

# **Data Use Agreement for Limited Data Set**

**Prepared by the  
NCHICA Research Work Group**

**Approved for Public Distribution  
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## Data Use Agreement for Limited Data Set Background Information

A Limited Data Set [45 CFR 164.514(e)] under HIPAA is a data set with fewer identifiers deleted than a “safe harbor” de-identified data set. In particular, the Limited Data Set allows the inclusion of all dates, 5 digit ZIP codes, and city as indirect identifiers.

A limited data set can only be used for research, public health, or operations. Its use or disclosure may be further limited by the purpose statements in the Data Use Agreement.

Identifiers to delete for a Limited Data Set (for individual, relatives, employers, and household members):

- (i) Names
- (ii) Postal address information, other than town or city, State, and ZIP code
- (iii) Telephone numbers
- (iv) Fax numbers
- (v) Electronic mail addresses
- (vi) Social security numbers
- (vii) Medical record numbers
- (viii) Health plan beneficiary numbers
- (ix) Account numbers
- (x) Certificate/license numbers
- (xi) Vehicle identifiers and serial numbers, including license plate numbers
- (xii) Device identifiers and serial numbers
- (xiii) Web Universal Resource Locators (URLs)
- (xiv) Internet Protocol (IP) address numbers
- (xv) Biometric identifiers, including finger and voice prints
- (xvi) Full face photographic images and any comparable images.

A limited data set can include a link field to allow the covered entity to re-identify the individual. The link field for a limited data set can be derived from the direct identifiers. For example, Initials + sequence number is a valid link field, as is an encrypted SSN.

Miscellaneous notes:

- If the recipient is not a corporation, as described in the first paragraph, then, that paragraph would require alteration.
- The limited data set is subject to the minimum necessary section of HIPAA.
- The limited data set is NOT subject to disclosure accounting.

## Data Use Agreement for Limited Data Set

**This Data Use Agreement for a Limited Data Set** (“DUA”) is effective on the \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, (“Effective Date”) by and between \_\_\_\_\_ (“Covered Entity”), a \_\_\_\_\_ corporation located at \_\_\_\_\_, and \_\_\_\_\_ (“Recipient”), a \_\_\_\_\_ corporation located at \_\_\_\_\_; collectively, the “Parties”.

The Covered Entity is a COVERED ENTITY as defined in the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”); and the Covered Entity is providing Recipient with a Limited Data Set of Protected Health Information (“PHI”) as defined in 45 Code of Federal Regulations (CFR) § 164.514(e)(2); so that the Recipient is a “LIMITED DATA SET RECIPIENT” as defined in HIPAA;

The Parties agree to the provisions of this DUA in order 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 provisions shall control. Where provisions of this DUA are different from those provided in HIPAA, but are permitted by HIPAA, the provisions of this DUA shall control.
2. **USE OR DISCLOSURE.** Recipient shall have the right to use and disclose all PHI provided to it by the Covered Entity for the Research, Public Health or Health Care Operations purposes as listed below:

**[INSERT THE “USES OF THE DATA” TO BE PROVIDED BY THE Covered Entity TO RECIPIENT; for example, research such as outcomes research and for further de-identification, health care operations, or public health such as registries]**

3. **RESTRICTIONS ON USE.** Recipient agrees that it, and any employees, agents and subcontractors to whom it discloses the PHI, will not use or further disclose the PHI other than as permitted by this DUA, or as otherwise required by law or regulation. Recipient shall use appropriate safeguards to protect the PHI from misuse or inappropriate disclosure and to prevent any use or disclosure of the PHI other than as provided in this DUA or as otherwise required by law or regulation. Recipient shall not attempt to identify the individuals to whom the PHI pertains, or attempt to contact such individuals.
4. **REPORTING.** Recipient shall report to Covered Entity any use or disclosure of the PHI not provided for in this DUA of which Recipient becomes aware. Recipient will take reasonable steps to limit any further such use or disclosure.
5. **TERMINATION.** This DUA shall be effective on the Effective Date set forth above and shall continue as long as Recipient retains the data, unless otherwise terminated by applicable law or regulation. Recipient may terminate this Agreement by returning or destroying the PHI and providing written notice to the Covered Entity. Should Recipient commit a material breach of this Agreement, which is not cured within thirty (30) days after Recipient receives notice of such breach from the Covered Entity,

then the Covered Entity will discontinue disclosure of PHI and will report the breach to the Secretary, Department of Health and Human Services.

\_\_\_\_\_  
Date

\_\_\_\_\_  
For Covered Entity

\_\_\_\_\_  
Printed Name and Title

\_\_\_\_\_  
Date

\_\_\_\_\_  
For Recipient

\_\_\_\_\_  
Printed Name and Title