

(03/08/2018; Version 1.0)

## RECOMMENDATION FOR WELCH CENTER MEMBERS RELATING TO RESEARCH DATA FILES

### Welch Center Ad Hoc Data Committee

- I. Introduction
- II. Storing Electronic Data
- III. Recommended Approaches to Conducting Analysis behind Fire Walls
- IV. Recommended Approaches to Archiving Data for Completed Studies
- V. Recommended Approaches to Archiving Analyses In Support Of Publications
- VI. Distributing JHU Data to Users
- VII. What Should New Trainees and Faculty do When They Arrive?
- VIII. What Should Trainees and Faculty Do When They Depart?
- IX. Appendix

### I. INTRODUCTION

This guide is to provide some introductory advice on managing and storing electronic data files and documents. Work is continuing to determine the best way to manage electronic records in the long term; this guide provides information on what you can be doing now. Johns Hopkins University has developed its university-wide IT policies; technical support is also available through multiple units.

#### 1. JHU IT Policies

<http://www.it.johnshopkins.edu/policies/>

#### 2. Johns Hopkins Medicine Data Trust

[http://intranet.insidehopkinsmedicine.org/data\\_trust/index.html](http://intranet.insidehopkinsmedicine.org/data_trust/index.html)

These policies mostly apply to JHM data, particularly clinical data (e.g. EHR). Most of this doesn't apply for research studies where participants have signed consent and data are collected by the individual studies.

#### 3. ICTR Data Management Interest Group

<https://ictr.johnshopkins.edu/collaboration/collaborations/data-managers-interest-group/>

The Interest Group is developing a best practice guide. New information will be provided once the guide is available.

#### 4. JHU Data Management Services

<http://dms.data.jhu.edu/>

As part of the Entrepreneurial Library Program of the JHU Sheridan Libraries, Johns Hopkins Data Management Services provides support and guidance to JHU researchers by helping them prepare data management plans for proposals and providing research data archiving services for making data available online.

### II. STORING ELECTRONIC DATA

Welch Center members should use the shared drive system for storing electronic records wherever possible. Please refer to the Table 1 below for instructions of setting up shared drive, and Table 2 for cloud capacity, accessibility, and related cost. There are no back-ups in the personal hard drive (C:), while the shared drives are backed-up regularly. For SOM personnel,

the personal file space on the H: drive is also backed up, but this is only accessible to the personal user.

**Table 1. Backup and storage options and recommendations**

Device	Comments
<b>RECOMMENDED</b> Institutional network*	<ul style="list-style-type: none"> <li>• Contact Brandon Smith (BAS@jhmi.edu) at the Client Technology Solutions <a href="http://www.it.johnshopkins.edu/services/clientcomputing/">http://www.it.johnshopkins.edu/services/clientcomputing/</a></li> <li>• Contact MNET for DOM supported computers (MNET@jhmi.edu) <a href="http://intranet.insidehopkinsmedicine.org/mnet/">http://intranet.insidehopkinsmedicine.org/mnet/</a></li> </ul>
<b>RECOMMENDED</b> SAFE Desktop*	<ul style="list-style-type: none"> <li>• Contact: Bonnie Woods (<a href="mailto:bonnie.woods@jhu.edu">bonnie.woods@jhu.edu</a>) or Brandon Smith (<a href="mailto:BAS@jhmi.edu">BAS@jhmi.edu</a>)</li> <li>• <a href="https://ictr.johnshopkins.edu/programs_resources/programs-resources/informatics/secure-research-data-desktop/">https://ictr.johnshopkins.edu/programs_resources/programs-resources/informatics/secure-research-data-desktop/</a></li> <li>• Research, statistical (e.g. STATA, SAS, R), and database applications are available</li> </ul>
<b>RECOMMENDED</b> JHBox*	<ul style="list-style-type: none"> <li>• Compliant with PHI use policies, and a secure method for sharing data, but not for permanent storage. <a href="http://www.it.johnshopkins.edu/services/collaboration_tools/jhbox/">http://www.it.johnshopkins.edu/services/collaboration_tools/jhbox/</a></li> </ul>
MyCloud Desktop	<ul style="list-style-type: none"> <li>• This is a virtual desktop that everyone has access to by default available at mycloud.jh.edu. Click on the Hopkins MyCloud shortcut.</li> <li>• No access to the MyCloud Desktop if already have access to the SAFE Desktop.</li> <li>• Has basic Microsoft and clinical applications (Word, Outlook, EPIC, etc.). No statistical software.</li> </ul>
USB Storage Device	<ul style="list-style-type: none"> <li>• Only use encrypted USB flash drives (available through commercial vendors such as Amazon).</li> <li>• Only take the data you really need. If it contains sensitive information, it should be password protected.</li> <li>• Delete this data as soon as it's no longer required to be on the USB. Store the data in a recommended method above.</li> </ul>
Hard drive in PC (c drive)	<ul style="list-style-type: none"> <li>• Need password protection and encryption. <a href="http://www.it.johnshopkins.edu/security/encryption.html">http://www.it.johnshopkins.edu/security/encryption.html</a>.</li> </ul>
Hard drive in laptop, iPad	<ul style="list-style-type: none"> <li>• All devices should be password or PIN protected.</li> <li>• All devices should be encrypted.</li> <li>• Do not retain this data when it's no longer required to be on laptop. Store the data in a recommended method above.</li> </ul>
Microsoft OneDrive	<ul style="list-style-type: none"> <li>• Sync specific folders, documents, and data across ANY computer.</li> <li>• NOT to be used to store PHI</li> <li>• Useful if you update personal documents at both work and home so they will stay synced</li> </ul>
Commercial clouds (e.g. Dropbox, Google)	<ul style="list-style-type: none"> <li>• No relationship with JHU and are not compliant for PHI</li> </ul>
<p>*Medicaid and Medicare (e.g. CMS) data may require additional process or FISMA documentation. Please contact clarify with PIs and IRB offices for more information. Further technical questions should be directed to <a href="mailto:itpolicy@jhu.edu">itpolicy@jhu.edu</a>.</p>	

**Table 2. Comparing Cloud Storage**

	Capacity	Backup	Cost	Outside User
Institutional network	Large	Yes	4¢ per GB	No
SAFE Desktop	200GB	Yes	No	No
MyCloud Desktop		Yes	No	No
JHBox	50GB	Yes	No	Yes
OneDrive (no PHI)	1 TB	Yes	No	Yes

### III. RECOMMENDED APPROACHES TO CONDUCTING ANALYSIS BEHIND FIRE WALLS

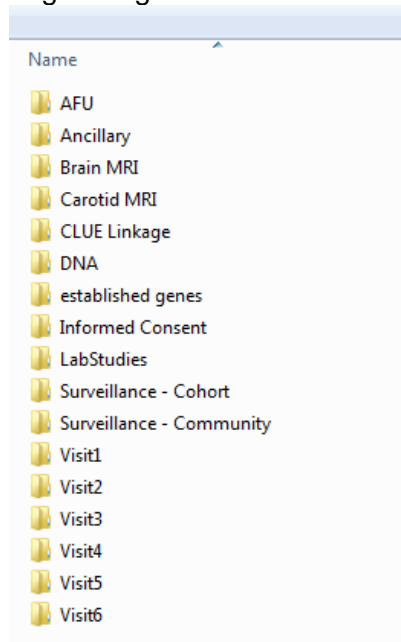
All analysis should be done behind the Johns Hopkins firewall. If you work from a remote site, you should use the Pulse Secure VPN, Remote Desktop, or SAFE Desktop to conduct the analysis.

### IV. RECOMMENDED APPROACHES TO ARCHIVING DATA FOR COMPLETED STUDIES

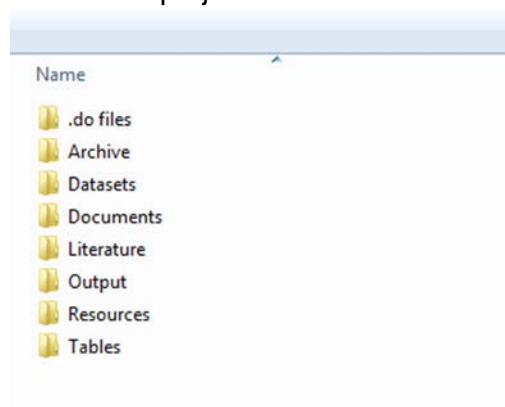
Records should be saved into a folder structure on a shared drive. Unorganized records also greatly increase the time spent in searching for information. Folders can be used to group documents into subject related categories which then sub-divide further, from the general down to the specific. However do not create too many levels of folders if possible to ease navigation.

#### Example: ARIC Study

Organizing ARIC data:



For each project:



### V. RECOMMENDED APPROACHES TO ARCHIVING ANALYSES IN SUPPORT OF PUBLICATIONS

For completed projects, the PI should request the lead author to send the following files for proper documentation:

- a. Final manuscript (annotated)
- b. Final program files

- c. Final analytical datasets
- d. Documentation regarding datasets, analysis, and issues/decisions

## VI. DISTRIBUTING JHU DATA TO USERS

Data Use Agreements (DUAs) are used for the transfer of non-public data that is subject to some restriction on its use. DUAs serve to outline the terms and conditions of the transfer. The understanding established by a DUA can help avoid later issues by clearly setting forth the expectations of the parties (provider and recipient). Having a signed DUA in place may be a required precondition to transfers of certain data, or it may simply be a good idea. Examples from two studies are included in the Appendix as references.

- To distribute JHU data to non-JHU users, PIs must follow the JHU Policy on Access and Retention of Research Data and Materials.  
[http://dms.data.jhu.edu/wp-content/uploads/sites/27/2016/08/JHUIDataRetentionPolicy2008\\_WithAppendices.pdf](http://dms.data.jhu.edu/wp-content/uploads/sites/27/2016/08/JHUIDataRetentionPolicy2008_WithAppendices.pdf)
- For School of Medicine projects  
<https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/agreements.html>
- For School of Public Health projects: <https://research.jhu.edu/jhura/agreement-intake/>
- For EHR data, review and approval from the Data Trust are required. Please follow the guideline carefully: [http://intranet.insidehopkinsmedicine.org/data\\_trust/](http://intranet.insidehopkinsmedicine.org/data_trust/)

## VII. What Should New Trainees and Faculty Do When They Arrive?

### 1. Check computer and laptop requirements:

- For School of Public Health faculty and students, please follow the laptop recommendations:  
<https://www.jhsph.edu/offices-and-services/information-technology/laptop-recommendations/>
- For School of Medicine affiliates, contact Brandon Smith or MNET about options and costs related to computer support.
  - Please check the following policies:  
<http://www.it.johnshopkins.edu/services/clientcomputing/>  
Contact Brandon Smith ([BAS@jhmi.edu](mailto:BAS@jhmi.edu))  
<http://intranet.insidehopkinsmedicine.org/mnet/>  
Contact MNET

### 2. Request data storage and analysis space in server. See Section II.

### 3. Sign data usage agreement. Include new users to corresponding IRB protocols. See Section VI.

### VIII. What Should Trainees and Faculty Do When They Depart?

Departing faculty and trainees should review the JHU guideline for departing investigators. It is recommended that the applicable procedures should begin at least two months prior to the departure date.

<https://research.jhu.edu/jhura/wp-content/uploads/sites/2/2017/09/Departing-Investigator-Checklist-090817.pdf>

With permission from the PIs, they may take copies of limited research data for projects on which they have worked on unless restricted by the specific terms of the applicable agreement with the sponsor of the research. Original data, however, must be retained at JHU by the Principal Investigator.

If the departing faculty or trainee is designated as a team member, a change in IRB research application must be submitted for each study to remove him/her from the study team, or arrangements must be made with the departing faculty's or trainee's new institution to permit reliance by the new institution on the JHU IRB.

Checklist for graduating trainees and departing faculty on data related elements:

	Signed data usage agreement.
	Current draft manuscript
	Current analysis program files
	Current analytical datasets
	Data documentations
	Change in IRB protocol

### APPENDIX

Example: Data Usage Agreement in CKD-PC

\*\*\*\*\*

Contact Dr. Jessica Yeh for questions

**Chronic Kidney Disease Prognosis Consortium (CKD-PC)  
Data Distribution Agreement for Investigators and Staff Using the Individual Participant Data (IPD)  
from the CKD-PC Collaborators at Johns Hopkins University**

The undersigned party hereby enters into this Distribution Agreement as of the date specified on the final page hereof.

**PRELIMINARY STATEMENT**

To optimize scientific productivity and the optimal use of its valuable data base, the CKD-PC has implemented a system of data analysis at the Data Coordinating Center (DCC) for publication that relies on the IPD from the CKD-PC Collaborators. The IPD from the CKD-PC Collaborators have been stripped of personal identifiers, but the nature of the data and the geographic specificity of the sites at which the study subjects were drawn require vigilant efforts to avoid the inadvertent or deliberate individual identification of some subjects. To protect the confidentiality and privacy of these participants and to ensure use of data only as permitted by the Collaborators, investigators granted access to the data must adhere to the requirements of this Distribution Agreement. Failure to comply with this Distribution Agreement can result in denial of further access to data. Violation of the confidentiality requirements of this agreement is considered a breach of confidentiality and may leave requesting investigators liable to legal action on the part of study participants and their families, or the collaborating entities.

**RECIPIENT**

The undersigned investigator is the recipient of the right to use Collaborator's IPD.

**AGREED TERMS AND CONDITIONS**

The IPD will be used by Recipient solely for the purposes authorized by the Collaborators, and the Steering, Operations, and Writing committees of the CKD-PC.

Supervision. Recipient may use these IPD for the purposes of statistical analysis and publication according to the policies established by the Operations/Steering Committees of the CKD-PC. All investigators who use these data will review the guidelines and sign this agreement to abide by them.

Non-transferability. This Distribution Agreement is not transferable. Each individual using the data must sign a distribution agreement.

Publication. The purpose for the collection of these data is the prompt publication and analysis of the results, through the channels established for this purpose by the Operations/Steering Committees of the CKD-PC.

Non-Identification. Recipient agrees that IPD from CKD-PC Collaborators will not be used, either alone or in

conjunction with any other information in any effort whatsoever to establish the individual identities of any of the subjects from whom IPD were obtained.

Use Limited to Research Project. Recipient agrees that IPD from CKD-PC Collaborators, its progeny, and unmodified or modified derivatives thereof will not be used in any experiments or procedures that are not disclosed and approved as part of the Research Project.

Compliance with Agreement Forms Between DCC and Collaborators. Recipient agrees that the IPD, its progeny, and unmodified or modified derivatives thereof will not be used for any purpose contrary to the applicable signed agreement form(s).

No Distribution. IPD cannot leave Johns Hopkins University without prior approval from relevant Collaborators. Recipient agrees to use IPD saved in the network drive or virtual machine at Johns Hopkins University and not to physically take any IPD out of Johns Hopkins University in any kind of device (e.g., laptop, USB drive, etc.). Synchronization of network drive with a Recipient laptop is not allowed. The data from Collaborators will be used only for the specific approved manuscript proposals, the resulting manuscript will not be submitted to a journal or an abstract to a meeting without specific CKD-PC approval for the purpose, under existing CKD-PC Publications procedures, and the data will be destroyed after such use. Recipient may demonstrate meta-analyzed data of the CKD-PC or analyzed data from individual studies at a CKD-PC official teleconference or meeting such as the Steering, Operations, and Writing committees for purposes of project progress.

Recipient's Compliance with IRB Requirements. The Johns Hopkins School of Public Health IRB has reviewed the study entitled "CKD-PC" and determined that the study currently involves secondary data analysis of a pre-existing, de-identified/de-linked dataset; and the Recipient was not involved in the original data collection. Therefore, the proposed research does not qualify as human subjects research as defined by Department of Health and Human Services regulations 45 CFR 46.102, and is exempt from IRB review (IRB No. 00003324) at this time. The PI of CKD-PC will notify the IRB and Recipient if any changes should develop in the methodology that might involve human subjects and require IRB review in the future.

Conflict of Interest. The Recipient agrees to promptly disclose direct and indirect conflicts of interest, such as affiliation(s) with any organization with an explicit or indirect financial interest in the subject matter of the proposed research employing Clinical Data from the CKD-PC Collaborators, to the CKD-PC Steering Committee, and to review and monitor or manage conflicts of interest and commitment as required by 42 CFR Part 50, Subpart F. Examples of such affiliations are employment consultancies, expert testimony, honoraria, stock, or retainers that may affect the work being considered.

Amendments. Amendments to this Distribution Agreement must be made in writing and signed by authorized representatives.

Termination. The CKD-PC Collaborator may terminate this Distribution Agreement if Recipient is in default of any condition of this Distribution Agreement and such default has not been remedied within 30

days after the date of written notice by the CKD-PC Collaborator of such default. Upon termination of this Distribution Agreement, Recipient agrees to return all IPD to the CKD-PC Collaborator.

Disqualification, Enforcement. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional data. The CKD-PC Collaborator shall have the right to institute and prosecute any proceeding at law or in equity against the Recipient for violating or threatening to violate the confidentiality requirements of this agreement, the limitations on the use of the data or materials provided, or both. Proceedings may be initiated against the violating party, legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding in law or equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this agreement. In addition, Recipient acknowledges and agrees that a breach or threatened breach of the confidentiality requirements or use limitations of this agreement may subject Recipient to legal action on the part of CKD-PC Collaborator's study participants and their families, or the universities participating in the CKD-PC Collaborator's study.

Accurate Representations. Recipient expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.



APPENDIX: EXAMPLE; Data Usage Agreement in CKD-PC

This Distribution Agreement is entered into as of: \_\_\_\_\_

RECIPIENT:

Name of the Recipient:

\_\_\_\_\_

Mail Address:

\_\_\_\_\_

E-Mail Address:

\_\_\_\_\_

Telephone Number:

\_\_\_\_\_

Fax Number:

\_\_\_\_\_

Signature and Date:

=====