

FOR IRB-HSR OFFICE USE ONLY

UVA IRB-HSR Study Tracking # 23563

Project is determined to NOT meet the criteria of Research with Human Subjects or a Clinical Investigation and therefore is not subject to IRB-HSR Review.

*All project team personnel are required to follow all requirements described in this form and follow:*

- *Procurement requirements if participants will be compensated for their time*
- *UVA Information Security policies to protect the data: See Appendix B: Privacy Plan.*
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**Pick One**

- No health information/specimens are to be collected or used for this project
- Health information/specimens to be collected or used for this project meet the criteria of Deidentified under HIPAA (No identifiers as noted in Appendix A may be collected/ used.) If data/specimens are from dbGaP, keep Appendix C on file with your project documents and contact School of Medicine Office of Grants and Contracts to obtain an Agreement and a dbGaP Data Request Form/Institutional Certification.
- Health information collected meets the criteria of identifiable. Follow the Privacy Plan Appendix B.
- Health Information meets the criteria of Limited Dataset. HIPAA Data Use Agreement is required to share data outside of UVA. Complete Appendix E.
- Data/Specimens used in this project are coded: Complete Appendix D.

Your project was determined to be non human subject research. If you decide to publish results of this project you must describe the project in the publication as non-human subject research and NOT as human subject research.

**IF SENDING OR RECEIVING DATA/SPECIMENS**

Provide this signed form to School of Medicine Office of Grants and Contracts and/or Medical Center Procurement if your project has external funding or plans to share data/specimens outside of UVA.

**Contact the IRB if anything concerning this project changes that might affect the non-human subject determination.**

Project is determined to be Human Subjects Research or a Clinical Investigation and must be submitted to the IRB-HSR for review and approval prior to implementation. Please go the [Protocol Builder](#) to create your submission.

Name of IRB Staff: Kristin Shelby

Date: 11-18-21

Website: <https://research.virginia.edu/irb-hsr>