

Policy and Procedure:

SDM Business Associate Agreement for Honest Brokers

(Adapted from UPMC Business Associate Agreement for Honest Brokers at <u>http://www.irb.pitt.edu/hipaa/UPMCBusinessAgreement.asp</u>)

Effective:	09/21/2009	Created:	08/13/2009	Last updated:	5/12/2012
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SDM Business Associate Agreement for Honest Brokers

Whereas, _____[NAME OF HONEST BROKER], (the "Honest Broker") desires to perform certain medical and dental record de-identification functions on behalf of the School of Dental Medicine (SDM) health care provider entities that hold protected health information.

Whereas, Honest Broker represents and warrants that it will be certified to perform the functions of an honest broker pursuant to the SDM policy titled "SDM Honest Broker Certification Policy" prior to it performing any honest broker functions.

Whereas, Honest Broker agrees to enter into and abide by this Business Associate Agreement as a prerequisite to performing honest broker functions, which include, but not be limited to, the receipt and deidentification of SDM patient protected health information (PHI), as that term is defined in the HIPAA Privacy Rule at 45 CFR 164.501.

Now, therefore the parties intending to be legally bound, agree as follows:

1. Definitions

Terms used herein, but not otherwise defined, shall have the same meaning as those terms in 45 CFR §160.103 and § 164.501.

2. Honest Broker Obligations

The Honest Broker shall ensure that approval of the IRB of record has been obtained for a research study whereby the Honest Broker receives a request for de-identified PHI (from an investigator that is served by the IRB of record).

The Honest Broker agrees to adhere to all of the terms and conditions specified by the IRB of record for any research study for which the Honest Broker will perform de-identification services.

If an investigator requests a Limited Data Set, rather than a fully/completely de-identified PHI data set, in order to be granted access to the SDM-held PHI, the Honest Broker shall obtain and retain evidence of an appropriately executed Data Use Agreement for a Limited Data Set. The IRB of record may also require evidence of a completed Data Use Agreement for a Limited Data Set as part of its application process for approval of the proposed research involving the use of a limited data set. This Data Use Agreement will provide evidence of all of the SDM-required detailed disclosures (honest broker data set specifications) relative to:

- a. where (what SDM entity) the PHI is located;
- b. what HIPAA-defined limited data set elements are needed for the research;



- c. the purpose of the limited data set request (detailed uses pertinent to the limited data set); and,
- d. who (names, titles, addresses) will access, use and disclose the limited data set information other that the principal investigator.

3. Permitted Uses

- a) Except as otherwise limited herein, Honest Broker may use and/or disclose PHI only to de-identify SDM-held/owned protected health information, to produce fully de-identified or limited data sets, that can be provided to investigators/researchers and other interested parties upon verification of their legitimate request, provided that such use or disclosure would not violate the Privacy Rule if done by SDM.
- b) Except as otherwise limited herein, Honest Broker may use PHI for its proper management and administration or to carry out its legal responsibilities.
- c) Except as otherwise limited herein, Honest Broker may disclose PHI for its proper management and administration, provided that such disclosures are Required By Law, or if Honest Broker obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies Honest Broker of any instances of which it is aware in which the confidentiality of the information has been breached.
- d) Except as otherwise limited herein, Honest Broker may use PHI to provide Data Aggregation services to SDM as permitted by 42 CFR §164.504(e)(2)(i)(B).
- e) Honest Broker may use PHI to report violations of law to the appropriate Federal and State authorities, consistent with 45 CFR § 164.502(j)(1).

4. General Conditions.

<u>Limitation on Use and Appropriate Safeguards.</u> Honest Broker agrees to not use or disclose PHI other than as permitted or required as provided for herein or as required by law. Honest Broker agrees to use appropriate safeguards to prevent inappropriate use or disclosure of PHI.

<u>Report of Breach.</u> Honest Broker agrees to report to SDM any use or disclosure of PHI not provided for herein of which it becomes aware of. Honest Broker agrees to mitigate, to the extent practicable, any harmful effect that is known to it of a use or disclosure of PHI by Honest Broker in violation of the requirements contained herein.

<u>Agents/Subcontractors.</u> Honest Broker agrees to ensure that any agents, including any subcontractor, to whom it provides PHI (whether received from or created or received by Honest Broker) on behalf of SDM agree to the same restrictions and conditions that apply in these terms to Honest Broker with respect to such information.

<u>Property Rights</u>. The PHI shall be and remain the property of SDM. Honest Broker agrees that it acquires no title or rights to the PHI, including any de-identified information, as a result of these terms and conditions.

<u>Availability of Books and Records to Secretary.</u> Honest Broker agrees to make its internal practices, books, and records, including policies, procedures and PHI relating to the use and disclosure of PHI received from, or created or received by Honest Broker on behalf of SDM available to us, or at the request of SDM, to the Secretary of the United States Department of Health and Human Services (the "Secretary"), in a time and manner as prescribed by the Privacy Rule or designated by the Secretary for purposes of the



Secretary determining SDM's compliance with the Privacy Rule. Such time and manner shall allow SDM to comply with its obligations under the Privacy Rule.

Term and Termination.

- a). The Term of this agreement shall be for one (1) year. The agreement shall automatically be renewed for like terms unless terminated by SDM. Either party may terminate this agreement without cause on ninety (90) days written notice.
- b). Termination for Cause. Upon SDM's knowledge of a material breach by Honest Broker, SDM shall either:
 - 1) provide an opportunity for Honest Broker to cure the breach or end the violation and terminate this Agreement if Honest Broker does not cure the breach or end the violation within the time specified by SDM.
 - 2) Immediately terminate these terms and conditions if Honest Broker has breached a material term and cure is not possible, or
 - 3) If neither termination nor cure are feasible, SDM shall report the violation to the Secretary.
- c). Actions upon Termination.
 - Except as provided in paragraph (d) of this section, upon termination of these terms and conditions, for any reason, Honest Broker shall return or destroy all PHI received from SDM, or created or received by Honest Broker on behalf of SDM. This provision shall apply to PHI that is in the possession of Honest Broker's subcontractors or agents. Honest Broker shall retain no copies of the PHI.
 - 2) In the event that Honest Broker determines that returning or destroying the PHI is not feasible, Honest Broker shall provide to SDM notification of the conditions that make return or destruction not feasible. Upon mutual agreement of the Parties that return or destruction of PHI is not feasible, Honest Broker shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction not feasible, for so long as Honest Broker maintains such PHI.

<u>SDM Access to Facilities, Books and Records.</u> Honest Broker shall, upon reasonable request, give SDM access for inspection and copying to its facilities used for the maintenance or processing of PHI, and to its books, records, practices, policies and procedures concerning the use and disclosure of PHI, for the purpose of determining Honest Broker's compliance with this Agreement. SDM is also permitted to perform reasonable audits of Honest Broker's management and use of PHI.

SDM Obligations. SDM shall:

- a) Notify Honest Broker of any limitation(s) in its Notice of Privacy Practices in accordance with 45 CFR §164.520, to the extent that such limitation(s) may affect Honest Broker's use or disclosure of PHI.
- b) Notify Honest Broker of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect Honest Broker's use or disclosures of PHI.
- c) Notify Honest Broker of any restriction to the use or disclosure of PHI that SDM has agreed to in accordance with 45 CFR §164.522 to the extent that such restriction may affect Honest Broker's use or disclosure of PHI.
- d) Not request Honest Broker use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by SDM.



5. Miscellaneous Items

<u>Regulatory References.</u> A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended.

<u>Amendment.</u> The Parties agree to take such action as is necessary to amend this Agreement, in writing, from time to time as is necessary for SDM to comply with the requirements of the Privacy Rule and HIPAA (Pub.L.No. 104-191).

<u>Survival</u>. Honest Broker's respective rights and obligations under the "Term and Termination" sections shall survive the termination of this Agreement.

Interpretation. Any ambiguity in this Agreement shall be resolved to permit SDM to comply with the Privacy Rule.

Agreed to this on _____[DATE]

[HONEST BROKER]	[SDM]
Name (print):	Name (print):
Signature:	Signature:
Title:	Title:
Date:	Date: