CHOP’s HIPAA Policies require that researchers wishing to make use of a limited data set agree to protect the privacy of the health information as described in the [Office of Research Compliance and Regulatory Affairs](https://intranet.research.chop.edu/display/deptcomp/HIPAA+and+Research) policy *Use & Disclosure of Protected Health Information for Research.*

This Data Use Agreement serves to define the responsibilities of investigators and to document their agreement to abide by these terms.

## Is this human subjects research?

If there is any possibility that individuals may be readily identifiable from the information in the data set, then IRB review is required prior to execution of this agreement.

## Definitions

***Limited Data Set****:* The following Protected Health Information (PHI) may be used by Recipient(s). A complete description of the limited data set should be provided including the types of date fields and postal address fields that are included.

The Limited Data Set shall **not** contain any of the following identifiers of the individual who is the subject of the PHI, or of relatives, employers or household members of the individual:

|  |  |  |
| --- | --- | --- |
| * Names * Postal address information, other than town or city, State, and zip code * Telephone numbers * Fax numbers’ * Electronic mail addresses * Social security numbers * Medical record numbers | * Health plan beneficiary numbers * Account numbers * Certificate/license numbers * Vehicle identifiers and serial numbers, including license plate numbers * Device identifiers and serial numbers; | * Web Universal Resource Locators (URLs); * Internet Protocol (IP) address numbers; * Biometric identifiers, including finger and voice prints; * Full face photographic images and any comparable images |

***Data Provider***: the investigator, clinician, or other custodian of data who possesses and shares a limited data set with a recipient investigator.

***Recipient Investigator (or Data User)***: the investigator who receives a limited data set from a provider.

***Source of the Data Set***: the original source for the creation and assembly of the data set. The source could be from medical charts, a clinical database, an IRB-approved research study or repository or a Quality Improvement review. If the data is from an IRB-approved study, the IRB study number should be included.

**Name of the Data Provider:**

**Source of the Data Set:**

## Description of the Limited Data Set:

## Obligations of Recipient Data User

* 1. *Performance of Activities.* Data User may use and disclose the Limited Data Set only in connection with the performance of the research activities described in the project summary (e.g., protocol, abstract, synopsis – whatever format the project is using) entitled,       (the “Activities”).
  2. *Permitted* *Access to Limited Data Set.* Data User shall limit the use or receipt of the Limited Data Set to the individuals listed at the bottom of this document who need access to the Limited Data Set for the performance of the Activities.
  3. *Nondisclosure Except As Provided In Agreement.* Data User shall not use or further disclose the Limited Data Set except as permitted or required by this Agreement. Access to the Limited Data Set by members of the research team who are not affiliated with CHOP requires the execution of a separate Data Use Agreement between the third party user and CHOP.
  4. *Identification of Individual.* Data User may not use the Limited Data Set to re-identify or contact any individual who is the subject of the PHI from which the Limited Data Set was created.
  5. *Disclosures Required By Law.* Data User shall not, without the prior written consent of the HIPAA Privacy Office, disclose the Limited Data Set on the basis that such disclosure is required by law without notifying the Privacy Office so that CHOP shall have an opportunity to object to the disclosure and to seek appropriate relief. If CHOP objects to such disclosure, Data User shall refrain from disclosing the Limited Data Set until CHOP has exhausted all reasonably available alternatives for relief.
  6. *Safeguards.* Data User shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided by this Agreement.
  7. *Reporting.* Data User shall report to the HIPAA Privacy Office twenty-four (24) hours of Data User becoming aware of any use or disclosure of the Limited Data Set in violation of this Agreement or applicable law.
  8. *Knowledge of Non-Compliance*. Any non-compliance by Data User with this Agreement or with HIPAA or the HIPAA Regulations automatically will be considered a breach or violation of a material term of this Agreement if Data User knew or reasonably should have known of such non-compliance and failed to immediately take reasonable steps to cure the non-compliance.

# ASSURANCE OF COMPLIANCE WITH DATA USE AGREEMENT

The following individuals (“Data User(s)”) are authorized to receive and use the Limited Data Set described in this Data Use Agreement for the purposes of conducting the research protocol listed above.

The Provider retains the original and the Recipient should retain a copy of the signed agreement.

By signing below, we acknowledge and agree to abide by the restrictions on our use and disclosure of the Limited Data Set in accordance with this Data Use Agreement.

### Data Users (Recipient Investigators and members of the Study Team)

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name |  | Name |
| Signature |  | Signature |
| Date |  | Date |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name |  | Name |
| Signature |  | Signature |
| Date |  | Date |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name |  | Name |
| Signature |  | Signature |
| Date |  | Date |