospecimens, either directly (including use for diagnostic purposes) or in the preparation of a product. I assume all risks and responsibility in connection with the receipt, handling, storage and use of the biospecimens. I assume all responsibility for informing and training personnel handling these biospecimens in the dangers and procedures for safe handling of human tissues.

I understand that the BTRF has no agreement with subjects donating biospecimens for the testing of infectious agents or other disease states, and that the BTRF will not, under any circumstances, make contact with the subjects for the purposes of obtaining such consent or to inform them of any tests performed on their samples.

Additionally, I understand that the BTRF will not, under any circumstances, reveal the identity of the subject from whom the tissue sample originated without properly documented informed consent from the subject allowing their identification. With the appropriate authorization of the University of Virginia Institutional Review Board for Health Sciences Research (IRB-HSR), de-identified information, as defined by the Health Insurance Portability and Accountability Act (HIPAA), linked to de-identified biospecimens may be provided to me by the BTRF. I agree not to attempt to obtain information identifying the individuals who provide any coded-linked or anonymized specimens obtained from the BTRF.

I understand that my responsibilities shall include, but are not limited to, handling the tissue specimens in accordance with their pre-approved IRB-HSR protocols, providing the BTRF with updated IRB-HSR approval forms upon renewal or change of IRB-HSR project number, and consenting any patients for release of HIPPA standardized patient identifiers.

I agree to acknowledge the contribution of the Biorepository and Tissue Research Facility in any publications arising from the use of these samples, and to inform the BTRF of these publications.

_____

Typed or printed name of principal investigator

_____ _____

Signature of principal investigator Date