



Policy and Procedure:

SDM Data Use Agreement for Limited Data Set

(Adapted from UPMC Data Use Agreement for Limited Data Set at <http://www.irb.pitt.edu/hipaa/DataUseAgreement.asp>)

Effective: 09/21/2009 **Created:** 08/13/2009 **Last updated:** 5/12/2012

SDM Data Use Agreement for Limited Data Set

[INVESTIGATOR - THIS AGREEMENT IS TO BE FILLED-IN BY THE INVESTIGATOR AND PRESENTED TO THE IRB OF RECORD AS PART OF THE STUDY PROTOCOL SUBMISSION TO THE IRB. THE IRB OF RECORD WILL FORWARD A COPY OF THIS AGREEMENT TO A SDM REPRESENTATIVE FOR SDM APPROVAL .THE HONEST BROKER MUST BE PRESENTED WITH A COPY OF THE FULLY-EXECUTED AGREEMENT (TO INCLUDE FINAL APPROVAL FROM SDM) IN ORDER FOR THE HONEST BROKER TO ACCESS SDM DATA FOR THE PURPOSE OF THE CORRESPONDING RESEARCH STUDY].

This Data Use Agreement for Limited Data Sets (the "Agreement") is made on _____ (date) by and between the School of Dental Medicine ("SDM") and _____ hereinafter termed "User".

WHEREAS, 45 CFR 164, Subpart E (titled "Standards for Privacy of Individually Identifiable Health Information" and herein referred to as the "HIPAA Privacy Rule") allows SDM to make available for the purposes of research, public health or health care operations a limited data set to User, provided that User agrees to be bound by the terms of this Agreement; and

WHEREAS, User desires for SDM to make available the limited data set as described below and agrees to be bound by the terms and conditions of this Agreement; and

WHEREAS, SDM agrees to make available such limited data set, provided that User agrees to abide by the terms and conditions of this Agreement as well as applicable SDM policies and IRB requirements.

NOW, THEREFORE, in consideration of the mutual covenants and promises hereinafter set forth, the parties hereto agree as follows:

A. DEFINITIONS

For the purposes of this Agreement, terms used herein shall have the same definition as set forth in the HIPAA Privacy Rule.



B. DATA TO BE PROVIDED BY SDM

The limited data set provided pursuant to this Agreement contains data acquired from
[INVESTIGATOR - SPECIFY THE SDM LOCATION AND SOURCE INFORMATION
SYSTEM/REPOSITORY]

and related to [INVESTIGATOR - IDENTIFY THE SPECIFIC NATURE OF THE DATA AND
THE SPECIFIC DATA ELEMENTS BEING REQUESTED.]

Such data shall be limited to data that is the Minimum Necessary to reasonably accomplish
the Authorized Purposes identified in Section (C)(1) of this Agreement.

For the purpose of this Agreement and consistent with the HIPAA Privacy Rule, "Minimum
Necessary" is defined as that protected health information that is "reasonably necessary to
achieve the purpose of the disclosure" and is disclosed to only "Those persons or classes of
persons, as appropriate, in its workforce who need access to protected health information to
carry out their duties."

Consistent with the HIPAA Privacy Rule, in no case will the limited data set include any of the
following identifiers:

1. Names
2. Postal address information (other than town or city, state and zip code)
3. Telephone numbers
4. Fax numbers
5. E-mail addresses
6. Social security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. Certificate/license numbers
11. Vehicle identifiers & serial numbers, including license plate numbers
12. Device identifiers & serial numbers
13. Web Universal Resource Locators (URL's)
14. Internet Protocol (IP) address numbers
15. Biometric identifiers, including finger and voice prints
16. Full face photographic images and any comparable images

C. PERMITTED USES AND DISCLOSURES

1. User agrees to limit the use and disclosure of the limited data set to the following purposes
("Authorized Purposes"): [INVESTIGATOR - SPECIFY THE GENERAL_PURPOSE(S) OF THE
PROPOSED RESEARCH.]

2. User shall allow only the following individuals access to the limited data set for the Authorized
Purposes and consistent with the assurances and obligations set forth in this Agreement:
[INVESTIGATOR - ADD LIST OF AUTHORIZED INDIVIDUALS WHO WILL HAVE ACCESS
TO THE LIMITED DATA SET].



3. User acknowledges that such individuals have a need to access the limited data set to carry out their duties.

D. ASSURANCES

1. User shall not use or further disclose the limited data set other than as permitted by this Agreement or as otherwise required by law.
2. User shall use appropriate safeguards to prevent use or disclosure of the limited data set other than as permitted by this Agreement.
3. User shall report to the SDM HIPAA Security Officer any use or disclosure of the limited data set not provided for by this Agreement of which User becomes aware.
4. User shall ensure that any specified agents (see C.2., above), 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 User with respect to such information.
5. User shall not re-identify the information or contact the individuals for whose records are contained within the limited data set.

E. BREACH AND TERMINATION

1. In the event that this Agreement is breached by User, SDM, at its sole discretion, may a) terminate this Agreement upon written notice to User or b) request that User, to the satisfaction of SDM, take appropriate steps to cure such breach. If User fails to cure such breach to the satisfaction of SDM or in the time prescribed by SDM, SDM may terminate this Agreement upon written notice to User.
2. Should this Agreement be terminated for any reason, including, but not limited to User's decision to cease use of the limited data set data, User agrees to destroy or return all limited data set data provided pursuant to this Agreement (including copies or derivative versions thereof).

F. MISCELLANEOUS

1. Notices

Any notice permitted or required as provided for herein shall be in writing and to the contact and address as noted below or as may be provided by either party to the other in writing from time to time.

Notice to SDM shall be to:

The School of Dental Medicine
Attn: Center for Dental Informatics
339 Salk Hall
3501 Terrace Street
Pittsburgh, PA 15261



Notice to User shall be to:

Name: _____

Address: _____

2. Governing Law

This Agreement shall be governed by, and construed in accordance with, the laws of the Commonwealth of Pennsylvania.

3. Processing Fees

For each limited data set file, the User shall reimburse SDM data service provider for all associated processing fees.

SDM

Name (print): _____

Title: _____

Signature: _____

Date: _____

User

Name (print): _____

Title: _____

Signature: _____

Date: _____

IRB Approval:

Name (print): _____ Title: _____

Signature: _____ IRB#: _____

Date: _____