 <p>West Virginia University Robert C. Byrd Health Sciences Center Office of Research and Graduate Education</p> <p><i>C8 Health Project Standard Operating Procedures</i></p>	<p>Section#: 1</p> <p>Title: Data Oversight Committee</p> <p>1st Effective 12/08/2015 Reviewed 12/08/2015</p>
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1 C8 Data Oversight Committee

1.1 Purpose


On September 4, 2013, an amended order was entered in *Leach v. E.I. du Pont de Nemours & Co.*, Civil Action No. 01-C-608 (Circuit Court of Wood County, West Virginia) designating the West Virginia University (WVU) Robert C. Byrd Health Sciences Center 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 Office of the Senior Associate Vice President for WVU Health Sciences Research and Graduate Education was authorized to designate “Receiving Individuals” within West Virginia University to assist in meeting the obligations of the “third party mechanism”.

1.2 Policy

A C8 Data Oversight Committee shall be created to implement all aspects of the amended court order.

1.3 Procedure

The Senior Associate Vice President for WVU Health Science Research and Graduate Education will periodically appoint individuals affiliated with West Virginia University to serve on the C8 Data Oversight Committee. This Committee will assist the Senior Associate Vice President in the implementation of the “third party mechanism” for data sharing. Members will be selected based on competence, scientific reliability, and trustworthiness. Members will serve at the sole discretion of the Senior Associate Vice President, and the court will periodically be informed of the current membership. This committee shall also contain one non-voting representative from the WVU Office of the Vice President for Legal Affairs and General Counsel.

 <p>West Virginia University Robert C. Byrd Health Sciences Center Office of Research and Graduate Education</p> <p><i>C8 Health Project Standard Operating Procedures</i></p>	<p>Section#: 2</p> <p>Title: Individual Class Member Reports</p> <p>1st Effective 10/16/2014 Reviewed 10/16/2014</p>
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2 Release of C8 Health Project and/or Science Panel Individual Data

2.1 Purpose

On September 4, 2013, an amended order was entered in *Leach v. E.I. du Pont de Nemours & Co.*, Civil Action No. 01-C-608 (Circuit Court of Wood County, West Virginia) designating the West Virginia University Robert C. Byrd Health Sciences Center 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 relevant portion of the amended order directs the “Receiving Individuals” to create a process wherein individual members of the Class can receive a copy of their own, individual information generated from their participation in any of the studies related to the original lawsuit settlement. The amended order permits the “Receiving Individuals” to create a mechanism to recover reasonable and legitimate costs associated with this process.¹

¹ Given the nature of “All Filed Data”, the “Receiving Individuals” will rely on W. Va. Code R. §16-29-2 {June 8th, 2014}, as a guide to the identification of costs that will comprise the user fee. The user fee shall be reviewed annually to ensure the validity of the associated costs that comprise the user fee, and to index these costs to account for inflation.

2.2 Definitions

All Filed Data: All data generated pursuant to the Brookmar Health Project and/or Science Panel Studies

Class Member: An individual who qualifies as a member of the “Class” as defined by the court in the settlement of *Leach v. E.I. du Pont de Nemours & Co.*, Civil Action No. 01-C-608 (Circuit Court of Wood County, West Virginia, entered Feb. 24, 2005).

Brookmar Health Project: The purpose of the C8 Health Project was to collect health data from Class Members of the lawsuit through written questionnaires and a battery of blood tests, including a test to ascertain the amount of C8 in the blood. Brookmar, Inc. was appointed by the Circuit Court of Wood County to conduct the C8 Health Project. Accordingly, the C8 Health Project began testing on July 27, 2005.

Science Panel Studies: The Science Panel was also appointed by the Circuit Court of Wood County as a part of the aforementioned Settlement Agreement. The Science Panel, as part of the Community Study, received the anonymized and non-identifiable health data collected by Brookmar, Inc. to examine and analyze as part of its work. In addition, identifiable health data was released to the Science Panel for those Participants who gave additional specific consents.

Members of the C8 Science Panel were:

Dr. Tony Fletcher, London School of Hygiene and Tropical Medicine

Dr. David Savitz, Brown University

Dr. Kyle Steenland, Emory University

Receiving Individuals: Individuals within West Virginia University and the Office of the Senior Associate Vice President for WVU Health Sciences Research and Graduate Education who have access to “All Filed Data” for the purposes of fulfilling the court’s order.

Requestor: An individual requesting individual level data from the Receiving Individuals, whether on his/her own behalf or on behalf of a Class Member for whom they are legally authorized to request and receive data.

2.3 Policy

The identity of Requestors shall be meticulously verified to ensure that each Requestor only receive his/her own data or data for Class Members for whom they are legally authorized to request and receive data.

2.4 Procedure for Release of Data

- 1) A Requestor will download, print, and complete the *C8 Health Project Individual Data Request Form* located at the Robert C. Byrd Health Sciences Center Office of Research and Graduate Education website (<http://www.hsc.wvu.edu/ResOff/C8/Science-Panel>).
- 2) The Requestor (or his/her legal representative) will sign the **completed** *C8 Health Project Individual Data Request Form* and have said form witnessed and notarized. If the Request Form is signed by someone other than the Class Member, documentation must be provided to sufficiently document that the Class Member has provided authority for the representative to request/receive the Class Member's data.
- 3) **Individual adult requestors** will present two of the following forms of identification, **at least one of which must have a photo**, to the Notary Public for identity verification (this requirement must be fulfilled regardless of whether the data is requested by the Class Member or his/her legal representative):
 - a. Current driver's License;
 - b. Current passport or passport card;
 - c. Certificate of Citizenship;
 - d. Certificate of Naturalization;
 - e. Social Security Card or Birth Certificate (original or certified copy);
 - f. State Issued Photo ID Card;
 - g. Government Employment ID card;
 - h. Student Photo ID Card issued by a US school, college, or university;
 - i. Military Photo ID Card;
 - j. Major Credit Card or Bank Card with Photo;
 - k. Resident of U.S. Alien Card;
 - l. Official Divorce Decree or Marriage Certificate;
 - m. Certificate of name change; or
 - n. Official baptismal record.

- 4) **Requestors seeking the individual data of a child** must provide:
 - a. The **completed, witnessed, and notarized C8 Health Project Individual Data Request Form and**
 - b. An original or certified copy of the birth certificate or court-issued custody papers to prove legal guardianship.
- 5) **Requestors seeking the individual data of a deceased person** must provide:
 - a. The **completed, witnessed, and notarized C8 Health Project Individual Data Request Form and**
 - b. Sufficient documentation to prove that the individual is either the administrator or executor of the estate. If there is no estate, then a certified copy of the death certificate with the Requestor named as the informant must be provided.
- 6) **Requestors seeking the individual data of any person determined to be "mentally incompetent," "intellectually disabled," or "mentally handicapped"** must provide:
 - a. The **completed, witnessed, and notarized C8 Health Project Individual Data Request Form and**
 - b. Sufficient documentation demonstrating power of attorney or medical power of attorney/Healthcare Surrogate or other legal documentation.
- 7) The Requestor will send the following to the Receiving Individuals via **certified mail with a signature upon delivery required**:
 - a. The completed, witnessed, and notarized *C8 Health Project Individual Data Request Form*;
 - b. The required verification documents (for third party requests); and,
 - c. A personal check or money order for the amount of the user fee.
- 8) Upon receipt of the request, the Receiving Individuals shall verify that the *C8 Health Project Individual Data Request Form* is complete and accurate.
- 9) A letter will be sent to the Requestor, asking for a properly executed authorization or other information if a discrepancy is discovered.
- 10) The Receiving Individuals shall deposit the personal check or money order into an established account..

- 11) Once the *C8 Health Project Individual Data Request Form* has been determined to be complete and accurate and the user fee deposited in an established account, the Receiving Individuals will generate a database report containing “all filed data” associated with the individual Class member.
- 12) The Receiving Individuals shall assign a password required to open the document using Adobe Acrobat X™ or later. **Importantly, the level of encryption shall not be less than 256 bit AES.**
- 13) **For those Requestors providing an e-mail address,** the Receiving Individuals shall use an established Health Sciences Center (HSC) email account to e-mail the encrypted report using the HSC’s Secure Web Delivery (SWD) server. **To use the SWD server, the Receiving Individuals shall insert “[Secure]” in the subject line of every message** to ensure that the report is securely transmitted over the internet to external parties by encrypting the transmission. Requestors will be required to register with the SWD system to retrieve the report.
- 14) The Receiving Individuals will then mail the password necessary to access the Adobe Acrobat report via certified mail with a signature required upon delivery.
- 15) **For those Requestors requesting a paper copy of the report,** the Receiving Individuals shall mail the paper copy of the report to the Requestor via certified mail with a signature required upon delivery. The envelope will be officially sealed prior to mailing.
- 16) The Receiving Individuals shall maintain a database detailing the following information:
 - a. Date and time that the request for individual information was received;
 - b. Date and time that the accuracy of the *C8 Health Project Individual Data Request Form* was verified and the name of the receiving individual conducting the verification;
 - c. Date and time that the request was fulfilled (i.e. secure e-mail sent or paper copy mailed);
 - d. Date and time mail was received and signed for by the Requestor;and,

- e. Notes detailing issues related to *C8 Health Project Individual Data Request Form* verification.

2.5 Cost of Releasing Data to Requestor


- 1) **The user fee for providing Class member reports will be \$25 per request and is based on the following factors:**
 - a. Effort and associated labor costs related to placing the records in electronic media. These costs include:
 - i. Development of the Microsoft Access™ database and reports.
 - ii. Generation of the individual Microsoft Access™ report.
 - b. Effort and labor costs related to transmission of the individual report to the requestor (either electronic or paper).
 - c. Mailing and supply costs related to transmission of the individual report to the requestor (either electronic or paper).
- 2) This fee will be reviewed annually for legitimacy and accuracy, and the associated costs that comprise the fee will be indexed to account for inflation.

References

Leach v. E.I. du Pont de Nemours & Co., No. 01-C-608 (Circuit Court of Wood County, West Virginia, entered Feb. 24, 2005);

Leach v. E.I. du Pont de Nemours & Co., No. 01-C-608 (Circuit Court of Wood County, West Virginia, entered Sept. 4th, 2013); and,

W. Va. Code §16-29-2 {June 8th, 2014}.

 <p>West Virginia University Robert C. Byrd Health Sciences Center Office of Research and Graduate Education</p> <p><i>C8 Health Project Standard Operating Procedures</i></p>	<p>Section#: 3</p> <p>Title: Release of Data for Research</p> <p>1st Effective 12/08/2015 Reviewed 03/21/2016</p>
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3 Release of Data for Research Purposes

3.1 Purpose

On September 4, 2013, an amended order was entered in *Leach v. E.I. du Pont de Nemours & Co.*, Civil Action No. 01-C-608 (Circuit Court of Wood County, West Virginia) designating the West Virginia University Robert C. Byrd Health Sciences Center 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 relevant portion of the amended order directs the “Receiving Individuals” to create “a process wherein members of the scientific or academic communities may utilize the data in “All Filed Data” and/or related serum stored in the WVU Tissue Bank for reasons that will benefit science, medicine, human health, the Class, or society in general.” The amended order permits the “Receiving Individuals” to create a mechanism to recover reasonable and legitimate costs associated with this process.

3.2 Definitions

WVU C8 Data Oversight Committee: A group of individuals appointed by the Senior Associate Vice President for WVU Health Sciences Research and Graduate Education for the purposes of fulfilling the court’s order.

WVU Affiliated Investigator: Any individual that is formally affiliated with West Virginia University either by employment or academic appointment and is eligible to serve as a principal investigator on an application submitted to the West Virginia University Institutional Review Board.

Non-affiliated Investigator: Any individual that is not formally affiliated with West Virginia University either by employee status or academic appointment.

Receiving Individuals: Individuals within West Virginia University and the Office of the Senior Associate Vice President for WVU Health Sciences Research and Graduate Education that have been given access to “All Filed Data” for the purposes of fulfilling the court’s order.

All Filed Data: All data generated pursuant to the Brookmar Health Project and/or Science Panel Studies

Class Member: An individual who qualifies as a member of the “Class” as defined by the court in the settlement of *Leach v. E.I. du Pont de Nemours & Co.*, Civil Action No. 01-C-608 (Circuit Court of Wood County, West Virginia, entered Feb. 24, 2005).

Brookmar Health Project: The purpose of the C8 Health Project was to collect health data from Class Members of the lawsuit through written questionnaires and a battery of blood tests, including a test to ascertain the amount of C8 in the blood. Brookmar, Inc. was appointed by the Circuit Court of Wood County to conduct the C8 Health Project. Accordingly, the C8 Health Project began testing on July 27, 2005.

Science Panel Studies: The Science Panel was also appointed by the Circuit Court of Wood County as a part of the aforementioned Settlement Agreement. The Science Panel, as part of the Community Study, received the anonymized and non-identifiable health data collected by Brookmar, Inc. to examine and analyze as part of its work. In addition, identifiable health data was released to the Science Panel for those Participants who gave additional specific consents.

Members of the C8 Science Panel were:

Dr. Tony Fletcher, London School of Hygiene and Tropical Medicine

Dr. David Savitz, Brown University

Dr. Kyle Steenland, Emory University

Serums: C8 serum samples obtained as part of the Brookmar Health Project that are currently stored in the WVU Tissue Bank.

3.3 Policy

The Receiving Individuals shall create procedures related to releasing C8 data for research purposes that honor the primacy of protecting the identity and anonymity of individuals. Therefore, studies that do not require direct access to data are preferred followed by studies that require access to de-identified data.

All researchers requiring direct access to data will be required to have both a valid, Institutional Review Board (IRB) approved protocol and project approval from the WVU C8 Data Oversight Committee prior to accessing any existing C8 Health Project data and/or Science Panel Studies (electronic and serum). The C8 Data Oversight Committee will ensure that proposed studies are both consistent with the Court's order dated January 25th, 2013 and will benefit science, medicine, human health, the Class, or society in general.

3.4 Procedures

3.4.1 West Virginia University Affiliated Investigator

- 1) The principal investigator shall obtain IRB approval for the research project from the West Virginia University Institutional Review Board
- 2) For each proposed research project, a copy of the following should be e-mailed to C8HealthProject@hsc.wvu.edu in preparation for review by the West Virginia University C8 Data Oversight Committee (as applicable):
 - a. The West Virginia University IRB approval letter
 - b. The West Virginia University IRB approved variable list
 - c. The approved Health Insurance Portability and Accountability Act (HIPAA) waiver of authorization
 - d. Approved and watermarked informed consent documents
 - e. Approved advertisements and/or recruitment letters
 - f. A completed *C8 Health Project Data Request* form
 - g. The *C8 Health Project Data Use Agreement*
- 3) Upon receipt of the required documents, the C8 project coordinator will electronically send the documents by e-mail to one C8 Data Oversight Committee member for scientific review.
- 4) The C8 Data Oversight Committee scientific reviewer will send the protocol along with a recommendation to the C8 Project Coordinator.

- 5) The C8 project coordinator will e-mail the protocol along with the recommendation of the C8 Data Oversight Committee scientific reviewer to all current members of the WVU C8 Data Oversight Committee for review, and solicit a vote of approve, disapprove, or defer pending more information. A simple majority of the current WVU C8 Data Oversight Committee shall be required to ratify any action. In cases where a simple majority cannot be obtained via electronic means, the research protocol will be placed on the agenda of the next scheduled meeting for further discussion.
- 6) The C8 project coordinator will formally notify the principal investigator once a committee decision has been reached.

3.4.2 Non-affiliated Investigator

- 1) The principal investigator shall obtain IRB approval for the research project from an IRB registered with the United States Office of Human Research Protections with a federalwide assurance number (FWA).
- 2) For each proposed research project, a copy of the following should be emailed to C8HealthProject@hsc.wvu.edu, in preparation for review by the West Virginia University C8 Data Oversight Committee:
 - a. The IRB approval letter
 - b. A copy of the approved IRB protocol with all associated attachments including an approved Health Insurance Portability and Accountability Act (HIPAA) waiver of authorization (if applicable)
 - c. A completed *C8 Health Project Data Request* form
 - d. The *C8 Health Project Data Use Agreement form*
 - e. Detailed code or other analysis details to be conducted by personnel at West Virginia University
- 3) Upon receipt of the required documents, the C8 project coordinator will electronically send the documents by e-mail to one C8 Data Oversight Committee member for scientific review.
- 4) The C8 Data Oversight Committee scientific reviewer will send the protocol along with a recommendation to the C8 Project Coordinator.
- 5) The C8 project coordinator will e-mail the protocol along with the recommendation of the C8 Data Oversight Committee scientific reviewer to

all current members of the West Virginia University C8 Data Oversight Committee for review, and solicit a vote of approve, disapprove, or defer pending more information. A simple majority of the current West Virginia University C8 Data Oversight Committee shall be required to ratify any action. In cases where a simple majority cannot be obtained via electronic means, the research protocol will be placed on the agenda of the next scheduled meeting for further discussion.

3.5 Release of Electronic Data for Research

For approved research requests for electronic data, a limited electronic datafile will be placed on a secure, internal WVU Health Sciences Center server. The datafiles themselves will be encrypted and password protected with a randomly generated password for each file.

Access to each file will be granted based on username and restricted to only the individual(s) listed in the IRB approved protocol. The file will only contain data elements listed in the approved IRB protocol, and the server/data will only be accessible from the WVU HSC internal network by WVU affiliated investigators. Pursuant to the amended court order, investigators external to WVU are not permitted to receive individual level data (de-identified or identified), unless partnering with a WVU affiliated principal investigator (see standard operating procedure 3.7). Whenever possible, a copy of this file should not be downloaded from the server to an individual computer. If a copy is downloaded from the server for analysis, the copy shall be destroyed according to the guidelines set forth in the executed C8 Data Use Agreement. It is the responsibility of the WVU affiliated investigator to notify the C8 project coordinator at C8HealthProject@hsc.wvu.edu when the data analysis is complete so that the electronically created file can be deleted from the C8 server.

3.6 Release of Serum Samples for Research

The C8 serum samples were not originally collected for research purposes, and thus not subjected to rigorous scientific controls. More specifically, these samples were a) not flash frozen; b) have had an unknown amount of time at room (or not -80C) temperature; and, c) have undergone multiple freeze-thaw cycles. Therefore, the samples are of unclear quality and may not be valid for certain types of assays /detection of some molecules, in particular proteins and

miRNA. Given this situation, all investigators, whether WVU affiliated or non-affiliated, requesting serums for use in research will be required to address this issue in their application. At a minimum, investigators must supply valid, supporting documentation that the proposed analyses will be scientifically valid in the face of the caveats of these samples.

To prevent freeze-thaw damage and thus preserve the integrity of the serums, approved research requests for serums shall be fulfilled no greater than four times in a calendar year. Researchers with approved serum requests will be informed of the approximate date when the next requests will be fulfilled. Pursuant to the amended court order, investigators external to WVU are not permitted to receive individual level data (de-identified or identified), unless partnering with a WVU affiliated principal investigator (see standard operating procedure 3.7).

3.6.1 Disclaimer Statement

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.]

3.6.2 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/>]”.

3.7 Access to Individual Level Data for Non-affiliated Investigators

Non-affiliated investigators seeking access to individual level data must partner with a WVU affiliated principal investigator, and be listed on an approved protocol by the WVU IRB. After fulfilling the requirements listed in sections 3.4.1 and 3.4.2, a non-affiliated investigator may be granted access to a limited electronic datafile as described in section 3.5. Access to this file is only possible from the campus of West Virginia University. Non-affiliated investigators who have been granted access shall make arrangements with the C8 project coordinator (C8HealthProject@hsc.wvu.edu) for travel to the Health Sciences Center campus to analyze the datafile.

Non-affiliated investigators seeking to analyze serum samples should contact the C8 project coordinator as soon as possible to query the possibility of analyzing such samples on the campus of West Virginia University. Such analyses may incur additional costs specific to the project and the nature the request.

3.8 Future Research using the Existing De-Identified C8 Dataset


Prior to the amended court order dated September 4, 2013 that released identifiers to the West Virginia University (WVU) Robert C. Byrd Health Sciences Center, investigators at the Robert C Byrd Health Sciences Center partnered directly with Brookmar, Inc. to clean and provide summary analyses of de-identified C8 data. Some additional research activities using this original de-

identified dataset under WVU IRB #17015-E (approved August 21, 2006) were conducted.

Any additional research activities using this de-identified C8 dataset will require submission, review, and approval of a WVU IRB expedited category 5 protocol. Upon approval of the protocol, the investigator shall be required to notify the C8 project coordinator and provide a copy of the approved protocol. Prior to commencement of the research, investigators will also be required to sign the C8 Data Use Agreement.

3.9 Cost of Releasing Data to Investigators

- 1) **The user fee for providing investigators with data will vary depending on the following factors:**
 - a. Effort and associated labor costs related to retrieving requested data (electronic and serum).
 - b. Effort and associated labor costs related to data analysis and report preparation.
 - c. Mailing and supply costs related to transmission of research data (including serums) and/or reports to investigators.
- 2) The factors comprising each fee will be itemized and made available to the requesting investigator and to the Court upon request.

 <p>West Virginia University Robert C. Byrd Health Sciences Center Office of Research and Graduate Education</p> <p><i>C8 Health Project Standard Operating Procedures</i></p>	<p>Section#: 4</p> <p>Title: Policy on Publications</p> <p>1st Effective 12/08/2015 Reviewed 12/08/2015</p>
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4 Publications

4.1 Purpose

On September 4, 2013, an amended order was entered in *Leach v. E.I. du Pont de Nemours & Co.*, Civil Action No. 01-C-608 (Circuit Court of Wood County, West Virginia) designating the West Virginia University Robert C. Byrd Health Sciences Center 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 relevant portion of the amended order directs the “Receiving Individuals” to “create a mechanism for monitoring how results from conducted studies are used and disseminated in a manner consistent with the intent to benefit science, medicine, human health, the Class, or society in general”.

4.2 Policy

All peer-reviewed publications, including published abstracts presented at national and international meeting as well as full manuscripts, shall be reported to the C8 Data Oversight Committee.

4.3 Procedure

Investigators shall send the following items in a timely manner to the C8 project coordinator at C8HealthProject@hsc.wvu.edu:

- 1) Final published pdf copies of the report, abstract, or peer-reviewed manuscript.
- 2) Any other citation or presentation information including the date and venue of presentation.