UNIVERSITY of VIRGINIA
SCHOOL OF MEDICINE

UVA Biorepository & Tissue Research Facility (BTRF)
Investigator Agreement & Study Information Form

Do not use this form to request support for investigator-initiated or sponsored clinical trials.
Submit a Clinical Trial Investigator Agreement & Service Request Form instead.

IMPORTANT INFORMATION REGARDING TERMS OF BTRF SERVICES

1) Human Subjects

Requests for BTRF services must specify one of the following categories with regard to subject identity:
Coded (Non-Human Subject Research): Samples and annotations are stripped of all HIPAA identifiers and are given a code that is linked to subject identity in Biorepository files. Clinical annotations provided will conform to a HIPAA Limited Data Set. The Biorepository functions as an Honest Broker and **will not disclose subject identity or the code key to you for any reason**. Additional clinical data and follow-up information may be requested after receipt of the specimens. Use of Coded Specimens requires you to submit an acknowledgement letter for Non-Human Subject Research from UVA Non-Human Subject Research online tool**.**

The IRB has created a UVA Non-Human Subject Research Online Tool https://hrpp.irb.virginia.edu/evaluate-my-project/*, an online tool that asks key questions to assist the study teams when determining whether they need to submit their proposal to the IRB. Activities that meet the definition of Human Subject Research will require submission of an application to the IRB-HSR for review and approval, If the responses to the key questions indicate the proposal is not human subject research, the individual that submitted the proposal will receive an email providing the acknowledgment letter for non-human subject research*

A copy of your **acknowledgement letter for Non-Human Subject Research must accompany this application**.

Alternatively, a standard IRB-HSR Protocol which includes the BTRF as a specimen source or an exemption may be used. **A copy of your IRB-HSR approval notice or exemption notice must accompany this application**.

Identified: 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. **Release of identified material requires an IRB-HSR approval.**

Informed Consent or Waiver of Consent: You are responsible for complying with the stipulations and consent requirements of your IRB-HSR protocol and for providing a study code to the BTRF for each subject if specimens cannot be labeled with patient identifiers. **Copies of your IRB-HSR approval notice and IRB protocol must accompany this application.**

The investigator must agree not to seek to obtain subject identity for coded specimens and to follow all University of Virginia policies and procedures regarding Human Subject Research by signing the Investigator Agreement.

2) Infectious Biohazards

The Biorepository does not screen samples or subjects for any infectious agents. Therefore, the researchers and all laboratory personnel should observe universal precautions when handling unfixed specimens. **You must understand that in receiving de-identified or coded 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.

3) Material Transfer

All University of Virginia policies and procedures regarding transfer of material to a third party apply to these biospecimens and data. 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.

4) Biorepository Fees

Internal users must provide a valid worktag for all work performed. Charges are posted as they occur and will be reconciled monthly to your account. UVA financial policy requires rate review and adjustment a minimum of once per year. Charges will reflect the current rate at the time service is provided. It is against Federal grant regulations to bill services in advance.

External applicants must make appropriate arrangements for payment prior to work being performed. Please refer to the BTRF web page, https://med.virginia.edu/biorepository-and-tissue-research-facility/, for current rates. For estimates, requests from outside UVA, or special services, please contact the Biorepository Manager.

5) BTRF Staffing and Hours of Operation

The BTRF lab is staffed Monday through Friday from 8:30 am to 6:00 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 website or with a staff member for 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.

6) 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 the 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

CODED RESEARCH DATA/SPECIMENS AGREEMENT

(For investigators who receive coded specimen and meet requirement for Non-Human Subject Research only)

THIS AGREEMENT, dated _____, is entered into by _____ (the "Data Source") and _____ (the "Researcher").

Recitals

a. The Data Source is providing coded, de-identified data (private health information about individuals or tissue specimens, referred to herein as the "Data") to the Researcher for a research project concerning _____ (the "Project").

b. The Researcher wishes the Project to be considered research involving coded private information or biological specimens under 45 CFR, Part 46.

c. To satisfy the conditions of the Office for Human Research Protections guidance on research involving coded private information or biological specimens, the Data Source and the Researcher wish to enter into this Agreement.

In consideration of the above, the parties agree that:

1. De-identified Data. The Data Source shall provide to the Researcher only Data that has been de-identified through the removal of all the identifiers listed on Attachment A.
2. Origin of Data. The parties agree that:
   i. The Data were not collected specifically for the Project through an interaction or intervention with living individuals, but are instead either existing or future data collected for other purposes; and
   ii. The Data Source will not otherwise be involved in the Project, such as in interpretation or analysis of the Data or creation and publication or presentation of research results.
3. Coding of Data. The parties acknowledge that the Data is "coded" by association with a number, letter or symbol and that the Data Source holds a key to decipher the codes and link the Data back to information (such as name or social security number) that would identify individuals to whom the private information or specimens pertain. The code may not be derived from or related to information about the individual, such as initials or last four digits of Social Security Numbers.
4. Prohibition on Disclosure. The Data Source may not release the key for deciphering the codes to the Researcher unless the Researcher presents documentation of an Investigational Review Board review of the Project as human research with appropriate action, such as a finding of exemption, waiver of informed consent, or signed informed consents of any individuals whose Data may be re-identified through release of the key.
5. Governing Law. This agreement shall be governed by the laws of the Commonwealth of Virginia.

_____ _____
(Data Source) Print Name (Data Source) Title

_____ _____
(Data Source) Signature Date

_____ _____
(Researcher) Print Name (Researcher) Title

_____ _____
(Researcher) Signature Date

PRINCIPLE INVESTIGATOR INFORMATION

Name: _____ Department: _____ Messenger Mailbox #: _____

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

Lab Building: _____ 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

Lab Contacts:

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

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

Study Funding & Description:

Worktag to be Billed: _____

Primary Funding source for this Project:

Extramural: ☐ NCI ☐ Other NIH ☐ ACS ☐ Other (Specify): _____

Internal: ☐ Cancer Center Pilot Project ☐ Other (Specify): _____

Project Title: _____

Brief Abstract or Study Description:

Primary Downstream Assays to be Performed on Specimens: _____

Will you be performing whole genome or whole exome sequencing on the specimens? ☐ Yes ☐ No

Will you be using the specimens to establish cell lines? ☐ Yes ☐ No

UVA Institutional Biosafety Committee (IBC) Approval # (Required for Unfixed Tissue or Biofluids): _____

Subject Identity:

☐ Coded - Non-Human Subjects Research. For more information and a guidance document, see: https://med.virginia.edu/biorepository-and-tissue-research-facility/services/requesting-biospecimens/

Please attach a copy of acknowledgement letter for Non-Human Subject Research obtained from UVA Non-Human Subject Research online tool.

☐ Coded-IRB-HSR - Approved Protocol IRB-HSR#: _____

Attach copies of IRB-HSR approval notice and protocol.

☐ Identified - Informed Consent IRB-HSR#: _____

Attach copies of IRB-HSR approval notice and protocol.

☐ Identified - Waiver of Consent IRB-HSR#: _____

Attach copies of IRB-HSR approval notice and protocol.

Direct questions to the Biorepository Technical Director: Pat Pramoonjago, (434)982-0487, pp6f@UVAhealth.org

BTRF Use Only: Date Received _____ *Date Approved:* _____