



## Policy and Agreement for Local Use of HCHS/SOL Data via Release of Investigator Use Datasets

**Basic Principle.** NIH recognizes that the Principal Investigators in a research project make significant investments of time, expertise, and other resources to plan and execute the project. The primary motivation for such investment is the ability to analyze the project dataset and publish manuscripts based on those analyses. Therefore, the PIs have a right to exclusive use of the data for a period of time prior to its release to the general scientific community in the form of a Limited Access Dataset.

As data collection is completed for various stages of HCHS/SOL, the Steering Committee will designate particular datasets to be eligible for release by the Coordinating Center for analysis by HCHS/SOL Principal Investigators. Ordinarily the full cleaned and validated dataset for a particular assessment window (e.g., baseline examination data, follow-up data, adjudicated outcome data) will be released, rather than pared datasets individually tailored by the CC for each analysis or investigator. The primary purpose of this timed release of datasets is to facilitate timely analyses and preparation of manuscripts for publication. These datasets will be released to Principal Investigator (PI) of an HCHS/SOL Field Center, Reading Center, Laboratory, Coordinating Center or their subcontractors and are referred to herein as Investigator Use Data.

**Access by HCHS/SOL Investigators and Project Staff.** A Principal Investigator (PI) may grant access to an HCHS/SOL co-investigator at their own institution (including collaborating statisticians, data analysts, programmers, post-doctoral fellows and trainees) to their copy of the Investigator Use Data or subset thereof. The PI shall certify that the individual(s) using the HCHS/SOL data is(are) collaborating on an approved manuscript, presentation, or other approved HCHS/SOL activity and agree(s) to abide by HCHS/SOL policies and procedures with regard to data use and publications as described in the Data Use Agreement governing the distribution of the Investigator Use Data to the PI. The PI shall further certify that he or she will oversee such use of the data and limit access to approved personnel at their institution. A list of personnel granted access and the duration of use will be kept at each site for periodic review by the HCHS/SOL Steering Committee or their designate.

**Signed Agreement.** Prior to receiving access to the Investigator Use Data from the PI, the co-investigator or project team member shall sign and provide to the Coordinating Center a written statement agreeing to the following conditions:

1. that the dataset shall not be further copied or released for any use by any other individual except through the approval procedure described above;
2. that study datasets will only be stored on access controlled, secure network servers and that the Data cannot be downloaded to an individual workstation, laptop or removable storage device,
3. that the co-investigator will adhere to all HCHS/SOL policies and procedures regarding data and publications;
4. that analyses shall not be conducted with the HCHS/SOL dataset without prior approval of a written proposal through the Publications Committee;
5. that no manuscript making any use of HCHS/SOL data shall be submitted for publication or released to anyone other than HCHS/SOL staff without prior review and approval from the Publications Committee;
6. that for any summary (computed) variables used in analyses, the investigator shall provide to the Coordinating Center a precise definition; and
7. that for primary outcome measures in the Study, the investigator shall use the Study summary variables as defined by the Coordinating Center.

**Required endorsements and signatures begin on the next page.**

**CHECKLIST:** As a Principal Investigator of HCHS/SOL, I understand and accept the following terms of this distribution policy (*Principal Investigator and receiving co-Investigator or analyst attests to their understanding by initialing and dating each item*):

1. I understand that this agreement governs distribution of all investigator use datasets (Data), which are not anonymized in that they contain potentially identifying information about HCHS/SOL participants, and as such, I am responsible for ensuring the security and confidentiality of these Data.

P.I. initials: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_  
Co-I. initials: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_

2. I understand that the Data are to be used only for HCHS/SOL activities that are approved by the HCHS/SOL Steering Committee and the NHLBI.

P.I. initials: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_  
Co-I. initials: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_

3. I understand that the Data cannot be copied or transferred to any entity or any individual not approved as a user within their institution, that I am responsible for storage of the Data in a secure location, and that I am responsible for use of the data by any persons to whom I give access.

P.I. initials: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_  
Co-I. initials: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_

4. I agree to store data only on a secure server and that authorized team members can access the data only from a local area network or a virtual private network. Data will never be stored on a workstation, laptop, or portable data storage media (memory key, CD, DVDs, etc.). Encrypted server backups are exempt from this requirement.

P.I. initials: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_  
Co-I. initials: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_

5. I understand that the NHLBI and HCHS/SOL must be acknowledged in any presentation or publication containing results from these Data.

P.I. initials: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_  
Co-I. initials: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_

6. I understand that failure to comply by the terms of this agreement may result in my being unable to receive future distributions of HCHS/SOL Data or access HCHS/SOL Data at my institution.

P.I. initials: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_  
Co-I. initials: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_

\_\_\_\_\_  
HCHS/SOL Co-Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
HCHS/SOL Principal Investigator

\_\_\_\_\_  
Date