

North Carolina Division of Public Health
Data Use Agreement

This Data Use Agreement (“DUA”) is effective on the ____ day of ____, 2017, (“Effective Date”) by and between the **NC Division of Public Health** (“Data Custodian”), and the following organization(s) ____ [Research Institution Name] _____ (“Recipients”), located at ____ [Institution Address] _____ collectively hereinafter referred to as the “Parties”.

The Division of Public Health, Chronic Disease and Injury Section, Injury and Violence Prevention Branch (IVPB) is providing the Recipient with a data set containing Individually Identifiable Health Information (“IIHI”) with potential to be considered Protected Health Information (“PHI”), which are defined in 45 Code of Federal Regulations (CFR) §160.103 and §164.501. The North Carolina Division of Public Health, Chronic Disease and Injury Section, IVPB (“Data Custodian”) is not a Covered Component within the North Carolina Division of Health and Human Services (as defined in the Health Insurance Portability and Accountability Act of 1996.). The Recipient may be a covered entity as defined by HIPAA. However, this DUA shall not be construed as creating HIPAA liabilities for the Data Custodian or Recipient if HIPAA is not applicable to the data use and disclosure provided for under this agreement.

The Parties agree to the provisions of this DUA to address the requirements of HIPAA and to protect the interest of both Parties.

1. **DEFINITIONS.** Except as otherwise defined herein, any and all capitalized terms in this DUA shall have the definitions set forth in HIPAA. In the event of any inconsistency between the provisions of this DUA and mandatory provisions of HIPAA, as amended, the HIPAA provision shall control. Where provisions of this DUA are different than those provided in HIPAA, but are permitted by HIPAA, the provisions of this DUA shall control.
2. This Agreement sets forth the terms and conditions under which the DPH IVPB will permit Data Recipient access to certain data, as described in Section III of this Agreement and **Attachment A** hereto. This Agreement also describes in **Attachment B** what use the Data Recipient may make of the Data.
3. **USE OR DISCLOSURE.** Data Recipient shall have the right to use all Individually Identifiable Health Information (IIHI) provided to it by the Data Custodian for Research, Public Health or Health Care Operations solely for the purposes set forth in **Attachment B** to this Agreement and for no other purposes.

Recipient Initials _____

4. **RESTRICTIONS ON USE.** All signatory recipients to this DUA agree not to use or further disclose the IIHI other than as permitted by this DUA, or as otherwise required by law or regulation. Data Recipient shall use appropriate safeguards to protect the IIHI from misuse or inappropriate disclosure and to prevent any use or disclosure of the IIHI other than as provided in this DUA or as otherwise required by law or regulation. This Agreement also sets forth the security requirements in **Attachment C** that such access and use is conditioned upon. Recipient shall not attempt to identify the individuals to whom the IIHI pertains, link the data elements to other data sets in attempt to identify individuals, or attempt to contact such individuals, or

REPORTING. Recipient shall report to Data Custodian any use or disclosure of the IIHI that is not provided for in this Data Use Agreement (DUA) within three (3) business days from the date it becomes aware of the disclosure. Recipient will take reasonable steps to limit any further such use or disclosure. Data Custodian in its sole discretion may require the Recipient to:

- Investigate and respond to Data Custodian regarding any alleged disclosure; promptly resolve any problems identified by the investigation.
- Submit a corrective action plan with steps designed to prevent any future unauthorized disclosures.
- Require that all Data Set files be returned or, if infeasible, destroyed immediately.

In addition:

- All publications and/or presentations that have been derived from the data provided under this Data Use Agreement must undergo the NC DPH, IVPB clearance process, to ensure that institutional and personal confidentiality is maintained. Data must be provided to NC Division of Public Health, IVPB at least 30 days before presenting or submitting for publication.
- All data presented in publications and/or presentations shall be presented in aggregate form only and in a way an individual cannot be identified.
- For oral or written presentations or publications, the source of the data must be attributed to NC DPH.
- All publications and/or presentations must include the following disclaimer: The NC Department of Health and Human Services (DPH) does not take responsibility for the scientific validity or accuracy of methodology, results, statistical analyses, or conclusions presented.

Recipient Initials _____

4. **TERM AND TERMINATION.**

DUA Termination Date is three (3) years after DUA effective date (page one).

- (a) Term. The Term of this DUA shall be effective as of the date first written above, and shall terminate three (3) year after the DUA effective date. All IIHI provided by the Data Custodian to Recipient must be destroyed or returned to Data Custodian, or, if it is infeasible to return or destroy IIHI, protections are extended to such information, in accordance with the termination provisions in this Section.
- (b) Term Extension. If the Recipient requires data for a period exceeding the term, a formal request for a term extension must be submitted to the “Data Custodian”. If a term extension is granted by the “Data Custodian”, this DUA must be amended.
- (c) Termination for Cause.

Should Recipient commit a material breach of this DUA, which is not cured within thirty (30) days after Recipient receives notice of such breach from the Data Custodian or resolved in a manner deemed acceptable by the Data Custodian, then the Data Custodian will discontinue disclosure of IIHI and will report the problem to the Secretary, U. S. Department of Health and Human Services.

- (d) Effects of Termination.
 - i. Except as provided in paragraph (ii) of this subsection, within ten (10) days upon termination of this DUA, Recipient shall return or destroy all IIHI received from Data Custodian. This provision shall apply to IIHI that is in the possession of subcontractors or agents of Data Recipient. Recipient shall retain no copies of the IIHI.

DPH IVPB must receive a written confirmation that all data has been destroyed by the DUA termination date.

- ii. If Recipient determines that returning or destroying the IIHI is infeasible, Recipient shall provide to Data Custodian notification of the conditions that make return or destruction infeasible. Upon agreement of the Parties that return or destruction of IIHI is infeasible; Data Recipient shall extend the protections of this DUA to such IIHI and limit further uses and disclosures of such IIHI to those purposes that make the return or destruction infeasible, for so long as Recipient maintains IIHI.

Recipient Initials _____

By signing this Agreement, the Recipient agrees to abide by all provisions set out in this Agreement and acknowledges having received notice of potential criminal or administrative penalties for violation of the terms of the Agreement.

Data will be released upon the receipt of the signature of the data custodian.

Recipient Initials _____

DATA CUSTODIAN (NC DPH):

(Date)

(Signature)

(Printed Name)

RECIPIENT (Organization Name):

(Date)

(Signature)

(Printed Name and Title)

ATTACHMENT A: DATA POINTS

Recipient Initials _____

ATTACHMENT B: PROJECT DESCRIPTION AND DATA USE

Data Recipient agrees to use the Data solely for the purposes and project set forth below, and for no other purposes: Please see the last page of this DUA for an example.

DESCRIPTION OF STUDY AND STUDY NUMBER:

[type description in this space]

PRINCIPAL RESEARCH AND CO-INVESTIGATORS

[type researchers full name and affiliations]

PUBLIC HEALTH SIGNIFICANCE:

[type significance in this space]

RESULTS OF PROJECT WILL BE USED FOR:

[type use of results in this space]

Recipient Initials _____

TIME PERIOD FOR DATA REQUESTED:

[type time period for data]

ESTIMATED STUDY COMPLETION DATA:

[type study completion date]

Recipient Initials _____

**ATTACHMENT C:
Data Security Summary**

Please detail here your institution's policies and procedures for ensuring security for all data collected, created, processed, transmitted, stored, or disseminated.

[type policies & procedures in this space]

Data Security Requirements:

1. All signatory data recipients shall use appropriate safeguards to protect the DPH data from misuse or inappropriate disclosure and prevent any use or disclosure of the OCME data other than as provided in this DUA or as otherwise required by law or regulation.
2. All signatory recipients must report any loss or misuse of DPH data to the North Carolina Division of Public Health (NC DPH) within three (3) business days after the loss or misuse is discovered.
3. DPH data must be housed on secure, password-protected servers and/or office computers, with access limited only to members of the study team.
4. Any laptop or portable device containing DPH data must be full-disk encrypted with an FIPS 140-2 Level 1 certified AES-256 encryption algorithm.
5. Any hard copies of DPH data will be kept in a locked office cabinet, with access limited only to members of the study team.
6. Data will not be transmitted between computer systems, or via email or email attachment, unless the transmission uses Secure Socket Layer (SSL) RC4 128 bit algorithms, SSL Server-Gated Cryptography (SGC) 128 bit algorithms, TLS 1.11 128 bit algorithms, or other algorithms accepted and certified by the National Institute of Standards and Technology.
7. Upon DUA termination, NC DPH must receive a written confirmation that all data have been destroyed. Paper copies must be crosscut shredded, and electronic copies must be removed from all computers, servers, and media using software meeting NIST SP-800-88 data destruction standards.

Recipient Initials _____

By signing this document, the Recipients agree to abide by all data security requirements detailed above:

(Date)

(Date)

(Signature)

(Signature)

(Printed Name)

(Printed Name)

Recipient Initials _____

Example of acceptable data storage and security statement:
(Delete before submitting completed Data Security Summary)

The data for this project will be maintained on a workstation located at _____ and a secure server located at _____. The workstation or server folder can only be accessed by persons physically working at _____ with the appropriate login credentials, and remotely via secure VPN requiring <name of researcher>'s login and password. The entire hard drive where the data are stored is encrypted with <name of product> which meets _____ encryption standards. A backup of the data files will be maintained on _____ at _____, and encrypted with _____. The only person or persons with access to the server files are _____, and the only person or persons with access to the backup files are _____. All files for this project will be password protected in for read, write, and alter protection and encrypted to prevent other programs from opening the files.

Recipient Initials _____