

Limited Data Set Background Information

1. A limited data set is protected health information that excludes certain identifiers but permits the use and disclosure of more identifiers than in a de-identified data set. In particular, the limited data set allows the inclusion of all dates, 5 digit ZIP codes, and city as indirect identifiers.
2. A limited data set may be used only for the purposes of research, public health, or health care operations.
3. UCDHS may use or disclose limited data set information only if it enters into a valid data use agreement.
4. The following identifiers must be excluded from a limited data set (for individual, relatives, employers, and household members):
 - Names
 - Postal address information, other than town or city, state, and ZIP code
 - Telephone numbers
 - Fax numbers
 - Electronic mail addresses
 - Social security numbers
 - Medical record numbers
 - Health plan beneficiary numbers
 - Account numbers
 - Certificate/license numbers
 - Vehicle identifiers and serial numbers, including license plate numbers
 - Device identifiers and serial numbers
 - Web Universal Resource Locators (URLs)
 - Internet Protocol (IP) address numbers
 - Biometric identifiers, including finger and voice prints
 - Full face photographic images and any comparable images.

A limited data set can include a link field to allow the covered entity to re-identify the individual. The link field for a limited data set can be derived from the direct identifiers. For example, Initials + sequence number is a valid link field, as is an encrypted SSN.
5. The limited data set is subject to the minimum necessary section of HIPAA.
6. The limited data set is *not* subject to disclosure accounting.
7. UCDHS has developed a model data use agreement to be used whenever it intends to disclose protected health information for research, public health, or health care operations. In order to protect protected health information to the greatest extent possible, the use and disclosure of the protected health information may be limited by the purpose statements in the data use agreement (attached).
8. If an outside entity creates the limited data set, it must first sign a business associate agreement with UCDHS.
9. If a UC employee creates the limited data set, that employee, will, for that purpose, be a member of the UCDHS workforce, and shall complete appropriate HIPAA training and follow applicable UCDHS policy regarding health information.

Data Use Agreement UC Davis Health System

This Data Use Agreement (the “Agreement”) is entered into by and between The Regents of the University of California, on behalf of its UC Davis Health System (UCDHS) (“Covered Entity”) and _____ (“Data User”), collectively, the “Parties”, and shall be effective as of _____ (the “Agreement Effective Date”).

1. **Definitions.** The parties agree that the following terms, when used in this Agreement, shall have the following meanings, and that the terms set forth below shall be deemed to be modified to reflect any changes made hereafter to such terms by law or regulation.
 - a. “*HIPAA*” means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
 - b. “*HIPAA Regulations*” means the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 C.F.R. Part 160 and 45 C.F.R. Part 164.
 - c. “*Covered Entity*” means a health plan, a health care clearinghouse, or a health care provider (each as defined by HIPAA and the HIPAA Regulations) who transmits any health information in electronic form in connection with a transaction covered by the HIPAA Regulations.
 - d. “*Protected Health Information*” or “*PHI*” means Individually Identifiable Health Information, except that Protected Health Information excludes Individually Identifiable Health Information in education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. § 1232g, records described at 20 U.S.C. § 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.

2. Obligations of Covered Entity.

- a. *Limited Data Set.* Covered Entity agrees to share the following Protected Health Information with Data User(s): _____ (the "**Limited Data Set**"). Such Limited Data Set shall not contain any of the following identifiers of the individual who is the subject of the Protected Health Information, or of relatives, employers or household members of the individual: names; postal address information, other than town or city, state and zip code; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

3. Obligations of Data User.

- a. *Performance of Activities.* Data User may use and disclose the Limited Data Set received from Covered Entity only in connection with the performance of the:
[] research activities, [] public health activities, [] health care operations described below:

- b. *Assurances of Data User's Non-Employee Agents.* Data User shall not disclose the Limited Data Set to any non-employee agent or subcontractor of Data User except with the prior written consent of Covered Entity. Data User shall ensure that any agents, including subcontractors, to whom it provides the Limited Data Set agree in writing to be bound by the same restrictions and conditions that apply to Data User with respect to such Limited Data Set.
- c. *Nondisclosure Except As Provided In Agreement.* Data User shall not use or further disclose the Limited Data Set except as permitted or required by this Agreement or as otherwise required by law.
- d. *Safeguards.* Data User shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided by this Agreement.
- e. *Reporting.* Data User shall report to Covered Entity within twenty-four (24) hours of Data User becoming aware of any use or disclosure of the Limited Data Set in violation of this Agreement or applicable law.
- f. *Identification and Contacting of Individuals.* Data User shall not identify the information or contact the individuals included in the Limited Data Set.

4. Material Breach, Enforcement and Termination.

- a. *Term.* This Agreement shall be effective as of the Agreement Effective Date, and shall continue until the Agreement is terminated by the Parties or in accordance with the provisions of this Section 4.
- b. *Covered Entity's Rights of Access and Inspection.* From time to time upon reasonable notice, or upon a reasonable determination by Covered Entity that Data User has breached this Agreement, Covered Entity may inspect the facilities, systems, books and records of Data User to monitor compliance with this Agreement. The fact that Covered Entity inspects, or fails to inspect, or has the right to inspect, Data User's facilities, systems and procedures does not relieve Data User of its responsibility to comply with this Agreement, nor does Covered Entity's (1) failure to detect or (2) detection of, but failure to notify Data User or require Data User's remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of Covered Entity's enforcement or termination rights under this Agreement. The parties' respective rights and obligations under this Section 4.b. shall survive termination of the Agreement.
- c. *Termination.* Covered Entity may terminate this Agreement:
 - i. immediately if Data User is named as a defendant in a criminal proceeding for a violation of HIPAA or the HIPAA Regulations;
 - ii. immediately if a finding or stipulation that Data User has violated any standard or requirement of HIPAA, the HIPAA Regulations, or any other security or privacy laws is made in any administrative or civil proceeding in which Data User has been joined;
 - iii. immediately if Covered Entity determines that Data User has breached or violated a material term of this Agreement; or
 - iv. pursuant to Section 5.b. of this Agreement.
- d. *Reporting to United States Department of Health and Human Services.* If any breach or violation is not cured, and if termination of this Agreement is not feasible, Covered Entity shall report Data User's breach or violation to the Secretary of the United States Department of Health and Human Services, and Data User agrees that it shall not have or make any claim(s), whether at law, in equity, or under this Agreement, against Covered Entity with respect to such report(s).
- e. *Disposition of Records.* Upon termination of this Agreement for any reason, including, but not limited to Data User's decision to cease use of the Limited Data Set, Data User agrees to return or destroy all Limited Data Set data, including copies and derivative versions.
- f. *Indemnification.* Data User shall indemnify, hold harmless and defend Covered Entity from and against any and all claims, losses, liabilities, costs and other expenses resulting from, or relating to, the acts or omissions of Data User in connection with the representations, duties and obligations of Data User under this Agreement. The parties' respective rights and obligations under this Section 4.f. shall survive termination of the Agreement.

5. Miscellaneous Terms.

- a. *Governing Law.* This Agreement shall be governed by and construed in accordance with applicable federal and California laws.
- b. *Amendment.* Covered Entity and Data User agree that amendment of this Agreement may be required to ensure that Covered Entity and Data User comply with changes in state and federal laws and regulations relating to the privacy, security, and confidentiality of PHI or the Limited Data Set. Covered Entity may terminate this Agreement upon thirty (30) days written notice in the event that Data User does not promptly enter into an amendment that Covered Entity, in its sole discretion, deems sufficient to ensure that Covered Entity will be able to comply with such laws and regulations.
- c. *No Third Party Beneficiaries.* Nothing express or implied in this Agreement is intended or shall be deemed to confer upon any person other than Covered Entity and Data User, and their respective successors and assigns, any rights, obligations, remedies or liabilities.
- d. *Primacy.* To the extent that any provisions of this Agreement conflict with the provisions of any other agreement or understanding between the parties with respect to use of the Limited Data Set provided hereunder, this Agreement shall control.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the Agreement Effective Date.

The Regents of the University of California,
on behalf of its
UC Davis Health System ("Covered Entity")

[DATA USER] ("Data User")

By: _____

By: _____

Title: _____

Title: _____

Date: _____

Date: _____