



### 25-4. Limited Data Set

Completion of this section is required based on the response provided to question 25-1.3.2.

The Principal Investigator is responsible for proper use of the limited data set. Only the PI and/or the study team members named on this application ("Authorized Parties") are authorized to use any or all of the limited data set. By submitting this application, the PI and each Authorized Party agrees to comply with this Statement on Use of Limited Data Set. The limited data set may not be disclosed outside the University of Michigan except with a separate Data Use Agreement.

**25-4.1\*** Affirm that the limited data set will NOT include ANY of the following information about subjects, or their relatives, employers or household members.

Affirm all:

- Names
- Postal address information other than city, town, state, or zip code
- Telephone, fax numbers, e-mail addresses, web URL addresses, IP addresses
- Social security number, medical record number, health plan beneficiary number, any account number, certificate, or license number
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Biometric identifiers (e.g., fingerprints, voice prints) -- *DNA is not considered a biometric identifier for HIPAA purposes*
- Full-face photographs and any comparable images

**25-4.2\*** Affirm that only the Authorized Parties will access, use or disclose information in the limited data set ("LDS"), and that they will comply with all of the conditions listed below:

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- The LDS will be used or disclosed only for the research project described in this application.
  - The LDS will be used or disclosed consistent with the IRB-approved protocol or as required by law.
  - Appropriate safeguards will be used to prevent use or disclosure of LDS information other than as provided for by this application and the IRB approval.
  - Any use or disclosure not permitted under the IRB-approved protocol will be promptly reported to the HIPAA Privacy Office.
  - No attempt will be made to re-identify or contact individuals whose information is included in the LDS.

**25-4.3\*** Will the limited data set be shared outside the U-M covered component?

Yes  No

**Note: if yes and a DUA has not been signed at the time of the application, a signed copy must be forwarded to the HIPAA Privacy office at 7319 Medical Science I, 1301 Catherine Street, Ann Arbor, MI 48109-0626 before disclosing the limited data set.**

**25-4.3.1\*** Upload the Data Use Agreement here. The Data Use Agreement form for UMHS (IRBMED) is available for download from the [UMHS policy on Limited data sets \(level 2 password required; if you don't have level 2, contact UMMS-RegAffairs@med.umich.edu to ask for the tip sheet for setting up an account\).](#)

Name	Version
<a href="#">01-04-342 DUA External Template.pdf(0.01)</a>	0.01