



Tucson, Arizona
Compliance Department
Requests for Limited Data Sets: Processing Data Use Agreements
November 2009

PROCEDURE:

1. The principal Investigator (PI) of the research project submits two original copies of the Data Use Agreement (see Data Use Agreement form below) to the University of Arizona's Privacy Officer for review and approval.
2. Following approval by the U of A Privacy Officer, the PI is responsible for picking up the signed and dated forms and sending them with a copy of the Institutional Review Board Approval (HSPP Correspondence Form) and a copy of the research project to the UMC Corporate Compliance Officer for review. If approved by UMC, The Corporate Compliance Officer will subsequently sign and date the Data Use Agreement forms and arrange for the production of the requested Limited Data Set.
3. Once the Data Use Agreements are approved by both the UMC Corporate Compliance Officer and the U of A Privacy Officer, they are to be sent to Assistant Vice-President, Research Compliance and Policy, U of A.
4. The Assistant Vice-President Research Compliance and Policy will distribute the Data Use Agreement as follows: one original to UMC Compliance Officer, one original for University files, and one copy will be forwarded will be forwarded to the PI.

University of Arizona's Privacy Officer

Jeniece Poole
U of A Privacy Officer
1618 E. Helen
PO Box 21-0409
621-1465
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UMC Corporate Compliance Officer

Valerie Evans
UMC Corporate Compliance Officer
1501 N. Campbell
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Assistant Vice-President, Research Compliance and Policy, U of A

Elizabeth Boyd, Ph.D
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Research Compliance and Policy
Office of the Vice-President, Graduate Studies and Economic Development
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DATA USE AGREEMENT

This agreement is made effective as of the ___ day of _____, 200_, between University Medical Center Corporation, an Arizona nonprofit corporation ("Covered Entity"), and _____(Recipient).

PREAMBLE

Pursuant to federal law, the Covered Entity is not permitted to authorize fully identified health information to be used by, or disclosed to, the Recipient. The Covered Entity has determined, however, that the Recipient may use, or that the Covered Entity may disclose to the Recipient, a Limited Data Set of information, for research, public health or healthcare operations purposes. The Covered Entity is permitted to authorize the use or disclosure of a Limited Data Set of health information by the Recipient only if it first obtains a Data Use Agreement from the Recipient.

THEREFORE, in consideration of the mutual covenants contained in this Agreement and intending to be legally bound hereby, the parties agree as follows:

Section 1. Definitions

- (a) A Limited Data Set consists of health information that has had all direct identifiers concerning the subject of the record (and his or her employer, family and household members) deleted.
- (b) Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the HIPAA Privacy Regulations, 45 C.F.R. ' ' 160.103 and 164.501.

Section 2. Obligations and Activities of Recipient

Recipient shall:

- (a) not use or further disclose the Limited Data Set other than as permitted or required by this Agreement or by law;
- (b) not re-identify the Limited Data Set, nor attempt to contact any individual who is the subject of the Limited Data Set provided to Recipient by the Covered Entity;
- (c) use appropriate safeguards to prevent the use or disclosure of the Limited Data Set other than as provided for by this Agreement;
- (d) report to the Covered Entity any use or disclosure of the Limited Data Set, that is not provided for by this Agreement, of which the Recipient becomes aware; and
- (e) ensure that any agent, including a subcontractor, to whom the Recipient provides the Limited Data Set received from Covered Entity, agrees to the same

restrictions and conditions that apply through this Agreement to the Recipient with respect to such information.

Section 3. Permitted Uses and Disclosures by Recipient

Except as otherwise limited in this Agreement, Recipient may use or disclose the Limited Data Set for the following purposes (*check one or more and provide explanation*):

- Research. Explain: _____

- Public Health. Explain: _____

- Health Care Operations. Explain: _____

Section 4. Obligations of Covered Entity

Covered Entity shall:

- (a) notify the Recipient of any limitation(s) in the Covered Entity's Notice of Privacy Practices in accordance with the HIPAA Privacy Regulations, 45 C.F.R. '164.520, to the extent that such limitation may affect the Recipient's use or disclosure of the Limited Data Set; and
- (b) notify the Recipient of any restriction to the use or disclosure of the Limited Data Set that Covered Entity has agreed to in accordance with the HIPAA Privacy Regulations, 45 C.F.R. '164.522, to the extent that such restriction may affect the Recipient's use or disclosure of Protected Health Information.

Section 5. Term and Termination

- (a) Term. The Term of this Agreement shall be effective as of _____, 200__, and shall continue for as long as Recipient maintains any Limited Data Set(s) provided by the Covered Entity.
- (b) Termination for Cause. Upon Covered Entity's knowledge of a material breach by the Recipient, Covered Entity shall attempt to directly cure, or cause the cure of, the breach or end the violation. If unsuccessful, Covered Entity shall immediately terminate this Agreement and report the violation to the UMC Privacy Officer.

Section 6. Miscellaneous

- (a) Regulatory References. A reference in this Agreement to a section in the HIPAA Privacy Regulations means the section in effect, or as amended.
- (b) Amendment. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for the Covered Entity to comply with the requirements of the HIPAA Privacy Regulations and the Health Insurance Portability and Accountability Act, Public Law 104-191.
- (c) Survival. The obligations of the Recipient under Sections 2 and 3 of this Agreement shall survive the termination of this Agreement.
- (d) Interpretation. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the HIPAA Privacy Regulations.

The parties have caused this Agreement to be executed on the date written below.

DATE: _____

University Medical Center Corporation

BY: _____

DATE: _____

(Name of Recipient)

BY: _____