

**West Virginia University C8 Health Project
(Brookmar Health Project & Science Panel Studies)**

**DATA USE AND CONFIDENTIALITY USER AGREEMENT
for use of the C8 Health Project (Brookmar Health Project & Science Panel
Studies) Data Repository and data contained therein**

The West Virginia University Board of Governors, on behalf of West Virginia University and its Robert C. Byrd Health Sciences Center ("WVU") was designated as the "third party mechanism" for overseeing, implementing, managing and administering all data generated as part of the Brookmar Health Project and/or Science Panel studies (the "Data"). WVU has access to and the authorization to provide eligible members of the scientific and academic community access to the Data. WVU is making the Data available solely for the purpose of enabling users to prepare for and to conduct research as contemplated by the authorizing court order, and in order to benefit science, medicine, human health, the identified class members, or society in general.

This Data Use and Confidentiality User Agreement explains the terms and conditions of access to the Data by the User. **ANY USER WHO WISHES TO ACCESS THE DATA MUST READ THE FOLLOWING TERMS AND AGREE TO AND ABIDE BY THEM BY ENTERING THE INFORMATION REQUESTED BELOW.**

For All Investigators:

1. User understands and agrees that any Data/Datasets that WVU provides to User are proprietary and confidential, and that access is provided under the terms and conditions required by the Circuit Court of Wood County, West Virginia (Amended Order, CV-01-C-608, *Leach v. E.I. du Pont de Nemours & Co.*), as implemented by the Standard Operating Procedures of the Robert C. Byrd Health Sciences Center Office of Research and Graduate Education.
2. User understands that any Data/Datasets that WVU provides to User may only be used for approved purposes as described herein, and in the above-referenced Standard Operating Procedures.
3. Specifically, User agrees that User will use the Data/Datasets solely for research and for no other purpose.
4. WVU has the right and obligation to preserve the integrity of any Datasets contained within, created from or retrieved from the Data. WVU reserves the right to create, amend, and promulgate new User requirements at any time as necessary to protect confidentiality, comply with its obligations under the Amended Order or any subsequent court action, and, where applicable, limit the possibility of identification or re-identification of any individual, group of individuals, or individual-level data. User agrees to comply with such requirements.
5. User agrees to cite the WVU C8 Health Project in any publication that results from usage of the Data and to submit evidence of such publication

to the C8 Health project in a timely manner as required by the Standard Operating Procedures.

6. All Data/Datasets disclosed pursuant to this Agreement, including without limitation all written and tangible forms thereof, shall be and remain the property of WVU. Upon termination of this Agreement as provided in Section 7 below, or upon any request by WVU, User shall immediately cease using the Data/Datasets, and return any Data/Datasets to WVU, or destroy same at the request of and in the manner prescribed by WVU.
7. WVU may terminate User's access to Data/Datasets under this Agreement for any reason upon written notice to User.
8. User's obligations under this Agreement shall survive the expiration or termination of the Agreement.
9. This Agreement may be modified or amended only in a writing signed by duly authorized representatives of both User and WVU. This Agreement shall be governed by and construed in accordance with the laws of the state of West Virginia.
10. User agrees that User will not attempt to identify or re-identify any individual or group of individuals from the Data/Datasets, and that if any identification or re-identification is made, regardless of whether such identification is inadvertent, User agrees that User will immediately inform the WVU Office of Research Integrity and Compliance (ORIC) Director and comply with all steps required by the WVU ORIC Director in response to such identification or re-identification.
11. User will maintain the security of the data, including, but not limited to:
 - a. Securing the username, password, and any other associated identifiers allowing User to access the server/data on the WVU HSC internal network.
 - b. All external access to data will be via Citrix software. In all cases, data will be stored on the WVU Health Sciences Center internal server network, and should not be downloaded from the server. Any exception to this downloading policy will require review and approval by the WVU HSC Information Technology department. If approval to download Data/Datasets to an individual computer is granted, the User must destroy these data as soon as the research is completed, and provide valid evidence of destruction.
 - c. User agrees that User will not disclose, disseminate, or otherwise share the Data/Datasets to or with any other person or entity except with persons or entities on User's research staff. User agrees that User will inform persons or entities on User's research staff of the obligations with respect to use and confidentiality of the Data under this Agreement and User agrees to ensure that all staff review this Agreement prior to Data/Dataset access or use. User shall be responsible for compliance by these persons/entities with the terms of this Agreement and any breach thereof.
12. Notice on the Methods for the Collection, Processing, Handling, and Storage of the Stored Serum Samples: Samples available for research are the residual serum samples remaining after PFC analysis for the C8 Health Project was completed. All samples were collected in 2005-2006, and there

is variation in the amount of sample remaining for each participant which may limit capacity to repeat experiments and therefore, reproducibility. It should be noted that, when collected, the samples were not specifically intended for inclusion in additional research projects. As such, for each sample the time from collection to initial freeze, and number of freeze-thaw cycles cannot be determined. The general collection and processing procedures, therefore, may not meet the most rigorous laboratory standards for specific types of analyses and individual *researchers must consider how sample age, processing, and freeze-thaw cycles affect the biological targets being measured in these samples.*

Prospective researchers will be required to acknowledge in writing this sample disclaimer and include the statement below in any forum (e.g., manuscript, grant, proposal, or presentation, etc.) that proposes the use of or reports the results from analysis of these samples. Disclaimer Statement for inclusion in manuscripts, grants, proposals, presentations, etc.:

“It is acknowledged and disclosed here that the residual samples from the C8 Health Project, collected during 2005-2006, have heterogeneity with regard to processing, including the number of freeze-thaw cycles subsequent to original analysis. All results reported here/analyses proposed here must be interpreted within the context of these limitations, which are more fully described elsewhere [<http://www.hsc.wvu.edu/resoff/research/c8/>]”.

For Investigators Not Affiliated with WVU:

User acknowledges and agrees that *User is not permitted to receive individual level data, whether identified or de-identified.* User agrees that User will not attempt to identify any individual level data from the Data/Datasets, and that if any such identification is made, regardless of whether such identification is inadvertent, User agrees that User will immediately inform WVU and comply with all steps required by WVU in response to such identification.

BY ENTERING THE INFORMATION REQUESTED IN THIS AGREEMENT AS DIRECTED ABOVE, USER AFFIRMS THAT USER HAS READ THE TERMS AND CONDITIONS OF ACCESS TO DATA AND AGREES TO THEM.

Signature

Date

Print Name