

OKLAHOMA STATE UNIVERSITY CENTER FOR HEALTH SCIENCES

POLICY AND PROCEDURE MANUAL

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

Effective Date: April 14, 2003

I. POLICY

It is the policy of Oklahoma State University Center for Health Sciences (“OSU-CHS”) 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/admsimp/final/PvcTxt01.htm>. Terms used in this policy, but not otherwise defined, shall have the same meaning as those terms in 45 CFR § 160.103 and § 164.501.

II. 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 circumstances. One such circumstance 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 that 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/participants 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 participants, 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 participant 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 participant 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 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 approval of an OSU-CHS 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).

III. HONEST BROKER CERTIFICATION CRITERIA

For an individual, organization or system to be an Honest Broker for OSU-CHS, 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 an OSU-CHS-recognized IRB of record AND who intend to use the honest broker's services.
2. The honest broker must submit an application to become an OSU-CHS- and IRB-certified honest broker. The honest broker certification application is found at Appendix "C" and is also available at the OSU-CHS IRB web site (www.chs.okstate.edu). The application is to be submitted by the investigator/researcher to the IRB staff member that is designated to receive these applications. After the IRB has approved the honest broker application, the application will then be forwarded to the OSU-CHS Privacy Officer for approval.
3. The OSU-CHS 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 OSU-CHS 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 participant protections (45 CFR 46) and the OSU-CHS'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 OSU-CHS with a written statement assuring that they will abide by all relevant OSU-CHS and IRB guidelines, policies and procedures, including continuing adherence to the OSU-CHS 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 OSU-CHS Business Associate Agreement for honest brokers.

IV. 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 OSU-CHS, the honest broker must perform the following OSU-CHS-defined duties and adhere to the following OSU-CHS-defined requirements:

1. All certified honest brokers, both OSU-CHS and non-OSU-CHS, must execute a Business Associate Agreement with OSU-CHS, the terms of which will specify the continuing confidentiality requirements, duties and other expectations OSU-CHS has of an honest broker service. The generic OSU-CHS Business Associate Agreement can be obtained at the office of the OSU-CHS Privacy Officer. The generic Business Associate Agreement will be customized by the OSU-CHS Privacy Officer to reflect the specific duties and other requirements OSU-CHS 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. 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 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 completely de-identified data set, in order to be granted access to the OSU-CHS-held PHI, an honest broker must obtain (and retain) evidence of an appropriately executed Data Use Agreement for a Limited Data Set. The Data Use Agreement approved for use by OSU-CHS is found at Appendix "G". [Note: the IRB 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 OSU-CHS-required detailed disclosures (honest broker data set specifications) relative to:
 - a. where (what OSU-CHS facility) 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.

IV. NON-COMPLIANCE

An employee honest broker’s failure to abide by this policy may result in disciplinary action pursuant to OSU-CHS policy entitled “Sanctions for HIPAA Non-Compliance”. Other non-employee work force members may be sanctioned in accordance with applicable OSU-CHS procedures.

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

Questions regarding this policy should be directed to the OSU-CHS Privacy Officer.

SIGNED: _____

OSU-CHS Compliance Officer/OSU-CHS Privacy Officer

APPROVAL DATE: _____