

## CODED RESEARCH DATA/SPECIMENS AGREEMENT

THIS AGREEMENT dated \_\_\_\_\_, 20\_\_\_\_, is entered into by

**The University of Virginia Biorepository & Tissue Research Facility**  
(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 or any of the identifiers listed on Attachment A to the Researcher, unless the

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Researcher presents documentation of an Investigational Review Board (IRB) 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 University of Virginia IRB will be consulted to determine if their review and approval or that of the IRB at another institution 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.

\_\_\_\_\_  
(Data Source) Print Name

\_\_\_\_\_  
(Data Source) Title

\_\_\_\_\_  
(Data Source) Signature

Date: \_\_\_\_\_

\_\_\_\_\_  
(Researcher) Print Name

\_\_\_\_\_  
(Researcher) Title

\_\_\_\_\_  
(Researcher)Signature

Date: \_\_\_\_\_

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## 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 . )