**PHI Included in a Limited Data Set**

A covered entity may use and disclose a limited data set (LDS) for research activities conducted by itself, another covered entity, or a researcher who is not a covered entity if the disclosing covered entity and the LDS recipient enter into a data use agreement (DUA). A LDS is health information that excludes the following listed identifiers but may include city; state; ZIP Code; elements of dates; and other numbers, characteristics, or codes not listed as a direct identifier. A LDS may be used or disclosed only for purposes of research, public health, or health care operations without obtaining a subject’s authorization or a waiver or alteration of authorization from the IRB, if the parties involved enter into a DUA.

|  |  |  |  |
| --- | --- | --- | --- |
| Project Title: |  | | |
| Principal Investigator: |  | Institution |  |
| Address/City/State/Zip: |  | | |
| Email address: |  | Phone: |  |
|  | | | |

Direct identifiers that must be removed to be considered a limited data set under the Privacy Rule:

|  |  |  |  |
| --- | --- | --- | --- |
| ● | Names | ● | Certificate/license numbers |
| ● | Postal address information *(other than town or city, state, and ZIP code)* | ● | Vehicle ID or serial #s, including license plate # |
|  | ● | Device identifiers or serial numbers |
| ● | Telephone or Fax numbers | ● | Web universal resource locators (URLs) |
| ● | E-mail addresses | ● | Internet protocol (IP) address numbers |
| ● | Social security numbers | ● | Biometric identifiers, including finger & voice prints |
| ● | Medical record numbers |  |
| ● | Health plan beneficiary numbers | ● | Full face photo images or any comparable images |

|  |  |  |
| --- | --- | --- |
| Identify research staff needing access to the limited data set (attach additional sheet if necessary): | | |
|  |  |  |
|  |  |  |
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| |  | | --- | | List identifiers being requested as part of this limited dataset: | |  | | | |
| Describe methodology to be used: | | |
|  | | |
|  | | |
| Describe how information will be protected from improper use or disclosure: | | |
|  | | |
|  | | |

As principal investigator for this study, I certify that:

* The limited data set will only be used for purposes of the research, public health or health care operations;
* The requested information constitutes the minimum necessary to accomplish the goals of the research;
* The PHI will not be re-used or further disclosed in a manner that would violate the Privacy Rule or that is permitted by the agreement;
* I will not identify the individual or contact the individual whose PHI is contained the limited data set;
* I will enter into a Data Use Agreement (DUA) and will abide by the terms of the DUA for this study.

(A copy of the DUA must be submitted to the PH IRB.)

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Signature Date