

**UPMC
POLICY AND PROCEDURE MANUAL**

**POLICY: HS-EC1807
INDEX TITLE: Ethics & Compliance**

SUBJECT: Honest Broker Certification Process Related to the De-identification of Health Information for Research and Other Duties/Requirements of an Honest Broker

DATE: November 12, 2007

I. POLICY

It is the policy of the University of Pittsburgh Medical Center (UPMC) to comply with the Health Insurance Portability and Accountability Act (HIPAA) privacy rule pertaining to the use and disclosure of protected health information (PHI) and the de-identification of PHI for Research and any applicable related state laws that are not preempted by HIPAA. The HIPAA Privacy Regulations can be located at 45 CFR Parts 160 & 164 or at <http://aspe.hhs.gov/admnsimp/final/PvcTxt01.htm>. Terms used herein, but not otherwise defined, shall have the same meaning as those terms in 45 CFR 160.103 § 164.501.

II. PURPOSE/SCOPE

This policy describes the process to be used when using an honest broker to de-identify PHI. This policy applies to all UPMC entities and locations.

III. BACKGROUND

The Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) permits protected health information (PHI) to be used without patient authorization in a number of limited cases. One such case is where the PHI is de-identified.

PHI can either be de-identified by an honest broker which is part of the covered entity (as defined by HIPAA) or by an honest broker which is a business associate of the covered entity. An honest broker is an individual, organization or system acting for, or on behalf of, the covered entity to collect and provide health information to research investigators in such a manner whereby it would not be reasonably possible for the investigators or others to identify the corresponding patients-subjects directly or indirectly. The honest broker cannot be one of the investigators. The information provided to the investigators by the honest broker may incorporate linkage codes to permit information collation and/or subsequent inquiries (i.e., a “re-identification code”), however the information linking this re-identification code to the patient’s identity must be retained by the honest broker and subsequent inquiries are conducted through the honest broker.

Since neither the Federal Policy nor HIPAA regulations require prior written informed consent/authorization of patients for the research use of their de-identified health information, this approach would address satisfactorily the regulatory requirements associated with the conduct of retrospective research involving existing health information. This approach can also be used to identify eligible patients for subsequent recruitment into clinical trials. For example, based on defined search criteria, the honest broker would provide a de-identified listing of the health information of potential eligible subjects, to include re-identification code numbers, to the clinical trial investigators. The investigators would determine which of these patients appear to meet eligibility criteria and convey the respective re-identification code numbers back to the honest broker. The honest broker would subsequently provide the names of the identified patients to the patients' personal physicians who would contact the patients to 1) introduce the research study; 2) ascertain their interest in study participation; and 3) instruct the patients to contact directly the investigators or obtain their written authorization to share their interest in study participation with the investigators and to be contacted by the investigators. **Note that direct contact of the patients by the honest broker would constitute "cold-calling", which is prohibited by the IRB.**

HIPAA defines multiple data elements that must be removed from health information in order for the information to be recognized as de-identified. A fully/completely de-identified data set is protected health information which meets the following criteria:

1. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
 - i. Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
 - ii. Documents the methods and results of the analysis that justify such determination; or
2.
 - i. The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:
 - A. Names;
 - B. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

1. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 2. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- C. 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;
- D. Telephone numbers;
- E. Fax numbers;
- F. Electronic mail addresses;
- G. Social security numbers;
- H. Medical record numbers;
- I. Health plan beneficiary numbers;
- J. Account numbers;
- K. Certificate/license numbers;
- L. Vehicle identifiers and serial numbers, including license plate numbers;
- M. Device identifiers and serial numbers;
- N. Web Universal Resource Locators (URLs);
- O. Internet Protocol (IP) address numbers;
- P. Biometric identifiers, including finger and voice prints;
- Q. Full face photographic images and any comparable images; and
- R. Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and
- ii. The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

Alternately, HIPAA will permit, without prior patient authorization, the use and disclosure of health information (for research) in the form of a "limited data set". A limited data set may include certain indirect identifiers that are excluded in a fully/ completely de-identified data set. A limited data set is protected health information which excludes the following direct identifiers of the individual, or of relatives, employers, or household members of the individual:

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, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URLs);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints; and
16. Full face photographic images and any comparable images.

If the health information provided to the investigators is based on a limited data set, the investigators must also complete and obtain (IRB and UPMC) approval of a UPMC Data Use Agreement for Limited Data Sets. This Agreement addresses various HIPAA conditions related to subsequent uses and disclosures of limited data sets (see attached).

IV. HONEST BROKER CERTIFICATION CRITERIA

For an individual, organization or system to be an Honest Broker for the UPMC, the proposed honest broker must be certified pursuant to the following process:

1. The honest broker must be initially sponsored by investigator(s) who are in good standing with a UPMC-recognized IRB of record AND who intend to use the honest broker's services.
2. The honest broker must submit an application to become a UPMC- and IRB-certified honest broker. The honest broker certification application is available at the University of Pittsburgh IRB web site (www.irb.pitt.edu). The application is to be submitted by the investigator/researcher to the IRB (of record) staff member that is designated to receive these applications. Once the IRB (of record) has approved the honest broker application, the application will then be forwarded to the UPMC Privacy Officer for approval.
3. The UPMC Privacy Officer will evaluate the honest broker application and related documentation to determine that the honest broker has presented satisfactory evidence to meet or exceed the following UPMC certification criteria:
 - a. honest brokers must have written documentation of the processes and/or systems that they use to develop both fully de-identified health information data sets and limited data sets, for both electronic and paper-based records;

- b. honest brokers must have written documentation of policies, procedures and controls necessary for:
 - i. compliance with the HIPAA Privacy Rule, the Federal Policy regulations for human subject protections (45 CFR 46) and UPMC's Business Associate Agreement;
 - ii. security and management of all PHI in the honest broker's possession during the performance of honest broker functions;
 - iii. audits and/or quality checks related to determining the efficacy of de-identification mechanisms;
 - iv. security and management of re-identification keys; and
 - v. documentation/maintenance/retention of all work performed (for whom, what was provided, IRB approval info, etc.).
4. All honest brokers must provide UPMC with a written statement assuring that they will abide by all relevant UPMC and IRB guidelines, policies and procedures, including continuing adherence to the UPMC honest broker certification criteria section of this policy, the duties and other requirements section (see section that follows) and the terms and conditions of the UPMC Business Associate Agreement for honest brokers (if applicable).

V. DUTIES AND OTHER REQUIREMENTS OF THE HONEST BROKER

In order for a certified honest broker to work on behalf of investigators to de-identify PHI that is owned/held by UPMC, the honest broker must perform the following UPMC-defined duties and adhere to the following UPMC-defined requirements:

1. Non-UPMC honest brokers must execute a Business Associate Agreement with UPMC, the terms of which will specify the continuing confidentiality requirements, duties and other expectations UPMC has of an honest broker service. The generic UPMC Business Associate Agreement can be viewed at <http://purchasing.upmc.com>. The generic Business Associate Agreement will be customized by UPMC to reflect the specific duties and other requirements UPMC specifies for honest broker services.
2. A certified honest broker must 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). This process may be as simple as being copied on an IRB approval letter from the IRB to the investigator. Relative to IRB approval of the proposed research, the honest broker specified in the research application must have been prior certified by the IRB of record in order for the IRB to approve the research application.
3. A certified honest broker must 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.

4. 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 UPMC-held PHI, an honest broker must obtain (and retain) evidence of an appropriately executed Data Use Agreement for a Limited Data Set. [Note: 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 UPMC-required detailed disclosures (honest broker data set specifications) relative to:
 - a. where (what UPMC 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 than the principal investigator.

VI. NON-COMPLIANCE

An employee honest broker's failure to abide by this policy may result in disciplinary action pursuant to UPMC policy HS-HR0704 entitled "[Corrective Action and Discharge](#)". Other non-employee work force members may be sanctioned in accordance with applicable UPMC procedures.

An honest broker's (business associate) failure to abide by this policy may result in immediate termination of their UPMC certification to serve as an approved honest broker and immediate termination of their business associate agreement with UPMC.

Questions regarding this policy should be directed to the UPMC HIPAA Program Office.

SIGNED: Tom Nigra
Chief Compliance Officer

ORIGINAL: April 25, 2003

REVIEW MONTH: April

Policy Review Subcommittee: October 11, 2007

Executive Committee: November 12, 2007 (formerly HS-RS0002)

PRECEDE: September 8, 2006

SPONSOR: UPMC HIPAA Program Office

Attachment

SAMPLE AGREEMENT

Attachment A - Honest Broker Certification Process Related to the De-identification of Health Information for Research and Other Duties/Requirements of an Honest Broker

DATA USE AGREEMENT FOR LIMITED DATA SETS

[INVESTIGATOR - THIS TEMPLATE 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 UPMC REPRESENTATIVE FOR UPMC APPROVAL. THE HONEST BROKER MUST BE PRESENTED WITH A COPY OF THE FULLY-EXECUTED AGREEMENT (TO INCLUDE FINAL APPROVAL FROM UPMC) IN ORDER FOR THE HONEST BROKER TO ACCESS UPMC DATA FOR THE PURPOSE OF THE CORRESPONDING RESEARCH STUDY].

This Data Use Agreement for Limited Data Sets (the “Agreement”) is made this ____ day of _____, 200_ by and between UPMC/University of Pittsburgh Medical Center (“UPMC”) and _____ (“Recipient”).

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 UPMC to make available for the purposes of research, public health or health care operations a limited data set to Recipient, provided that Recipient agrees to be bound by the terms of this Agreement; and

WHEREAS, Recipient desires for UPMC 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, UPMC agrees to make available such limited data set, provided that Recipient agrees to abide by the terms and conditions of this Agreement as well as applicable UPMC 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 UPMC

The limited data set provided pursuant to this Agreement contains data acquired from *[INVESTIGATOR - SPECIFY THE UPMC 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. Recipient 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. The Recipient 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. Recipient acknowledges that such individuals have a need to access the limited data set to carry out their duties.

D. ASSURANCES

1. Recipient shall not use or further disclose the limited data set other than as permitted by this Agreement or as otherwise required by law.
2. Recipient shall use appropriate safeguards to prevent use or disclosure of the limited data set other than as permitted by this Agreement.
3. Recipient shall report to the UPMC Privacy Officer any use or disclosure of the limited data set not provided for by this Agreement of which Recipient becomes aware.
4. Recipient 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 Recipient with respect to such information.
5. Recipient 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 Recipient, UPMC, at its sole discretion, may a) terminate this Agreement upon written notice to Recipient or b) request that Recipient, to the satisfaction of UPMC, take appropriate steps to cure such breach. If Recipient fails to cure such breach to the satisfaction of UPMC or in the time prescribed by UPMC, UPMC may terminate this Agreement upon written notice to Recipient.
2. Should this Agreement be terminated for any reason, including, but not limited to Recipient's decision to cease use of the limited data set data, Recipient 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 UPMC shall be to:

UPMC Corporate Compliance Office
Attn: Data Use Agreement Management
3600 Forbes Ave-Rear Entrance
Forbes Tower, Suite 7015
Pittsburgh, PA 15213

Notice to Recipient 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.

UPMC/University of Pittsburgh Medical Center

Recipient

Name (print): _____

Name (print): _____

Title: _____

Title: _____

Signature: _____

Signature: _____

IRB Approval:

Name (print): _____ Title: _____

Signature: _____ IRB#: _____