



Policy and Procedure:

## **SDM PHI Research Agreement**

(Adapted from UPMC Research Agreement at <http://www.irb.pitt.edu/hipaa/ResearchAgreement.asp>)

**Effective:** 09/21/2009

**Created:** 08/13/2009

**Last updated:** 5/12/2012

### **SDM PHI Research Agreement**

*[INVESTIGATOR - THIS AGREEMENT IS TO BE FILLED-IN BY THE INVESTIGATOR AND PRESENTED TO SDM IT SERVICE PROVIDER IN ORDER TO ACCESS ELECTRONIC PHI]*

In order to ensure that the disclosure and use of data derived from the patient health information (PHI) in the School of Dental Medicine (SDM) Privacy Act System of Records comply with the Privacy Act of 1974 (5 U.S.C. § 522a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (45 C.F.R. Parts 160 and 164), SDM and

\_\_\_\_\_ enter into this Agreement:

1. This Agreement is by and between SDM, and \_\_\_\_\_, hereinafter termed "User."
2. The parties mutually agree that SDM retains all ownership rights to the PHI file(s) referred to in this Agreement, and that the User does not obtain any right, title, or interest in any of the data furnished by SDM. The parties further agree that SDM makes no representation or warranty, either implied or express, with respect to the accuracy of any data in the PHI file(s).
3. The User represents that the PHI files in section 4 above will be used solely for the following research purpose (provide a brief summary of the purpose below):

\_\_\_\_\_  
Name of Study/Project

\_\_\_\_\_  
IRB No.

4. The following SDM PHI file(s) is/are covered under this Agreement.

File	Year (s)




5. Absent informed consent/authorization from SDM, the User shall not attempt to identify or contact any specific individual whose record is included in the PHI file(s) specified in section 4 and the User shall not attempt to link records included in the file(s) specified in section 4 to any other beneficiary-specific source of information.
  
6. The parties mutually agree that the aforesaid file(s) (and/or any derivative file(s)) including those files that indirectly identify individuals and those that can be used in concert with other information to identify individuals may be retained by the User until \_\_\_\_\_, hereinafter known as the "Retention Date." The User agrees to notify SDM within 30 days of the completion of the purpose specified in section 4 if the purpose is completed before the aforementioned retention date. Upon such notice or retention date, whichever occurs sooner, the User must destroy such data. The User agrees to destroy and notify to SDM within 30 days. The User agrees not to retain SDM PHI files or any parts thereof, after the aforementioned file(s) are destroyed.
  
7. The User shall not use, disclose, market, release, show, sell, rent, lease, loan, or otherwise grant access to the PHI files specified in section 4 of this Agreement, except as expressly permitted by this Agreement or otherwise required by law.
  
8. The User agrees that any use of SDM PHI data in the creation of any document (manuscript, table, chart, study, report, etc.) concerning the purpose specified in section 4 (regardless of whether the report or other writing expressly refers to such purpose, to SDM, or to the files specified in section 5 or any data derived from such files) must adhere to Health Sciences' current medical research policies. By signing this Agreement you hereby agree to abide by these rules.
  
9. The User may not disclose the PHI file(s) specified in section 4 of this Agreement to a Secondary User until and unless the Secondary User enters into this Agreement with SDM. SDM will only enter into this Agreement with a Secondary User if the purpose for which the secondary use of the PHI file(s) is approved by IRB.
  
10. The User agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the PHI file(s) and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III—Security of Federal Automated Information Systems (<http://www.whitehouse.gov/omb/circulars/a130/a130.html>), which sets forth guidelines for security plans for automated information systems in Federal agencies. The User acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the PHI file(s) specified in section 4 is prohibited. Further, the User agrees that the PHI file(s) must not be physically moved or electronically transmitted in any way from the site indicated in section 15 without prior written approval by SDM HIPAA Security Officer.



11. Even if the User has grant of an IRB waiver, SDM may require that the following four identifiers are removed:
  - 1) Patient name
  - 2) Patient SSN
  - 3) Patient home street address
  - 4) Patient phone number
12. For each PHI file, the User shall reimburse SDM data service provider for all associated processing fees.
13. The User shall promptly report to SDM HIPAA Security Officer any use or disclosure of the information not provided for by this Agreement of which it becomes aware. SDM HIPAA Security Officer in its sole discretion may require the User to: (a) promptly investigate and respond to SDM concerns regarding any alleged disclosure; (b) promptly resolve any problems identified by the investigation; (c) submit a corrective action plan with steps designed to prevent any future unauthorized disclosures; and/or (d) require that all PHI files be immediately returned.
14. The User acknowledges that penalties under §1106(a) of the Social Security Act [42 U.S.C. § 1306(a)], including possible imprisonment, may apply with respect to any disclosure of information in the file(s) that is inconsistent with the terms of the Agreement. The User further acknowledges that criminal penalties under the Privacy Act [5 U.S.C. § 552a(i)(3)] apply if it is determined that the User, or any individual employed or affiliated therewith, knowingly and willfully obtained the file(s) under false pretenses. The User also acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641.
15. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement for protection of the PHI file(s) specified in section 4, and acknowledges having received notice of potential criminal, civil, and/or administrative penalties for violation of the terms of the Agreement.
16. 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

**Researcher:**

**SDM Data Service Provider:**

\_\_\_\_\_ (Print name)

\_\_\_\_\_ (Print name)

\_\_\_\_\_ (Signature)

\_\_\_\_\_ (Signature)

\_\_\_\_\_ (Date)

\_\_\_\_\_ (Date)