



Policy and Procedure:

SDM Honest Broker Certification Policy and Procedures

(Adapted from UPMC Application for Certification of Honest Broker Systems at <http://www.irb.pitt.edu/hipaa/UPMCBusinessAgreement.asp>)

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

Application for SDM Certification of Honest Broker System/Processes

1. Specify the School, Department, Division, or Center for which this Honest Broker System/Process is being developed:

2. Specify the individual who will assume responsibility for the appropriate management and oversight of this Honest Broker System/Process:

Name:

Title:

Address:

Telephone Number:

FAX Number:

E-mail Address:

3. Specify the names of all additional individuals who will be involved in performing honest broker services under this Honest Broker System/Process:

4. HIPAA Complete (i.e., "Safe Harbor") De-Identification of Medical/Dental Record Information:

- a. For electronic medical/dental record information, address the processes and/or systems that will be used to fully de-identify (i.e., HIPAA "Safe Harbor" compliant) the information for subsequent use by your affiliated researchers. (Note: See Attachment A for HIPAA "Safe Harbor" de-identification requirements.)



(Attach additional pages if required for an adequate response.)

- b. For paper-based medical/dental record information, address the processes and/or systems that will be used to fully de-identify (i.e., HIPAA "Safe Harbor" compliant) the information for subsequent use by your affiliated researchers. (Note: See Attachment A for HIPAA "Safe Harbor" de-identification requirements.)

(Attach additional pages if required for an adequate response.)

5. Limited Data Sets of Medical/Dental Record Information:

- a. For electronic medical/dental record information, address the processes and/or systems that will be used to develop Limited Data Sets of the information for subsequent use by your affiliated researchers. (Note: See Attachment A for HIPAA Limited Data Set requirements.)

(Attach additional pages if required for an adequate response.)

- b. For paper-based medical/dental record information, address the processes and/or systems that will be used to develop Limited Data Sets of the information for subsequent use by your affiliated researchers. (Note: See Attachment A for HIPAA Limited Data Set requirements.)

(Attach additional pages if required for an adequate response.)

- c. Address your policies, procedures and controls for ensuring that Limited Data Sets of medical/dental record information that you provide to your affiliated researchers contain only the minimum necessary information needed to perform the research. (Note: These policies should include statements specifying that the medical/dental record information provided to researchers under a Limited Data Set will be consistent with the specific data elements requested in the corresponding IRB-approved research application and Data Use Agreement.)

(Attach additional pages if required for an adequate response.)



6. Assignment of Re-Identification Codes to De-Identified (HIPAA “Safe Harbor”) Medical/Dental Record Information and Limited Data Sets:

Address your policies, procedures and controls for the assignment of re-identification codes to the de-identified (HIPAA “Safe Harbor”) medical/dental record information and/or Limited Data Sets of medical/dental record information provided to your affiliated researchers. (Note: These policies should include statements specifying that the assignment of re-identification codes will be based on project-by-project verification that the IRB granted approval of the use of re-identification codes. In addition, include statements addressing how re-identification codes will be appropriately managed by the honest broker so as to prevent researcher access to information linking these codes with corresponding patient-subject identifiers.)

(Attach additional pages if required for an adequate response.)

7. Documentation and Quality Assurance:

- a. Address your policies, procedures and controls for ensuring that Institutional Review Board approval has been granted for the use of de-identified (HIPAA “Safe Harbor”) medical/dental record information or a Limited Data Set of medical record information prior to providing such to your affiliated researchers.

(Attach additional pages if required for an adequate response.)

- b. Address your policies and procedures for documenting each honest broker transaction with your affiliated researchers (e.g., documentation of the identity of researcher, identity of the research study, the nature of the information provided, corresponding IRB approval information, etc.).

(Attach additional pages if required for an adequate response.)

- c. Address your policies and procedures for routine monitoring (auditing) of de-identified (HIPAA “Safe Harbor”) medical/dental record information and Limited Data Sets of medical/dental record information provided to affiliated researchers so as to ensure that this information has been de-identified in compliance with respective HIPAA requirements.



(Attach additional pages if required for an adequate response.)

- d. Address your policies and procedures for managing and ensuring the security of all identifiable medical/dental record information that is in the Honest Broker's possession during the performance of its de-identification (HIPAA "Safe Harbor") or creation of Limited Data Set functions.

(Attach additional pages if required for an adequate response.)

8. Business Associate Agreement:

Are all individuals serving as honest brokers employees of SDM?

Yes. A business associate agreement is not required.

No. Please submit a completed signed business associate agreement.

(Note: the standard SDM Business Associate Agreement can be found at <http://www.dental.pitt.edu/hipaa/sdmHBbaa.doc>).

CERTIFICATION OF HONEST BROKER RESPONSIBILITIES

By signing below I agree/certify that:

1. I am cognizant of and will comply with the Federal Policy (Common Rule) and HIPAA regulations and the IRB and SDM policies governing research involving the use of identifiable medical/dental record information.
2. I have reviewed this Honest Broker System/Process application in its entirety and I am fully aware of and in agreement with all submitted statements.
3. I will ensure that the Honest Broker System/Processes will be implemented and followed in strict accordance with this application.
4. I will request and obtain IRB and SDM HIPAA Security Officer approval for any proposed modifications to this application prior to implementing such modifications.
5. I will ensure that all individuals involved in providing the Honest Broker System/Process services are provided with a copy of this current version of this application.
6. I and/or my Honest Broker staff will not provide identifiable medical/dental record information, de-identified medical/dental record information, or Limited Data Sets of medical/dental record information to affiliate researchers until evidence of IRB approval of the corresponding research study is provided.



7. I will respond promptly to all requests for information or materials solicited by the SDM HIPAA Security Officer or the IRB.
8. I will maintain adequate documentation of all Honest Broker transactions with affiliated researchers.
9. I and/or my Honest Broker staff will, under no circumstances, provide the researchers with information that would permit de-identified (HIPAA "Safe Harbor") medical/dental record information or Limited Data Sets of medical/dental record information to be linked to patient identifiers.
10. I and/or my Honest Broker staff will not intervene or interact with patients in the conduct of Honest Broker functions.
11. I and/or my Honest Broker staff will maintain complete confidentiality of identifiable medical/dental record information in our possession during the performance of Honest Broker functions.

Signature of Individual Responsible for Honest
Broker System/Processes

Date

Honest Broker System/Process Application Approved:

SDM HIPAA Security Officer

Date

IRB Chair/Vice Chair

Date



ATTACHMENT A

A. HIPAA “Safe Harbor” De-Identification of Medical/Dental Record Information

HIPAA requires that each of the following identifiers of the individual or of relatives, employers, or household members of the individual must be removed from medical record information in order for the records to be considered de-identified (HIPAA “Safe Harbor”)

1. Names
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial 3 digits of a zip code if, according to the currently publicly available data from the Bureau of Census:
 - a. The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people; and
 - b. The initial 3 digits of a zip code for all such geographic units containing 20,000 or fewer people is changes to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers
5. FAX numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers; license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code, except a code to permit re-identification of the de-identified data by the Honest Broker.



ATTACHMENT A (continued)

B. Limited Data Sets

For Limited Data Sets, HIPAA requires that each of the following identifiers of the individual or of relatives, employers, or household members of the individual must be removed from medical/dental record information.

1. Names
2. Postal address information, other than town or city, State, and zip code
3. Telephone numbers
4. FAX numbers
5. Electronic 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 and serial numbers; license plate numbers
12. Device identifiers and serial numbers
13. Web Universal Resource Locators (URLs)
14. Internet Protocol (IP) address numbers
15. Biometric identifiers
16. Full face photographic images and any comparable images