UVA Biorepository & Tissue Research Facility (BTRF)

Clinical Trial Investigator Agreement & Service Request

IMPORTANT INFORMATION REGARDING TERMS OF BTRF SERVICES

1) Study Initiation Meeting

A face-to-face meeting between key study personnel (CRC) and BTRF management is mandatory prior to initiation of study enrollment in order to finalize services expected, fees, SOPs and logistics. No services will be provided by the BTRF without prior consultation and approval.

2) Human Subjects

Processing of samples for clinical trials is presumed to require patient-identifiable samples and data from subjects who have signed consent to participate in the study. If your study requires preliminary activities or pilot studies utilizing specimens from subjects who have not signed a consent and these will be obtained from or processed by the BTRF, a separate request for de-identified or coded specimens may be necessary. ***The University of Virginia Institutional Review Board for Health Sciences Research (IRB-HSR) considers the BTRF to be a pass-through facility in the same manner as the Medical Laboratories. Therefore, BTRF staff should not be listed as personnel on the study IRB-HSR protocol.*** Samples and annotations are provided to you either with subject identifying information or identified by a study code which is known to you and linked to the donor. The study team is responsible for complying with the requirements of your IRB-HSR protocol and consent and for providing a study code to the BTRF for each subject if specimens cannot be labeled with patient identifiers. **A copy of your IRB-HSR approval notice must be on file with the BTRF prior to any sample processing.**

3) Infectious Biohazards

The Biorepository does not screen samples or subjects for any infectious agents, and therefore the researchers and all laboratory personnel should observe universal precautions when handling unfixed specimens. **Subject identity cannot be disclosed even in the event of exposure of laboratory personnel to potentially infectious material.** It is the responsibility of the Principal Investigator to adhere to all regulations and all University of Virginia policies and procedures regarding biohazardous materials, including the appropriate training of and notification of risk to all personnel exposed to these materials.

4) Material Transfer

All University of Virginia policies and procedures regarding transfer of material to a third party apply to these biospecimens and data or received from outside the institution. **The transfer of coded and/or identified human materials or Protected Health Information (PHI) to individuals or entities not authorized by the IRB-HSR is a violation of Federal Law.**

5) Biorepository Fees

You must provide a valid PTAEO for all work performed. Charges are posted as they occur and will be reconciled monthly to your account. UVA financial policy requires Core Facility rate review and adjustment a minimum of once per year, and charges will reflect the current rate at the time service is provided. It is against Federal grant regulations to bill services in advance. Please refer to the BTRF web page https://med.virginia.edu/biorepository-and-tissue-research-facility/ for current rates. Fee estimates are provided based on current rates and study procedures at the time the estimate is prepared and are subject to change. Investigators should anticipate potential rate increases of 3-5% per year over the course of the study and budget accordingly. Investigators should also be aware that changes in processing requirements by the sponsor may result in additional charges.

Management Fee – A face-to-face meeting between study personnel (CRC) and BTRF staff is mandatory prior to initiation of the study, and you will not be charged for this meeting. Time required by BTRF management or staff to attend additional meetings, solve problems related to the protocol, or trouble-shoot protocol issues once the study is underway will be billed at the current hourly rates for BTRF administration or pathologist services. Additional staff effort to perform extra data entry, manage specimens, prepare extra paperwork and generate reports will be charged at an hourly rate.

6) BTRF Staffing and Hours of Operation

Normal operating hours are Monday – Friday from 8:30 AM to 6 PM. The BTRF follows the standard UVA academic calendar and work schedule. The BTRF operates with reduced staffing and hours when Health System clinics are open on scheduled academic holidays. Please consult the BTRF web pages or with BTRF staff regarding cutoff times for receiving samples in the lab for processing. Accession and processing of specimens outside of normal working hours must be arranged in advance and is subject to staff availability. Required work outside of standard hours will incur hourly charges in addition to regular specimen processing fees.

7) Communication with Study Sponsors

The BTRF will not provide specimen or patient information directly to the sponsor or other entities. The study team is responsible for all communications with the sponsor, centralized labs, regulators and other entities involved with the study.

8) 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 by UVA authors arising from the use of our services. We also request that a copy of the manuscript(s) be sent to us upon publication. The BTRF receives support from the University of Virginia Cancer Center National Cancer Institute P30 Center Grant, and this is an NCI requirement.

I understand and agree to the above terms. Initialed by Principal Investigator: _____ Date: _____

Investigator Agreement

I understand that, unless otherwise specifically stated, the Biorepository and Tissue Research Facility (BTRF) has not performed any such test or 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 agents, 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 acknowledge that I have obtained appropriate approvals from the University of Virginia Institutional Biosafety Committee (IBC), and I assume all responsibility for informing and training personnel handling these biospecimens in the dangers and procedures for safe handling of human biospecimens.

I understand that the BTRF has no agreement with subjects providing 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 the results of any tests performed on their samples.

Additionally, I understand that the BTRF will not, under any circumstances, reveal the identity of a subject from whom a biospecimen was obtained 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 clinical 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 de-identified or coded biospecimens or clinical information which I receive from the BTRF.

I understand that my responsibilities shall include, but are not limited to, handling the specimens and data in accordance with applicable 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 HIPAA standardized patient identifiers.

I agree to acknowledge the contribution of the Biorepository and Tissue Research Facility in any UVA-authored 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

Clinical Trial Investigator Agreement & Service Request

Direct questions to Pat Pramoonjago, (434)982-0487, pp6f@hsc.mcc.virginia.edu

Principal Investigator Information:

Name: _____ Department: _____ Messenger Mailbox #: _____

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

Lab Building and Room Number: _____

Is the P.I. a member of the School of Medicine? ☐ Yes; ☐ No

Is the P.I. a Cancer Center member? ☐ Yes; ☐ No

Primary Study Coordinator responsible for this study:

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

Additional Study Coordinators:

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

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

Study Funding & Description:

Protocol Full Name: _____

Proposed Protocol Short Name: _____

(*Note: will be used on future e-mail and other communication with BTRF about this study*)

Brief abstract or study description: _____

IRB-HSR#: _____

☐ This study has received IRB-HSR approval. ***Please attach a copy of IRB-HSR approval page***

☐ This study has not yet received IRB-HSR approval. Approval expected by _____

Study Sponsor:

☐ Industry: _____

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

Internal: ☐ Cancer Center Pilot Project; ☐ Other: _____

Grant #: _____ Start Date: _____ End Date: _____

Account number to be billed (WorkTag): _____

(if WorkTag is pending, must be provided to BTRF before any services are provided)

BTRF Use Only: Study short name: _____

Date Rec'd: _____ Meeting Date: _____ Date Approved: _____

Study Design and Details:

Study Organization:

☐ This is a single site trial, and only samples from UVA will be processed by the BTRF

☐ This is a multi-site trial and only samples from UVA will be processed by the BTRF

☐ This is a multi-site trial and samples from other sites will be shipped to UVA for processing by the BTRF

☐ This study involves collection from a single visit, procedure or time point only

☐ This study involves collection from multiple visits, procedures, or time points

[*Note: please provide a copy of the study calendar*]

Study Population and Eligibility: *Refer only to the study population with which the BTRF will be involved.*

Anatomic site(s): _____

Type of neoplasm or disease: _____

General pathologic or diagnostic criteria for inclusion: _____

Subject sex: ☐ Male; ☐ Female; ☐ Either

Study population: ☐ Adults; ☐ Minors; ☐ Both

Number of subjects anticipated to enroll: _____

Estimated starting date for recruitment: _____

How long will the study be open to enrollment?: _____

Summarization of Protocol Activities

Prior to our meeting with the study team, please provide us with a copy of the protocol and any lab manuals BUT do not expect the BTFF to review the entire protocol to figure out what services will be required. Please use the document checklist at the end. The person requesting the estimate should be familiar enough with the study requirements to explain specifically what is expected and also be prepared to answer questions at our face-to-face meeting. We are here to help you! It will also be helpful to highlight any sections of the protocol pertinent to tissue or fluid processing in which we will be involved when you send this form and supporting documents. (NOTE: Many times important information is also included in an Appendix.).

If you are performing only part of a larger protocol (e.g. only one arm of a study) or the BTRF will not be involved with processing some specimens in the protocol, please briefly summarize here:

_____

Specimen Types to be Processed:

Study requires BTRF to provide archival pathology material: ☐ Yes; ☐ No; ☐ Optional

Is archival material required for pre-enrollment screening tests: ☐ Yes; ☐ No

[*Note: Original diagnostic blocks and slides may not be released outside of the UVA Pathology Department. The BTRF may provide recut sections, core punches, or scrolls from these cases, provided this does not deplete the diagnostic material. The budget estimate will include time for pulling and re-filing of materials and time for pathologist review and approval of the materials for release.*]

Study requires BTRF to process fluid specimens: ☐ Yes; ☐ No; ☐ Optional

Study requires BTRF to collect and/or process solid tissue samples or biopsies: ☐ Yes; ☐ No; ☐ Optional

☐ Tissue specimens obtained from Operating Room

☐ Tissue specimens obtained from Outpatient Surgery Center

☐ Tissue specimens obtained in Clinic setting (specify location: _____)

Study Logistics:

☐ This study has sponsor-provided collection kits

[*Note: will need to review kit contents with BTRF staff*]

☐ Specimens will be sent out or picked up from the BTRF lab immediately after processing

☐ Specimens will be held temporarily in the BTRF lab (<30 days) and picked up or sent out in batches

☐ Specimens will be stored long-term in the Biorepository for a UVA investigator

☐ This study requires BTRF assistance with shipping specimens to an outside sponsor, central lab or institution

☐ Domestic shipping; ☐ International shipping; ☐ Both

☐ Dry ice shipments; ☐ Wet ice/refrigerated shipments; ☐ Ambient shipments

☐ Study team does not require BTRF assistance with shipping specimens

☐ The study sponsor requires a site qualification visit to the BTRF lab prior to study initiation

Supporting Document Checklist:

☐ Copy of Protocol (required)

☐ Copies of any Lab Manuals or Specimen Flowsheets

☐ Copy of Appendices

☐ Copy of Study Calendar (if included elsewhere, provide page numbers: _____)

☐ Copies of Specimen Submission Forms (if separate from lab manual)

☐ Copy of IRB-HSR approval page (required prior to start of any BTRF services)