

## The DC Cohort Data and Statistics Coordinating Center

### Data Use Agreement for Disclosures of Limited Data Set

This Data Use Agreement (DUA) is entered into the \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_ between the George Washington University Milken Institute School of Public Health Department of Epidemiology and Biostatistics, which along with its designed Data Management Team serves as the Data and Statistics Coordinating Center (hereafter DSCC) and \_\_\_\_\_ (Receiving Agency) wherein \_\_\_\_\_ (Researcher) is the researcher responsible for the projects using the DC Cohort Limited Dataset.

#### RECITALS

DSCC and Receiving Agency hereby set forth the terms and conditions under which the DSCC will disclose to the Receiving Agency certain Protected Health Information (PHI) in the form of a Limited Data Set (LDS) described in this Agreement for the uses described in this Agreement.

In consideration of the mutual promises below, and DSCC's disclosure of the LDS to Receiving Agency under this Agreement, the parties agree as follows:

#### ARTICLE I DEFINITIONS

1.1 **Limited Data Set**, as defined in the Privacy Rule at 45 CFR Section 164.514(e), is PHI that can include specific identifiers and must exclude others considered to be PHI. A limited data set may **include**: 1) dates (e.g., admission, discharge, and service dates, dates of birth and death); and 2) five-digit zip codes and state, county, city, and precinct, but not any other postal address information. A limited data set must **exclude** the following direct identifiers of an individual and his or her relatives, employer(s), and household members: name; postal address information (except town or city, state and zip code which are permitted); telephone numbers; fax numbers; electronic mail addresses; Social Security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; license plate numbers and other vehicle identifiers and serial numbers; device identifiers and serial numbers; URLs; Internet Protocol (IP) address numbers; biometric identifiers including finger and voice prints; and full-face photographic and any comparable images. In the event of any conflict between this description and the definition in the Standards for Privacy of Individually Identifiable Health Information (45 CFR, Parts 160 and 164, Subparts A and E) ("the Privacy Rule"), the Privacy Rule definition will govern.

1.2 Security Rule means the Standards for Security for the Protection of Electronic Protected Health Information, codified at 45 CFR parts 160 and 164, Subpart C, effective April 20, 2005.

1.3 The following terms shall also have the meanings given to them in the Privacy Rule: Covered Entity, Individual, Protected Health Information, and Required by Law.

## ARTICLE II DSCC'S OBLIGATIONS

2.1 DSCC shall provide Receiving Agency with access to a Limited Data Set as described in Section 2(b) below in accordance with the terms and conditions of this Agreement and consistent with HIPAA and the HIPAA Regulations.

2.2 The Limited Data Set provided pursuant to this Agreement contains data obtained or created by a Covered Entity and related to

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[insert general description of data such as the research described in the protocol entitled "(Insert Title)". Specific data elements to be given by DSCC to Receiving Agency include:

*See appended Data Request Form for a comprehensive list of data elements included.*

2.3 The Limited Data Set **shall not include** any of the following identifiers:

- 1) Names
- 2) Postal address information (other than town or city, state and zip code)
- 3) Telephone numbers
- 4) Fax numbers
- 5) E-mail addresses
- 6) Social security numbers
- 7) Medical record numbers
- 8) Health plan beneficiary numbers
- 9) Account numbers
- 10) Certificate/license numbers
- 11) Vehicle identifiers & serial numbers, including license plate numbers
- 12) Device identifiers & serial numbers
- 13) Web Universal Resource Locators (URL's)
- 14) Internet Protocol (IP) address numbers
- 15) Biometric identifiers, including finger and voice prints
- 16) Full face photographic images and any comparable images

**The health information that may remain in the information disclosed includes:**

- dates such as admission, discharge, service, date of birth (DOB), date of death (DOD);
- city, state, five digit or more zip code; and
- ages in years, months or days or hours.

### **ARTICLE III RECEIVING AGENCY'S OBLIGATIONS**

The undersigned researcher agrees to abide by the following guidelines:

3.1 The use of the LDS provided by the DSCC to the researcher will be confined to the research described in the application to access this dataset, attached hereto as Exhibit [REDACTED].

3.2 This LDS is confidential. Access to LDS will be limited solely to the researcher who is the signatory to this Agreement and to research staff who are approved to work on any projects associated with this dataset. Under no terms can data be shared with scholars at other institutions outside those designated above without written approval of the DSCC. Only those researchers and research staff listed under Section 5.8 of this Agreement are approved to access this dataset and work on related projects. In the event new researchers and/or research staff require access to the dataset, this document is to be amended to include their names on the aforementioned list.

3.3 Though the LDS provided by the DSCC will not contain any direct participant identifiers, the researcher will not attempt to learn nor permit others to learn the identity of any participant in the DC Cohort.

3.4 The researcher is limited to linking the Limited Dataset with individually identifiable records to the extent permitted by the overseeing IRBs. Unauthorized or unapproved data linkages are prohibited. Records linked to individually identifiable records with IRB approval become subject to the Privacy Rule as described in Article I, above.

3.5 The researcher affirms that he/she has the capacity to restrict access to confidential data. Such capacity may include features of a computer operating system, software that removes electronic images of data from physical storage devices, locking cabinets in which to store the drives, or disks on which confidential data, including back-up copies, are written, and the training of personnel who will handle confidential data. The DSCC reserves the right to judge the adequacy of such protections.

3.6 The researcher will report to the GW HIPAA Privacy Officer by email at [comply@gwu.edu](mailto:comply@gwu.edu) and Dr. Amanda Castel at 202.994.8325 or by email at [acastel@gwu.edu](mailto:acastel@gwu.edu), any breach of this agreement within 48 hours of his/her discovery of such breach.

3.7 In the event of a suspected security incident, security breach related to systems or data, the researcher will notify within 24 hours Dr. Amanda Castel at 202.994.8325 or by email at [acastel@gwu.edu](mailto:acastel@gwu.edu).

**ARTICLE IV  
TERM AND TERMINATION**

- 4.1. This Agreement shall commence on the Effective Date and terminate on \_\_\_\_\_ unless otherwise terminated as provided for herein. The term of the Agreement may be extended upon the mutual written agreement of the parties.
- 4.2. In the event that Receiving Agency commits a material breach of this Agreement, DSCC may: i) terminate this Agreement upon thirty (30) days written notice to Receiving Agency, or ii) request that Receiving Agency take reasonable and appropriate steps to resolve such breach. If Receiving Agency fails to resolve such breach to DSCC's satisfaction or in the time prescribed by DSCC, DSCC may terminate this Agreement upon written notice to Receiving Agency.
- 4.3. In the event that Receiving Agency decides to cease use of the LDS, Receiving Agency may terminate this Agreement upon thirty (30) Days prior written notice to DSCC.
- 4.4. Should this Agreement be terminated for any reason, including, but not limited to Receiving Agency's decision to cease use of the LDS data, or upon expiration of the Agreement, Receiving Agency agrees to destroy or return all LDS data provided pursuant to this Agreement (including copies or derivative versions thereof). Data should be destroyed by use of pertinent software, such as "Drive Erase Pro-Total Privacy Protection." The DSCC reserves the right to judge the adequacy of the methods used for data destruction.

**ARTICLE V  
MISCELLANEOUS**

- 5.1. Notices. Any notice permitted or required as provided for herein shall be in writing and to the contact and address as noted below or as may be provided by either party to the other in writing from time to time.

Notice to GW shall be to:  
Attn: GW HIPAA Privacy Officer  
The George Washington University  
2121 Eye St. NW  
Washington, DC 20052  
comply@gwu.edu

Notice to Receiving Agency shall be to:

User  
Attn: Privacy Officer

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5.2. Governing Law. This Agreement shall be governed and construed, and the rights and obligations of the parties shall be determined, in accordance with the laws of the District of Columbia without regard to conflicts of laws issues.

5.3. Dispute Resolution. Any dispute arising from this Agreement shall be resolved by good faith negotiations between the parties. If the parties cannot resolve the dispute via negotiations, either party may file suit solely in the local or federal courts of the District of Columbia, and all parties hereby consent to the personal jurisdiction and venue of such courts for any such action, regardless of where they may reside or work at the time of such dispute.

5.4. No Third Party Beneficiaries. There are no third party beneficiaries to this Agreement. Nothing contained in this Agreement shall be construed to create any contractual or other rights on behalf of any individual whose protected health information is used or disclosed under this Agreement.

5.5. Survival. Articles III and IV and Sections 5.2, 5.3, 5.4 shall survive the termination or expiration of this Agreement.

5.6 Entire Agreement; modification. This Agreement (and its attachments, if any) constitutes the entire understanding between the parties with respect to the subject matter hereof and may not be amended except by an agreement signed by both parties. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision

5.7. Nothing in this Agreement is intended nor shall be construed to create an agency, partnership, employer-employee, or joint venture relationship between DSCC and Receiving Agency.

5.8. Researchers accessing the dataset. Under this Agreement, the individuals listed below are allowed access to the dataset and work on any related analyses.

Name: \_\_\_\_\_ Institution \_\_\_\_\_

Name: \_\_\_\_\_ Institution \_\_\_\_\_

Name: \_\_\_\_\_ Institution \_\_\_\_\_

Name: \_\_\_\_\_ Institution \_\_\_\_\_

Name: \_\_\_\_\_ Institution \_\_\_\_\_

Name: \_\_\_\_\_ Institution \_\_\_\_\_

I have read and understand the implications of this agreement.

**RESEARCHER**

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**RECEIVING AGENCY REPRESENTATIVE**

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**DSCC REPRESENTATIVE**

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**GWU INSTITUTIONAL OFFICIAL**

Signature \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date \_\_\_\_\_