

**Vanderbilt University Medical Center
Data Use Agreement
(Synthetic Derivative/BioVU/PathLink – VUMC/VU Non-PI)**

I, _____ “Data Recipient”, acknowledge that as a condition of receiving and using any data component(s) “Data” from the Vanderbilt University Medical Center (VUMC) biobank (“BioVU” and/or “PathLink”) including the Synthetic Derivative (SD) alone or together with other components of BioVU and/or PathLink, I must comply with VUMC policies and procedures.

I am familiar with VUMC policies and procedures applicable to use of Data from BioVU and/or PathLink and the SD, including Sanctions for Privacy and Information Security Violations, and agree to follow all such policies and procedures to protect the integrity and confidentiality of all information disclosed or made available to me from VUMC’s BioVU, PathLink and/or other associated VUMC records.

1. DATA REQUEST SCOPE AND PURPOSE

- A. I agree to use or disclose the Data for only the limited purposes necessary to conduct the following research (enter Research Project Title):

and certify that my data request is limited in scope to the minimum information necessary to conduct the Research Project.

- B. I understand and agree that I have no authority to grant access or use of the Data I may obtain from the SD, BioVU and/or PathLink to any other person. In the event that I identify a need for access or use of the data by another individual in order to conduct the Research Project, I agree to notify the Principle Investigator for his or her approval and handling.

2. DATA RECIPIENT HEREBY AGREES:

- A. not to use or disclose the Data for any purpose other than as described in this Agreement and in the IRB approved protocol or as required by law.
- B. to use appropriate safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement.
- C. to report in writing to the VUMC Privacy Official at privacy.office@vanderbilt.edu any use or disclosure of any portion of the Data not provided for by this Agreement of which it becomes aware, including without limitation, any disclosure to an unauthorized subcontractor or any other individual or entity not named, within ten (10) days of its discovery.
- D. to obtain and maintain, for the term of this Agreement, a written agreement with each contractor or with any agent, including a subcontractor, to whom it provides any portion of the Data (named in 1.B above) holding them to the same restrictions

and conditions that apply through this Agreement to the Data Recipient with respect to such information.

- E. not to identify the information contained in the Data by any means, including using Star Panel or other information together with the Data , or to contact any individual whose information is contained in the Data.
- F. in the event the Data Recipient becomes aware of any personally identifiable health information unintentionally missed by the de-identification process, such that the personally identifiable health information is retained in the Data Set received by Data Recipient, to report all such occurrences only to SD, BioVU and/or PathLink program staff and/or the privacy office for quality assurance purposes, and not to any third party.
- G. to immediately notify VUMC's Office of Legal Affairs of Data Recipient's receipt of any request or subpoena for any portion of the Data or any information related to this Agreement. To the extent that VUMC decides to assume responsibility for challenging the validity of such request, Data Recipient will cooperate fully with VUMC in any such challenge.
- H. If genomic sequence data are generated, to provide those data back to BioVU on any BioVU dataset(s) and DNA samples made available to him/her within one year of when access was granted. This will enable the goal of the BioVU to grow a robust resource continually enriched by its users.
- I. If new pathology slides are created or stained when using PathLink resources, that scanned images will be provided back to PathLink within one year of when access was granted. If any genomic sequences data are generated from PathLink DNA, to provide those data back to PathLink within one year of when access was granted. This will enable the goal of PathLink to grow a robust resource continually enriched by its users.
- J. to retain control over the Data, and further agrees not to distribute the Data in any form to any entity or individual other than a subcontractor pursuant to the restrictions set forth in subsection 2.D. above and/or his/her research team member(s) who agree to the terms within this Data Use Agreement, subject to applicable law. The Data Recipient acknowledges responsibility for ensuring appropriate use of the Data.
- K. that if he/she changes institutions any data from BioVU will be returned and/or destroyed and that data may not transferred to the new institution.
- L. to acknowledge the Synthetic Derivative, BioVU and/or PathLink in all oral and written presentations, disclosures, and publications resulting from any analyses of the BioVU and/or PathLink datasets. A sample statement to be used in acknowledgements is "The dataset(s) used for the analyses described were obtained from Vanderbilt University Medical Center's [INSERT: BioVU, PathLink, or Synthetic Derivative] which is supported by institutional funding and by the CTSA grant ULTR000445 from NCATS/NIH."

3. DATA DISCLAIMER

VUMC disclaims all warranties as to the accuracy of the data in BioVU, PathLink, or the acceptable performance or fitness of the data for any particular purpose. As such, the Data recipient acknowledges that VUMC does not and cannot warrant the results that may be obtained by using data included in the Data Set.

4. DEFINITIONS

Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in the Privacy Rule.

- A. Individual shall have the same meaning as the term “individual” in 45 CFR Sect. 164.501 of the Privacy Rule and shall include a person who qualifies as a personal representative in accordance with 45 CFR Sect. 164.502(g) of the Privacy Rule.
- B. Data shall mean certain de-identified genomic, pathologic, and/or health record information contained within the VUMC BioVU DNA Databank repository of DNA samples, the PathLink Databank repository of tissue samples, and/or the Synthetic Derivative Database of health record information.
- C. Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.
- D. Protected Health Information or PHI shall have the same meaning as the term “protected health information” in 45 CFR Sect. 164.501 of the Privacy Rule, to the extent such information is created or received by Data Recipient from VUMC.
- E. Required by Law shall have the same meaning as the term “required by law” in 45 CFR Sect. 164.501 of the Privacy Rule.

RECOMMENDED BY:

Principal Investigator:

X _____
Sign physically or insert pdf of signature here

PI Name:

PI Title:

IRB #:

Date:

AGREED AND ACCEPTED BY:

Data Recipient:

X _____
Sign physically or insert pdf of signature here

Name:

Data Recipient Title:

Date:

(Original to be filed with Synthetic Derivative/BioVU/PathLink)
(PI to retain copy for research file)