

The University of Texas SOUTHWESTERN MEDICAL CENTER At Dallas	Privacy Compliance Program Privacy Manual Section 5: De-identification, Re-identification, and Limited Data Sets Policy No: 5.2 Last Revised: March 10, 2003 Effective Date: April 14, 2003
Limited Data Sets	

POLICY:

UT Southwestern may use or disclose a Limited Data Set of PHI without the Individual’s written authorization for research, public health, or health care operations purposes. Disclosures of a Limited Data Set may only be made pursuant to a Data Use Agreement.

DIFINITION:

A Limited Data Set may be created by the removal of direct identifiers as described in this policy. A Limited Data Set differs from de-identified information in that a limited data set may include dates relating to a patient (dates of service, admission, or discharge; date of birth; date of death) and information relating to the town or city, state, and five-digit zip code of the patient, his or her employer, and the patient’s household members.

PROCEDURE:

1. When to Use a Limited Data Set?
 - a. A Limited Data Set may only be employed for the use and disclosure of PHI in the following circumstances:
 - i. Research
 - ii. Public Health
 - iii. Health Care Operations
 - b. A Limited Data Set is typically appropriate to use and disclose certain PHI in circumstances where the standards for de-identification of PHI cannot be met. See Section 5.1 of this Manual, which sets forth the policy and procedure on De-identification and Re-identification.

2. How to Create a Limited Data Set?
 - a. UT Southwestern will create a Limited Data Set by excluding from the PHI the following direct identifiers of the Individual (and of relatives, employers, or household members of the Individual):
 - i. names;
 - ii. postal address information, other than town or city, State, and zip code;
 - iii. telephone numbers;

- iv. fax numbers;
 - v. electronic mail addresses;
 - vi. Social Security numbers;
 - vii. medical record numbers;
 - viii. health plan beneficiary numbers;
 - ix. account numbers;
 - x. certificate/license numbers;
 - xi. vehicle identifiers and serial numbers, including license plate numbers;
 - xii. device identifiers and serial numbers;
 - xiii. web Universal Resource Locators (URLs);
 - xiv. internet protocol (IP) address numbers;
 - xv. biometric identifiers, including finger and voice prints; and
 - xvi. full face photographic images and any comparable images.
- b. UT Southwestern may use PHI to create a Limited Data Set.
 - c. UT Southwestern may disclose PHI to a Business Associate so that the Business Associate can create a Limited Data Set.
3. Obtaining a Data Use Agreement.
- a. UT Southwestern may disclose a Limited Data Set only if UT Southwestern obtains satisfactory assurances, in the form of a data use agreement, that the Limited Data Set recipient will only use or disclose the PHI for limited purposes.
 - b. All data use agreements will be prepared and approved by the Office of Contracts Management and will follow the general format attached to this policy. The sample form is available from the Office of Contracts Management.
 - c. The Office of Contracts Management will be responsible for ensuring that all data use agreements comply with the Privacy Laws. Specifically, the agreements must:
 - i. Establish whether the permitted disclosure of the information is for research, public health, and/or health care operations;
 - ii. Not authorize the Limited Data Set recipient to use or further disclose the information in a manner that would violate the Privacy Laws if performed by UT Southwestern;
 - iii. Establish who is permitted to receive the Limited Data Set;
 - iv. Provide that the Limited Data Set recipient will:
 - 1. not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
 - 2. use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
 - 3. report to UT Southwestern any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
 - 4. ensure that any agents, including a subcontractor, to whom it provides the Limited Data Set agrees to the same restrictions and conditions that apply to the Limited Data Set recipient with respect to such information; and
 - 5. not identify the information or contact the Individuals.

- d. The department responsible for disclosing the Limited Data Set will be responsible for ensuring that the disclosures by UT Southwestern are in accordance with the terms of the data use agreement.
4. Violations of Data Use Agreements.
- a. If any UT Southwestern employee becomes aware of a pattern of activity or practice of a Limited Data Set recipient that constitutes a material breach or violation of the data use agreement, the employee must report the problem to the Privacy Officer.
 - b. In the event the Privacy Officer receives a report of a violation of a data use agreement, the Privacy Officer will work with the department that initiated the relevant data use agreement to take reasonable steps either to cure the breach or end the violation. If such steps are unsuccessful, the Privacy Officer will:
 - i. Arrange for the relevant department(s) to discontinue disclosure of PHI to the recipient;
 - ii. Coordinate with the Office of Contracts Management to terminate the data use agreement; and
 - iii. Report the problem to the Department of Health and Human Services.
5. UT Southwestern as a Recipient of a Limited Data Set (Originating from Outside UT Southwestern).
- a. If UT Southwestern desires to be a recipient of a Limited Data Set, it may execute a data use agreement in compliance with the Privacy Laws.
 - b. The department that is the recipient of the Limited Data Set will work with the Office of Contracts Management to sign an acceptable data use agreement.
 - c. The department that is the recipient of the Limited Data Set will be responsible for ensuring that all UT Southwestern employees who use and/or disclose the elements of the Limited Data Set comply with the terms of the data use agreement.
6. Documentation
- The Office of Contracts Management will be responsible for maintaining copies of all data use agreements signed by UT Southwestern for a minimum of 6 years from the effective date of the agreement.

LEGAL REFERENCES:

45 C.F.R. § 164.514(e) (2001)
67 Fed. Reg. 53234-38 (Aug. 14, 2002)