I. PURPOSE

The purpose of the PHACS Data Sharing and Repository policy is to outline the governance of the overarching process as well as provide guidance for the use and sharing of data and biological specimens collected by PHACS-affiliated studies and substudies. It also sets forth the responsibilities of each entity involved in requesting, reviewing, and approving any data sharing activities. The procedures and related information for requesting data (with or without analysis support) and requesting specimens are outlined below.

II. SCOPE

This policy will apply to investigators, both internal and external to the PHACS network, seeking PHACS data and or biological specimens for the purposes of conducting approved research.

III. RESPONSIBILITIES AND PROCEDURES FOR DATA SHARING

A. Responsibilities of Proposing Investigator

1. To begin the process, an investigator must complete the Capsule and Concept Sheet process outlined in the Research Development Policy, and obtain approval of their Concept[1].
2. The investigator will then work with the Data Resources Core (DRC) to determine if all analyses can be performed by the DRC, as outlined in C.1-2 below. The DRC is based at the Harvard T.H. Chan School of Public Health (HSPH) and includes Frontier Science as the PHACS Data Management Center (DMC).
3. If the investigator is to perform data analysis (See C.2), they must complete a Data Use Agreement (DUA) as outlined in C.4 below.

B. Responsibilities of Scientific Leadership Committee (SLC) and Operations Committee (OC)

1. The SLC provides centralized oversight of the resources of the PHACS network, and approval for access to PHACS data.
2. After approval of the Concept Sheet and data request by the Scientific Leadership Committee (SLC), the Operations Committee (OC) will grant the final approval of the data request.
3. Any SLC approved proposal to use specimens generated by a PHACS-affiliated study protocol must be approved by the OC, as described above, unless the proposal concerns the use of the last remaining specimen of a particular type for a

participant or requires additional funding, in which case the Leadership Group (LG) must review and approve.

C. Responsibilities of the PHACS Cores

1. The DRC serves as the centralized data and resource management entity for the PHACS Network and will provide programming and analytical core services for integrated study design and data analysis. It also manages all data storage and access.

2. The DRC will work with the investigator to establish the set of variables to be included in the shared dataset based on the approved Concept Sheet.

3. If all analyses proposed can be carried out by analysts from the DRC, possibly with further support from the Epidemiological and Statistical Methods Core (ESC), the investigator will generally not need to be provided direct access to the datasets. In these cases, the DRC will perform the analyses and will share the results with the proposing investigator in the form of statistical analysis reports, including the appropriate summary tables and figures.

4. If the analysis cannot be carried out by the DRC, or if the proposing investigator has the necessary expertise and wishes to conduct the analysis themselves, or intends to merge PHACS data into a broader dataset for analysis (using laboratory results from PHACS biological specimens, for example), a DUA (refer to Figure 1) and/or Material Transfer Agreement (MTA) must be completed and submitted to the DRC prior to providing a limited dataset to the proposing investigator. The DRC will negotiate any PHACS rights to data and authorship with the proposing investigator.

5. The dataset will be stripped of participant identifiers by the DRC, if any exist, prior to being securely transferred to the investigator. For investigators requiring biological specimens, see Section IV below for details.

6. Public use datasets from some PHACS-affiliated studies and substudies and corresponding documentation are also available on NICHD's Data and Specimen Hub (DASH)[2]. Investigators can request the use of DASH data directly at the DASH portal, where a separate Data Use Agreement must be completed. Additional data generated from PHACS-affiliated studies and substudies will continue to be added to DASH over time.

7. **Note** that in order to provide additional confidentiality protections to participants, DASH data are completely de-identified and cannot be linked back to PHACS participants. The participant ID that is used in DASH is different than that used by clinical research sites; rather, a randomly-generated public code is assigned for the DASH public use datasets.

8. Public use datasets are likewise available from certain PHACS-affiliated studies and substudies for which journals required availability of data as a condition for publication. To request these datasets, investigators must complete the Data Request Form found on the PHACS website

IV. RESPONSIBILTIES AND PROCEDURES FOR REPOSITORY SPECIMEN REQUESTS AND TRANSFERS

A. Responsibilities of Proposing Investigator

1. Once a Concept Sheet Proposal and Specimen Request Form are approved by the SLC, the proposing investigator will work with the DRC to draft, negotiate and execute the required Material Transfer Agreement (MTA) for any specimens that will be assayed.
2. The investigator should complete the Specimen Request Form (Appendix I, a fillable PDF) and email it to the PHACS Data Management Center (DMC) at Frontier Science phacs.dms@fstrf.org.
3. Once received, the investigator should communicate to the DMC that the transferred specimens have arrived and have been reconciled. If there are discrepancies discovered upon receipt of the transfer that cannot be resolved they will be documented accordingly at the DMC.
4. Work with the DMC to transfer the resultant data to the central database for PHACS-affiliated studies and substudies.
5. Specimens remaining after completion of the testing should be reported to the DMC, who will notify the PHACS leadership for further instructions.

B. Responsibilities of the Scientific Leadership Committee (SLC)

1. The SLC will review and approve proposals to obtain specimens from the PHACS Repository based on the scientific merit of the proposal. The SLC retains primary authority over all PHACS data and related to that, all discretion as to the approval of data sharing agreements or other such data sharing activities.

C. Responsibilities of the Scientific Administrative Core (SAC)

1. The Scientific Administrative Core (SAC) on behalf of the SLC will forward approved Concept Sheet proposals and the Specimen Request Form (and data request form, if applicable) to the LG for further review and approval.

D. Responsibilities of the Operations Committee (OC)

1. Confirm that the research is within the scope of the original consent.
2. Ensure that the necessary resources to complete the proposed work have been approved before operationalizing the proposal to access specimens stored in the PHACS Central Repository.
3. Ensure that the specific protocol for which the samples were collected has the required specimens needed to carry out its primary objectives before releasing specimens.

E. Responsibilities of the Leadership Group (LG)

1. The LG will oversee that the necessary resources are available to conduct the project.
2. If the proposal concerns the use of the last remaining specimen of a particular type for a participant or requires additional funding, the Leadership Group (LG) must review and approve.

F. Responsibilities of the Data Resources Core (DRC)

1. If approved, the DRC will coordinate the initiation and execution of an MTA as required before the DMC initiates the specimen transfer.
2. The DRC will notify the DMC and instruct it to work with the institution(s) where the specimens of interest reside ("repository") to begin the specimen transfer. For most specimens, this will be the PHACS Central Repository (supported by the NICHD and located at Fisher BioServices).
3. The DMC informs the NICHD repository contact of the upcoming transfer request.
4. The DMC will prepare and send a formal specimen request (based on the completed specimen request form) to the repository that includes a shipping timeline, address of the receiving laboratory, and a detailed specimen list.
5. The DMC will notify the OC when the specimen transfer has been completed.
6. The DMC will coordinate the transfer of the resultant data to the central database for all PHACS-affiliated studies by providing instructions and guidance to the investigator/entity transferring the data.
7. The DRC will ensure that the relevant data sharing procedures have been followed.

G. Responsibilities of the Central Repository

1. Confirm receipt of the specimen request with the DMC.
2. Inform the proposing investigator that the requested specimens have been shipped
3. Provide the receiving entity with a copy of the bill of lading and shipper's name and a designated representative for the shipper who can be reached 24 hours a day, 7 days a week to determine the status on the shipment in the event of delays. Include relevant customs documents for an international shipment.
4. Work directly with the shipper in the event of delays to ensure that the shipment is being properly maintained, including replenishment of dry ice or liquid nitrogen as applicable.
5. Communicate to the DMC when the specimen transfer has been completed.

V. GENOMICS DATA SHARING

PHACS-affiliated studies and substudies may also generate large-scale human genomic data. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. The PHACS Network will make these available in accordance with the National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy[3].

VI. REFERENCES

1 PHACS Research Development Policy After logging in, go to Documents, then select PHACS Manual of Network Policies and Procedures (MNPP). Scroll down to Section 1 of the table.

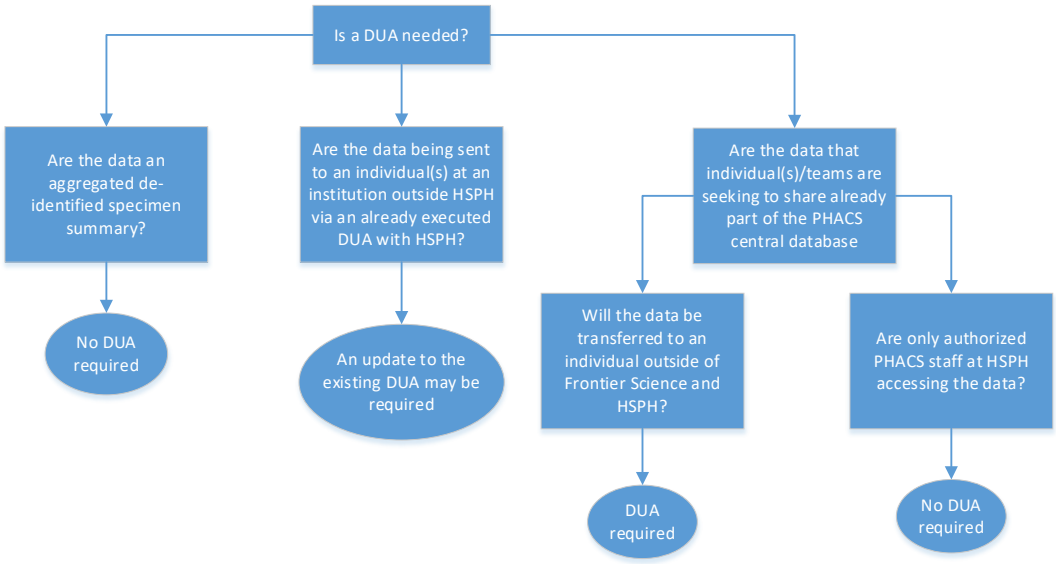
2 NICHD's Data and Specimen Hub (DASH) https://dash.nichd.nih.gov/

3 National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/

VII. INQUIRIES

For questions, please email phacs.pm@fstrf.org

FIGURE 1: DUA Requirements



Abbreviations:
DUA – Data Use Agreement
HSPH – T.H. Chan Harvard School of Public Health

APPENDIX I

SPECIMEN REQUEST FORM

Instructions:

- This fillable PDF form should be completed and emailed to phacs.dms@fstrf.org after the specimen request has been approved by the appropriate leadership.
- An approved Concept Sheet and Material Transfer Agreement (MTA) must be in place before submitting this form.
- The DMC requires one to two weeks (depending on complexity) to compile the specimen inventory data and complete the documentation required by the NICHD.
- Once approval is received from the NICHD, the specimen request will be prepared by the Repository for shipment to the testing lab.
- If this specimen request has an associated participant list for specific specimens, please email this list to phacs.dms@fstrf.org

Request Information

Study number:	
CS number:	

Person Approving Specimen Request

Name:	

Person Requesting Specimens

Name:	
Institution:	
Phone number:	
Email address:	

Specimen Request Details

Date of request (dd-mmm-yyyy):	
Date specimens are needed by (dd-mmm-yyyy):	
Purpose of request:	

Specimen type needed: (Example, EDTA Plasma)	Primary type: Derivative: ☐ Plasma ☐ Serum ☐ PBMCs ☐ Other, specify: Additive: ☐ EDTA ☐ Heparin ☐ No Additive ☐ Other, specify:
Volume requested per participant:	Minimum volume: Ideal volume:
Specific storage or shipping instructions:	
Is there a specific list of participants/patids? If yes, please provide the DMC with this list.	☐ Yes ☐ No ☐ Other, specify:
Is there a specific timepoint/date/week? If yes, please specify the time point.	☐ No ☐ Yes, specify:
Type of request:	☐ One-time data request ☐ Recurring request ☐ Other, specify:

Data Request Comments

Contact Information

Person to Receive Specimens

Name:		
Institution/Laboratory:		
Address:	Street	
	Department / building	
	City, state	
	Country	
	Zip code	
Phone number:		
Email address:		
Is this an international shipment?	☐ Yes ☐ No	
Are any special shipping permits required? If Yes, email phacs.dms@fstrf.org for further information.	☐ Yes ☐ No	

Release Information (To be completed by Frontier Science)

Frontier Science person assigned:	
Is a Materials Transfer Agreement (MTA) required?	☐ Yes ☐ No

Approval Signatures

Study Specimen Request Approver	**Specimen Requestor**
The Study Specimen Request Approver affirms that the specimen request is approved and information has been reviewed for completeness and accuracy.	The Specimen Requestor affirms that the specimen request information and shipping information have been reviewed for completeness and accuracy.