

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 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 may take several days to be finished. 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 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 the UVA electronic medical records by BTRF staff and provided scrubbed of identifiers. If the clinical information requested is deemed to be outside the scope of BTRF's resources, a protocol for identified specimens will be required instead so that study staff may obtain chart information directly.

Quick Start Guide:

Step 1: log into Protocol Builder <http://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. Appendix B is not required and may be deleted.

Step 7: bring the Coded-Specimens Agreement to the Biorepository Manager or Faculty Director for signature.

Step 8: submit to the IRB for approval. [Note: these go to a single person in the IRB and are approved without committee review. Turnaround is usually less than 1 week.

Step 9: submit your BTRF application, including a copy of the signed Coded-Specimens Agreement to the Biorepository Manager.

Biorepository Manager: Craig Rumpel
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HSR Submission Number: xxxx

Questions Answered Thus Far		Answer
1.	Are you doing research with human subjects?	YES
2.	In addition to the IRB protocol that will be written using this program is there an additional protocol (ie Sponsors protocol)?	NO
3.	Is this a 5 year update of a previously approved protocol?	NO
4.	Is this protocol funded by an external grant?	
5.	Do you/will you have a contract with an outside entity to support this protocol?	
10.	Is there an entity inside of UVA supporting/sponsoring this study?	
11.	Will this study be submitted through the PI's current school and department?	YES
12.	Is this a multi-site trial?	NO
14.	Does this study meet the criteria for research only involving coded private information or biological specimens?	YES

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answer questions
4,5 & 10 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, print, sign, date and submit to the IRB-HSR.

Project Title: INSERT TITLE OF PROJECT HERE

fill in for your project.

Project Summary: INSERT A BRIEF SUMMARY OF PROJECT HERE

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
<input type="checkbox"/>	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.
<input type="checkbox"/>	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.)
<input type="checkbox"/>	<u>If 2 above is checked one of the following is required:</u>
<input type="checkbox"/>	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. (See attached)
<input type="checkbox"/>	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.
<input type="checkbox"/>	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.

If 2a is checked you must submit a signed “Coded Research Data/Specimens Agreement”(See Appendix A).

Identifiers:

Will you receive any of the following identifiers?

answer all "NO"

YES	<input checked="" type="radio"/>	1. Name
YES	<input checked="" type="radio"/>	2. Postal address information, other than town or city, state, and zip code
YES	<input checked="" type="radio"/>	3. Telephone numbers
YES	<input checked="" type="radio"/>	4. Fax numbers
YES	<input checked="" type="radio"/>	5. Electronic mail addresses
YES	<input checked="" type="radio"/>	6. Social Security number
YES	<input checked="" type="radio"/>	7. Medical Record number
YES	<input checked="" type="radio"/>	8. Health plan beneficiary numbers
YES	<input checked="" type="radio"/>	9. Account numbers
YES	<input checked="" type="radio"/>	10. Certificate/license numbers
YES	<input checked="" type="radio"/>	11. Vehicle identifiers and serial numbers, including license plate numbers
YES	<input checked="" type="radio"/>	12. Device identifiers and serial numbers
YES	<input checked="" type="radio"/>	13. Web Universal Resource Locators (URLs)
YES	<input checked="" type="radio"/>	14. Internet Protocol (IP) address numbers
YES	<input checked="" type="radio"/>	15. Biometric identifiers, including finger and voice prints
YES	<input checked="" type="radio"/>	16. Full face photographic images and any comparable images
YES	<input checked="" type="radio"/>	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	<input checked="" type="radio"/>	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.

NOTE: If you 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.

Will the work for this study be done in the GCRC? YES

No

If yes, complete and attach Appendix B

Principal Investigator Name (PRINT)

Principal Investigator Signature

Date

IRB-HSR Office Use Only:

IRB-HSR # _____

Appendix A:

CODED RESEARCH DATA/SPECIMENS AGREEMENT

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

P.I. Name

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 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.

Bring to Biorepository Manager for Completion and Signature. Submit signed original to IRB with the protocol above

(Data Source)Print Name (Data Source) Title

(Data Source)Signature Date: _____

(Researcher)Print Name (Researcher) Title

(Researcher)Signature Date: _____

IRB-HSR Office Use Only

Reviewed by: _____
IRB-HSR Director or Designee

IRB-HSR # _____

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 .)

Appendix B:

This attachment is ONLY required if the work for this protocol will be done in the GCRC.



Appendix B will print automatically with the template and is about 8 pages. It is not required for BTRF protocols and may be deleted