Drexel University

LIMITED DATA SETS IN RESEARCH

The Privacy Rule primarily addresses identifiable and de-identified information. But it also includes a middle option where in investigators may use patient data that qualifies as "identified data" in the form of a "limited data set" without HIPAA Authorization or a waiver of HIPAA Authorization. The Limited data set permits the use of select identifiers with limited Privacy Rule requirements can be used for research, health care operations and public health purposes only. The Limited Data Set is identified data requiring permission of the record custodian for data use.

What is a Limited Data Set?

A limited data set is personal health information from which all of the following information pertaining to an individual or of relatives, employers or household members have been removed:

- 1. Names
- 2. Postal address information (e.g., street address is not permitted. Note: Town, city, state, five digit zip code, and other geographic identifiers are permitted)
- 3. Telephone numbers
- 4. FAX numbers
- 5. Electronic mail addresses
- 6. Social Security Number
- 7. Medical record numbers
- 8. Health plan beneficiary numbers
- 9. Account numbers
- 10. Certificate/license numbers
- 11. Vehicle identifiers and serial numbers, including license plates
- 12. Device identifiers and serial numbers
- 13. Web universal resource locators (URLs)
- 14. Internet protocol (IP) address
- 15. Biometric identifiers, including finger and voice prints
- 16. Full-face photos and comparable images.

Limited Data Sets can include the following identifiers:

- 1. Geographic data:
 - A limited data set can include town, city, State and zip code, but no street address.
- 2. Dates:
 - A limited data set can include dates relating to an individual (e.g., birth date, admission and discharge date).
- 3. Other unique identifiers:
 - A limited data set can include any unique identifying number, characteristic or code other than those specified in the list of 16 identifiers that are expressly disallowed.

Important requirements/restrictions for use and/or disclosure of limited data set:

- Limited data sets may NOT be used to re-identify or contact an individual.
- The "minimum necessary" standard applies to the limited data set, which means a researcher must explain that the data elements requested are necessary for the research.
- A Data Use Agreement must be signed by the covered entity and the recipient of the Limited Data Set.
- The requirement of accounting for disclosures of protected health information (PHI) does not apply.

What is a Data Use Agreement?

The Data Use Agreement is a specific document that (1) describes the permitted uses and disclosures of the information and (2) prohibits any attempt to reidentify or contact the individuals. The agreement is between the investigator and the institution, through its privacy officer. The Chief Privacy Officer at Drexel University is Mr. Edward Longazel. He can be contacted at 215-255-7819.

Drexel University College of Medicine Policy:

An investigator in need of the use of "Limited Data Set" should submit his/her protocol to Human Research Protection (HRP) along with "Limited Data Use" Agreement. The HRP after consultation with the Chief Privacy Officer will determine if the protocol is exempt or requires review under the Common Rule.

To submit a proposal to use de-identified data or a limited data set, investigators must specify how identifiers in the information will be handled. The investigator must agree to use the Limited Data Set only as described in the protocol.

If the IRB approves the use of a Limited Data Set, the investigator is permitted to use only the minimum protected health information necessary to accomplish the research. To permit proper IRB review, the investigator must specify the information to be used in the study on the Protocol Summary Form. If the investigator subsequently determines that use of additional information is necessary, an amendment to the protocol must be submitted to the IRB describing the additional protected health information required. Such additional information may be used for the research only after IRB approval.

If the approved protocol involves sharing the Limited Data Set with other investigators outside Drexel University, the investigator must contact the Chief Privacy Officer for further Guidance. The contact number for the Chief Privacy Officer is 215-255-7819 and inquiries may also be sent to Mr. Edward Longazel via e-mail (Edward.longazel@drexelmed.edu).