

HIPAA Privacy Rule

Limited Data Set

The HIPAA Privacy Rule allows the use of a “limited data set” for research purposes. A limited data set is one in which the direct identifiers have been removed, but certain potential identifiers remain. Use of a limited data set is contingent upon the negotiation of a data use agreement.

A **limited data set** is protected health information that **excludes** the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- 1) Names;
- 2) Street address/Postal address information, other than town or city, State, and zip code;*
- 3) Telephone and fax numbers;
- 4) Electronic mail addresses;
- 5) Social security numbers;
- 6) Medical record numbers, health plan beneficiary numbers or other account numbers;
- 7) Certificate/license numbers;
- 8) Vehicle identifiers and serial numbers, including license plate numbers
- 9) Device identifiers and serial numbers;
- 10) Web universal resource locators (URLs) or Internet protocol (IP) address numbers;
- 11) Biometric identifiers, including finger and voice prints; and
- 12) Full face photographic images and any comparable images.

*Unlike de-identified data, the limited data set may include five-digit zip code or any other geographic subdivisions, such as State, county, city, precinct and their equivalent geocodes. These geographic designations are permitted in order to support a range of research and public health activities, such as the analysis of local variations in disease burdens or statistics on the provision of health care services.

Prior to using the limited data set, the researcher must provide a **data use agreement**. The agreement must contain the following elements:

- The permitted uses and disclosures by the recipient
- The approved users and recipients of the data
- Agreement by the recipient not to re-identify the data or contact the individuals
- Assurances that the recipient will use appropriate safeguards to prevent use or disclosure of the limited data set other than as permitted by the data use agreement

- Agreement to report to the covered entity any improper uses or disclosures of the limited data set of which the researcher becomes aware
- Agreement to require that any agents and subcontractors adhere to the same safeguards

Sample data use agreements are available from the KUMC HIPAA Compliance Office.

Other Considerations

Two other provisions of the Privacy Rule apply to the use of limited data sets in research.

Minimum necessary: Under HIPAA a covered entity must make reasonable efforts to limit the information requested and used to that which is minimally necessary to accomplish the intended purpose. As an example, birth date should only be requested when it serves the purposes of the research.

Role-based access: A covered entity must ensure that access by personnel to identifiable data conforms to individual job requirements and must limit access to that which is necessary to accomplish job duties. The data use agreement meets this requirement by specifying the approved users of the data; principal investigators are responsible for ensuring that data access by research personnel is appropriate to the needs of the research project.

Because certain potential identifiers are allowed, research employing a limited data set is subject to federal human subjects regulations. The project must be approved by the Human Subjects Committee prior to initiation.