BTRF Coded Specimens Quick Start Guide

Here is how to set up a protocol for coded specimens with the UVA Biorepository & Tissue Research Facility. Coded specimens satisfy the criteria for de-identified samples and data, and it do not require an IRB submission (non-Human Subjects Research under current regulations). Once set up with the BTRF, this type of coded specimens protocol can remain open and does not require annual review.

The BTRF maintains a code link which is not disclosed to you without proper IRB authorization. This ensures we can go back to the same cases or prevent reuse and also access clinical information after you receive the specimens. All samples will be provided to you with a BTRF code, and any clinical data abstracted for you by BTRF staff will conform to a HIPAA Limited Data Set.

Please go to https://research.virginia.edu/irb-hsr/forms-irb-hsr and download a copy of the "Determination of Human Subjects Research Form".

This form does not have to be sent to the IRB unless Human Subjects approval documentation is required by a funding agency, such as for a grant application. These are reviewed by one person at the IRB and have quick turnaround of a few days, if you do send it in.

Complete as follows:

1) complete the PI and Project information at the top of page 2. Keep the project summary brief and general as possible to cover any future activities you anticipate (e.g. "We will study biomarkers related to disease progression and metastasis in breast cancer, related cancers and normal controls. We will utilize specimens collected prospectively or banked by UVA Biorepository or obtained from the Pathology Clinical Archive. The BTRF will abstract and de-identify the clinical data (pathologic diagnosis, demographics, treatment information) accompanying the specimens.").

We recommend you don't detail specific markers or assay methods. This is not relevant to the determination and keeping things general avoids repeating this process for future projects/specimen requests.

2) skip to 1I "Research using Coded Data/Specimens or Creation of a Database/Repository including Coded Data/Specimens" and check this box. In the middle of the page check the box next to option a. "A signed agreement…" and also sub-option "Source of data/specimens internal to UVA." Answer 'No' to genomic data sharing (most likely). **Please be aware that many specimens accessible to the BTRF, including archival pathology specimens, are collected under Waiver of Consent and may not be used in GWAS (whole genome/whole exome) studies. If such activities are planned, this needs to be discussed with the BTRF to determine feasibility prior to making a request for specimens.**

3) Review the guidance in "Appendix B: Privacy Plan." Data from the BTRF will conform to a HIPAA Limited Data Set and is considered Moderately Sensitive Data.

4) Go to Appendix D. Complete using "UVA Biorepository and Tissue Research Facility" as the Data Source with the same project title as above and with the PI as the Researcher. Sign and date.

If not submitting to the IRB, the completed Determination of Human Subjects Research form should be retained in your files. Please forward a copy of the Determination form **AND** the signed original of Appendix D with your completed BTRF Application to the Biorepository Manager.

If submitting to IRB, follow the instructions in the document. The IRB gets the completed document, but you do not need to send in Appendix D. Please forward a copy of the Determination form **AND** the signed original of Appendix D with your completed BTRF Application to the Biorepository Manager. Please forward a copy of the IRB acknowledgement to the BTRF when received.

In either instance, the Biorepository will sign Appendix D and retain the original in our files. We will return a copy to you for your records.

On the BTRF Application form, you should check off the option for coded-linked specimens and put "non-human subjects agreement" in the space for the IRB#.