

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 RESPRESENTATIVE 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 SDMto make available the limited data set as described below and agrees to be bound by the terms and conditions of this Agreement; and

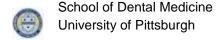
WHEREAS, SDM agrees to make available such limited data set, provided that User agrees to abide by the terms and conditions of this Agreement as well as applicable SDM policies and IRB requirements.

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

#### A. <u>DEFINITIONS</u>

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

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#### 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

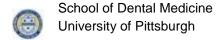
#### C. PERMITTED USES AND DISCLOSURES

 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].

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

#### D. ASSURANCES

- 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.
- 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

- 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.
- Should this Agreement be terminated for any reason, including, but not limited to Usert's
  decision to cease use of the limited data set data, Useragrees to destroy or return all limited
  data set data provided pursuant to this Agreement (including copies or derivative versions
  thereof).

#### F. MISCELLANEOUS

#### Notices

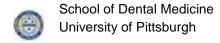
Any notice permitted or required as provided for herein shall be in writing and to the contact and address as noted below or as may be provided by either party to the other in writing from time to time.

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

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	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.	3. <u>Processing Fees</u>	
For each limited data set file, the User shassociated processing fees.		ser shall reimburse SDM data service provider for all
SDM	U	Jser
Name (print): _	N	Name (print):
Title:	1	Title:
Signature:		Signature:
Data:		Date:
IRB Approval:	:	
Name (print): _	Т	itle:
Signature:	II	RB#:
Date:		

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