

TERMS OF ACCESS AND DATA USE AGREEMENT

I, _____, (“Data Recipient”), acknowledge that as a condition of receiving and using any data component(s) (defined as “Data” below) from the Indiana Biobank (“BioBank”), I must comply with Indiana University (“IU”), IU School of Medicine, and BioBank, policies and procedures.

I am familiar with IU, IU School of Medicine, and BioBank, policies and procedures applicable to use of Data from BioBank, including the policies related to 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 BioBank.

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 IRB Number):

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

- B. The associated IU School of Medicine research team members, or classes of team members, who are permitted to use or receive the Data for purposes of the Research Project in addition to me include [insert Box or format you prefer in order to have PI make a list].
- C. I understand and agree that I have no authority to grant access or use of the Data I may obtain from the BioBank to any other person, aside from the research team members listed above. 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 Biobank for further approval and handling.
- D. I understand that I am responsible for the proper use and safeguarding of the data on behalf of my entire research team.
- E. I understand that if I do not agree to these terms, I should not accept the data.

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 all applicable federal and Indiana state laws.
- 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 both the Biobank at inbiobnk@iu.edu and IU’s Office of the Vice President and General Counsel at vpgc@iu.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, 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 BioBank program staff and/or the privacy office for quality assurance purposes, and not to any third party.
- G. to immediately notify IU's Office of the Vice President and General Counsel 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 IU decides to assume responsibility for challenging the validity of such request, Data Recipient will cooperate fully with IU in any such challenge.
- H. If genomic sequence data are generated, to provide those data back to BioBank on any BioBank 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 BioBank to grow a robust resource continually enriched by its users.
- I. If new pathology slides are created or stained when using BioBank resources, that scanned images will be provided back to BioBank within one year of when access was granted. If any genomic sequences data are generated from BioBank DNA, to provide those data back to BioBank within one year of when access was granted. This will enable Biobank 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 BioBank will be returned and/or destroyed and that data may not transferred to the new institution.
- L. to acknowledge the BioBank in all oral and written presentations, disclosures, and publications resulting from any analyses of the BioBank datasets. A sample statement to be used in publications is "This [(publication was made possible) (project was supported), or (project was funded)], in part, with support from the Indiana Biobank and the Indiana Clinical and Translational Sciences Institute funded, in part by Award Number UL1TR002529 from the National Institutes of Health, National Center for Advancing Translational Sciences, Clinical and Translational Sciences Award. The content is solely the responsibility of the

authors and does not necessarily represent the official views of the National Institutes of Health.”

- M. that any violation of the Terms of Access and Data Use Agreement will result in a breach of this Agreement and that Data Recipient’s access to the Data may be revoked. If Data access is revoked, Data Recipient must return or destroy the Data.

3. DATA DISCLAIMER

BioBank disclaims all warranties as to the accuracy of the data in BioBank, or the acceptable performance or fitness of the data for any particular purpose. As such, the Data recipient acknowledges that BioBank 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. 160.103 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 data maintained by the Indiana BioBank and provided by the Indiana BioBank to the Data Recipient
- 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. 160.103 of the Privacy Rule, to the extent such information is created or received by Data Recipient from BioBank.
- E. Required by Law shall have the same meaning as the term “required by law” in 45 CFR Sect. 164.103 of the Privacy Rule.

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 BioBank)
(PI to retain copy for research file)