UVA Biorepository & Tissue Research Facility (BTRF) Coded-Specimens Guidance

Setting up a new coded-specimens protocol with the IRB is very easy and will allow you to receive coded specimens and abstracted clinical annotations from the Biorepository, including banked specimens and archival pathology materials.

It is important to note that de-identified fresh tissue cannot be linked to a pathology report, as the IRB requires that any link be severed when the specimen leaves our custody and the path report takes several days to be finalized. For that reason, a coded-specimens protocol is essential if you plan to receive fresh tissue and need pathology data on the case.

The BTRF will not disclose patient identifying information to you. The BTRF will maintain a link to allow additional materials (if available) and clinical information to be obtained on the case in the future, and to ensure you do not receive duplicate specimens unnecessarily, which may deplete valuable resources. Clinical information requested will be abstracted from UVA electronic records by BTRF staff and provided scrubbed of identifiers. If the information requested is deemed outside the scope of BTRF resources, a protocol for identified specimens and data will be required instead so that study staff may obtain chart information directly.

This type of protocol can only be used for studies utilizing whole-genome or whole-exome sequencing (e.g. GWAS) in very specific and limited circumstances. Please consult with the BTRF Faculty Director or the Biorepository Manager concerning options for those types of studies before proceeding.

Quick Start Guide:

Step 1: log into Protocol Builder https://www.irb.virginia.edu/ and start a new protocol.

Step 2: answer the Protocol Builder questions using the guide provided below.

Step 3: add the PI, other administrative personnel, and sub-investigators in Protocol Builder as needed. Do not put BTRF staff on the protocol, as we are considered a pass-through facility like the Medical Labs and are not part of the research.

Step 4: complete the sponsor information in Protocol Builder as needed.

Step 5: check progress and if complete, generate the forms (coversheet and protocol template).

Step 6: complete the protocol template using the guide provided below.

Important: Keep the information in the project summary as brief and broad as reasonable—just a few sentences! This will ensure that your approval with cover a range of sample types and assays so that you do not have to re-submit in the future. Discuss the experimental approaches instead of details of specific markers or mutations. See the following examples:

"The proposed study seeks to identify biomarkers which are upregulated in cancers and will predict metastasis and/or recurrence. Tumor samples of prostate, bladder and ovarian cancer, other related malignancies, and normal controls will be obtained through BTRF. These may include banked samples, archival clinical samples, and newly accrued samples (clinical remnants). Samples will be utilized for proteomic and gene expression profiling experiments. Additional confirmatory studies using immunohistochemistry and mutation analysis will be performed."

"Fresh specimens of normal colon (clinical remnants) will be obtained by the BTRF and treated to obtain viable cells for flow cytometry and T-cell functional assays. The BTRF will also provide fixed tissue sections from the same patients from the pathology clinical archive to stain for biomarkers of interest and banked samples of frozen colon tissue for use in western blotting and as controls. The BTRF will provide a de-identified pathology report and a list of current medications for use in correlative studies."

Step 7: follow the IRB instructions to submit the protocol for pre-review. [Note: This goes through a single person at the IRB office. Turnaround is usually less than 1 week.]

Step 8: once you have obtained OK from the IRB for your pre-review submission, submit to the IRB for final approval. [Note: This goes through a single person at the IRB office without committee review. Turnaround is usually less than 1 week.]

Step 9: ,obtain a Coded-Specimens Agreement from the BTRF website and complete per the guide instructions. Bring the Coded-Specimens Agreement to the Biorepository Manager or Faculty Director for signature.

Step 10: submit your BTRF application, including your final approval letter from the IRB to the Biorepository Manager.

Biorepository Manager: Craig Rumpel
RM B705A Carter-Harrison Research Bldg (MR6)
434-982-6453 E-mail:crumpel@virgnia.edu

HSR Submission Number: xxxx

Questions Answered Thus Far		Answer
1.	**Are you doing research with human subjects as an agent for UVa?**	YES
2.	**Will the IRB-HSR be the IRB of record for this protocol for the research to be done by UVa personnel?**	YES
36.	**Do you plan to do research with data previously collected as part of an Improvement Project (e.g. Performance Improvement, Practice Improvement, Quality Improvement) in which there was no interaction or intervention with an individual and the project only involved the use of information from UVa medical records?**	NO
38.	**Is there a protocol already in existence (e.g. sponsor's protocol, investigator initiated)?**	NO
39.	**Is this a 5 year update of a previously approved protocol?**	NO
40.	**Is this protocol funded by an external grant?**	
43.	**Do you or will you have a contract with an outside entity to support this protocol OR to share data with anyone not listed on the protocol, other than sponsor or CRO, prior to publication?**	
48.	**Is there an entity inside of UVA supporting/sponsoring this study?**	
49.	**Will this study be submitted through the PI's current primary school and department appointment?**	YES
50.	**Is this a multi-site trial?**	NO
51.	**Will data from this study be combined with data from other sites conducting the same or similar study?**	NO
54.	**Will any of your data involve information about students governed by the federal FERPA regulations, such as information from Student Health, the Registrar's Office, the Office of Assessment and Studies, or the Student Information System (SIS)?**	NO
55.	**Does this study meet the criteria for research only involving coded private information or biological specimens?**	YES

answer questions 40, 43 & 48 as appropriate for your protocol and add sponsor information in Protocol Builder as necessary

answering this question "YES" ends the questions and takes you back to the screen to enter sponsor and PI info and generate the protocol template which will include the coded specimens agreement form

IRB-HSR Authorization for Research Involving Coded Private Information or Biological Specimens

Enter responses electronically. Prior to obtaining signatures, email the completed form to IRBHSR@virginia.edu for pre-review. An IRB staff member will reply with any changes to be made.

Following pre-review, submit this signed form to the IRB-HSR with an *IRB-HSR Routing Form*
May be submitted via Messenger Mail, PO Box 800483, to the Drop Box in West Complex, Davis Wing- Grants and Contracts Office or in person to the IRB-HSR Office at One Morton Drive, Suite 400.
This application is to be completed by the person RECEIVING or PROVIDING the coded data/ specimens.

Project Title: _____

Project Summary: _____

fill in for your project

Non- FDA Use- Confirmation

I confirm that the data from this study will not be submitted to the FDA as part of an IND/IDE application.

☐ Yes ☐ No

IF NO- this project will not be allowed to be done under this type of application process.

GWAS Confirmation

Will this study involve genome wide association studies: ☐ Yes ☐ No

IF YES, I confirm I am aware that the content of the consent form used to collect the original specimens will influence whether this data is able to be submitted to the NIH Database of Genotype and Phenotype Data, (dbGaP), and may therefore affect NIH funding opportunities. ☐ Yes ☐ No

For additional information see NIH dbGaP policies, including consent requirements. For new recruitment, Protocol Builder will include the GWAS consent elements required by the NIH under current policies in the consent template.

Coded Research Criteria

Check all that apply	Categories
☐	**1.** The material/data, in its entirety, was or will be collected for purposes other than this project (e.g. the material was or will be collected solely for clinical purposes, or for unrelated research purposes, with no "extra" material collected for the purpose of this project).The person providing the materials/data to the researcher will not otherwise be involved in this project, such as in interpretation or analysis of the data or creation and publication or presentation of research results. No data will be given back to the source of the specimens/data.
☐	**2.** The material/ data are given to the researcher with a code. The researcher receiving the specimens/ data will never have access to the key to the code. The code cannot be derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)
☐	**If 2 above is checked one of the following is required:** **a.** A signed agreement is required between the person releasing the specimens/ data and the researcher receiving the specimens/data stipulating the key to the code will never be released to the researcher.
☐	**b.** Confirmation of IRB approval of written policies and operating procedures for a repository or data management center that prohibit the release of the key to the researchers under any circumstances, until the individuals from whom the information or specimens were collected are deceased.
☐	**c.** There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

NOTE: In order to qualify for research involving coded private information or biological specimens you must have checked both # 1 and #2. Then either 2a, 2b or 2c must be checked.

Identifiers:

Will you receive any of the following identifiers? answer all "NO"

☐ YES	☐ NO	1. Name
☐ YES	☐ NO	2. Postal address information, other than town or city, state, and zip code
☐ YES	☐ NO	3. Telephone numbers
☐ YES	☐ NO	4. Fax numbers
☐ YES	☐ NO	5. Electronic mail addresses
☐ YES	☐ NO	6. Social Security number
☐ YES	☐ NO	7. Medical Record number
☐ YES	☐ NO	8. Health plan beneficiary numbers
☐ YES	☐ NO	9. Account numbers
☐ YES	☐ NO	10. Certificate/license numbers
☐ YES	☐ NO	11. Vehicle identifiers and serial numbers, including license plate numbers
☐ YES	☐ NO	12. Device identifiers and serial numbers
☐ YES	☐ NO	13. Web Universal Resource Locators (URLs)
☐ YES	☐ NO	14. Internet Protocol (IP) address numbers
☐ YES	☐ NO	15. Biometric identifiers, including finger and voice prints
☐ YES	☐ NO	16. Full face photographic images and any comparable images
☐ YES	☐ NO	17. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)
☐ YES	☐ NO	18. Any other information that could be used alone or in combination with other information to identify an individual. (e.g. rare disease, study team or company has access to the health information and a HIPAA identifier or the key to the code .)

NOTE: In order to qualify for research involving coded private information or biological specimen you must have answered NO to all the questions in the table above.

If I am receiving the coded information, I confirm I understand that if I unexpectedly learn the identity of one or more living individuals or wish to identify the individual(s), the research would then not meet the criteria for research involving coded private information or biological specimens and would require further IRB-HSR approval.

I also confirm that once received, the IRB confirmation of this application will be submitted to the SOM Grants and Contracts Office or OSP to obtain a Material Transfer Agreement PRIOR to sharing of any data/specimens.

_____

Principal Investigator Name

will not apply to internal investigators receving specimens from the BTRF. However, an MTA may still be required when sharing specimens or data outside of UVA.

Date _____

IRB-HSR Office Use Only:

IRB-HSR # _____

Form Revised: 06/12/15

download the Agreement below from the BTRF website or request from the Biorepository Manager

CODED RESEARCH DATA/SPECIMENS AGREEMENT

P.I. Name

THIS AGREEMENT dated _____, 20_____, is entered into by _____ (the "Data Source") and _____ (the "Researcher").

UVA Biorepository & Tissue Research Facility

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 _____Your project title here _____(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 or any of the identifiers listed on Attachment A 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. The IRB of each institution will be consulted to determine if their review and approval is required to release the key or any of the identifiers in Attachment A.
5. Governing Law. This agreement shall be governed by the laws of the Commonwealth of Virginia.

Bring to the Biorepository Manager for Signature.

_____ _____

(Data Source)Print Name (Data Source) Title

_____ Date: _____

(Data Source)Signature

_____ _____

(Researcher)Print Name (Researcher) Title

_____ Date: _____

(Researcher)Signature

Attachment A

Identifiers:

1. Name
2. Postal address information, other than town or city, state, and zip code
3. Telephone numbers
4. Fax numbers
5. Electronic mail addresses
6. Social Security number
7. Medical Record number
8. Health plan beneficiary numbers
9. Account numbers
10. Certificate/license numbers
11. Vehicle identifiers and serial numbers, including license plate numbers
12. Device identifiers and serial numbers
13. Web Universal Resource Locators (URLs)
14. Internet Protocol (IP) address numbers
15. Biometric identifiers, including finger and voice prints
16. Full face photographic images and any comparable images
17. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)
18. Any other information that could be used alone or in combination with other information to identify an individual. (e.g. rare disease, study team or company has access to the health information and a HIPAA identifier or the key to the code .)