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SECTION: RESEARCH

AREA: RESEARCH ADMINISTRATION

SUBJECT: HONEST BROKER CERTIFICATION FOR RESEARCH

PURPOSE

This policy describes the process to be followed when using an honest broker to de-identify protected health information (PHI).

SCOPE

UAMS Workforce

DEFINITIONS

Business Associate is a person or entity who is not a member of the UAMS Workforce, and who performs or assists in the performance of a function of activity *for or on behalf of UAMS* which involves disclosures that are regulated and permitted by HIPAA and which involve the creation, use or disclosure of Protected Health Information by the Business Associate.

Data Use Agreement is a written agreement between UAMS and the Limited Data Set recipient which establishes the permitted uses and disclosures of such information and certain administrative safeguards to protect the information. The standard UAMS Data Use Agreement is attached to the [UAMS HIPAA Research Policy \(Section 3.1.27\)](#).

De-Identified Information means information which does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. UAMS may determine that health information is de-identified if all of the following identifiers of the individual or of relatives, employers, or household members of the individual, are removed, and UAMS does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information:

- Names;
- All geographic subdivisions smaller than a state, including street address, city, county, precinct, and ZIP Code;
- 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 90 or older;
- Telephone numbers;
- Fax numbers;

- Electronic mail address;
- Social Security numbers;
- Medical Record numbers;
- Health Plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including voice and finger prints; and
- Full face photographic images and any comparable images.

Disclosure means the release, transfer, provision of access to, or divulging of information in any manner (verbally or in writing) by UAMS to persons outside of UAMS or outside the covered components of the UAMS hybrid entity.

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 conducted through the honest broker.

Limited Data Set means information that excludes the following direct identifiers of the individual and of relatives, employers, or household members of the individual:

- Names;
- Street or Postal address information (other than town, city, state and zip code);
- Telephone numbers;
- Fax numbers;
- Electronic mail address;
- Social Security numbers;
- Medical Record numbers;
- Health Plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including voice and finger prints; and
- Full face photographic images and any comparable images.

If the information is necessary for the Research, a Limited Data Set can include:

- Geographic identifiers, such as town, city, county, State, and five-digit zip code (but not street name, street address, or post office box)
- All elements of dates
- Admission dates
- Discharge dates
- Service dates
- Date of birth and date of death
- Age (including 90 or over)
- Other unique codes or identifiers not listed above as a direct identifier

Protected Health Information (PHI) means information that is part of an individual's health information that identifies the individual or there is a reasonable basis to believe the information could be used to identify the individual, including demographic information, and that (i) relates to the past, present or future physical or mental health or condition of the individual; (ii) relates to the provision of health care services to the individual; or (iii) relates to the past, present, or future payment for the provision of health care services to an individual. This includes PHI which is recorded or transmitted in any form or medium (verbally, or in writing, or electronically). PHI excludes health information maintained in educational records covered by the federal Family Educational Rights Privacy Act and health information about UAMS employees maintained by UAMS in its role as an employer.

Re-identification Code means an assigned number or other means of record re-identification that is not derived from or related to the information about the individual and is not otherwise capable of being translated to identify the individual.

Research shall mean any research or systematic investigation on living or deceased human subjects (retrospective or prospective) seeking the use of PHI, including research development, testing, and evaluation, designed to contribute to generalizable knowledge. This includes research that is consistent with what the IRB currently reviews under the Common Rule.

UAMS Workforce means for the purposes of this Policy, physicians, employees, volunteers, trainees, and other persons whose conduct, in the performance of work for UAMS, are under the control of UAMS, whether or not they are paid by UAMS.

POLICY

It is the policy of the University of Arkansas for Medical Sciences (UAMS) 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](#). Terms used herein, but not otherwise defined, shall have the same meaning as those terms in [45 CFR 160.103 § 164.501](#).

PROCEDURES

A. Honest Broker System Certification Procedure

For an individual, organization or system to serve as an honest broker for UAMS, the proposed honest broker system must be certified pursuant to the following procedure:

1. The honest broker system must be initially sponsored by investigator(s) within a department or unit who is/are in good standing (i.e., no revoked research privileges) with a UAMS-recognized Institutional Review Board (IRB) who intend to use the honest broker's services.
2. Honest broker systems 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.
3. Honest broker systems 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 [UAMS' Business Associate Policy 3.1.33](#);
 - 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. Each individual honest broker within a system must submit a written statement assuring that s/he will abide by all relevant UAMS and IRB guidelines, policies and procedures, including continuing adherence to the UAMS honest broker certification criteria section of this policy, the duties and other requirements section (see section that follows) and the terms and conditions of [UAMS' Business Associate Policy 3.1.33](#) (if applicable).
5. Personnel engaged in an honest broker system must complete the following training:
 - i. [CITI Training](#): Basic Human Subject Protection training course and Health Information Privacy & Security Course (HIPS) including HITECH
 - ii. [HIPAA Privacy and Security Training](#)
 - iii. i2b2 Training
6. Each honest broker system must submit a one-time application to receive UAMS- and IRB- certification of the system. The certification application is available at the UAMS TRI web site. The application is to be submitted by the sponsoring department or unit to

the Honest Broker Manager within the Division of Biomedical Informatics (DBMI).

7. Once the Honest Broker Manager has determined the application is complete and verified that individuals listed in the application have fulfilled eligibility and training requirements, a copy of the application will be forwarded to the IRB. The DBMI Honest Broker Office will maintain the original signed application.
8. Once the IRB office (e.g. expedited reviewer) has reviewed and approved the honest broker application, it is forwarded to the UAMS IT Security Office.
9. The UAMS IT Security Office will evaluate the application and related documentation to determine that the honest broker has presented satisfactory evidence to meet or exceed the criteria outlined in steps 2 and 3 above. Approved applications will be assigned a code that enables the IT Security Office and DBMI Honest Broker Office to track and audit the system.
10. The UAMS IT Security Office will notify the IRB and the DBMI Honest Broker Office of approved applications and certification will be provided to the applicant.
11. Honest broker systems will be audited within the first six months of operation to ensure data requests are fulfilled in compliance with UAMS policies, HIPAA, and IRB protocols. If concerns are raised during the first audit, the system will undergo a second audit. If identified issues have not been resolved by the time of the second audit, the sponsoring department or unit will be notified that certification has been revoked and that the honest broker system must cease all operations.

B. 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 UAMS, the honest broker must perform the following UAMS-defined duties and adhere to the following UAMS defined requirements:

1. Individuals serving as an honest broker must have legitimate access to the data requested by the investigator and they must be completely independent of the research team.
2. Non-UAMS honest brokers must execute a Business Associate Agreement with UAMS, the terms of which will specify the continuing confidentiality requirements, duties and other expectations UAMS has of an honest broker service. Business Associate Agreements will be customized by UAMS to reflect the specific duties and other requirements UAMS specifies for honest broker services.
3. 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 a limited data set 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 received prior certification.

4. 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.
5. The UAMS personnel providing the data extract shall record the date the extract was provided to the requesting party and shall maintain a copy of the request for a minimum of six years from the date of the request.
6. Per UAMS' [HIPAA Research Policy](#) (Section 3.1.27), if a limited data set is to be disclosed outside UAMS, a data use agreement must be entered with the recipient of the limited data set information. In such instances, the honest broker must obtain (and retain) evidence of an appropriately executed data use agreement.
7. The honest broker will provide the requested data, including re-identification codes, to the investigator. The investigator will determine which patients appear to meet eligibility criteria and convey the respective re-identification codes back to the honest broker. The honest broker will subsequently provide the names of identified patients to the patients' personal physician. The prospective subject's physician will then contact his/her patients to 1) introduce the research study; 2) ascertain their interest in study participation; and 3) instruct interested patients to contact the investigative team or obtain the patient's written authorization to share their interest with the investigative team. Note that direct contact of patients by the honest broker would constitute "cold-calling" which is prohibited by the IRB.
8. 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. The Data Use Agreement will include a list of UAMS-required disclosures (honest broker data set specifications) relative to:
 - i. where the PHI is located (i.e., what UAMS entity);
 - ii. what HIPAA-defined limited data set elements are requested for the research;
 - iii. the purpose of the limited data set request (i.e., detailed uses pertinent to the limited data set); and,
 - iv. who (names, titles, addresses) will access, use and disclose the limited data set information other than the principal investigator.
9. If an investigator requires data from two or more honest broker systems for the same project, the IRB application must indicate each honest broker system involved. This will allow independent honest broker systems to share linkage codes with one another.
10. Honest Broker Systems may add personnel by submitting the following information to the Honest Broker Office within the DBMI: a) individual's name, credentials and evidence of successful completion of required training. The Honest Broker Office will

notify the Honest Broker System of approved or denied requests to add personnel.
Personnel may not participate in any honest broker activities without prior approval.

11. The Honest Broker Office within the DBMI must be notified if an individual serving as an honest broker terminates his/her position with UAMS or their standing with the UAMS IRB is in jeopardy.

C. Non-Compliance

An employee's failure to abide by this honest broker policy or an employee's violation to HIPAA in relation to an honest broker may result in disciplinary action pursuant to UAMS policy [4.4.02 entitled "Employee Disciplinary Notice."](#) Other non-employee work force members may be sanctioned in accordance with applicable UAMS procedures.

In accordance with [UAMS' Business Associate Policy \(section 3.1.22\)](#), an honest broker's failure to abide by this policy may result in immediate termination of their UAMS certification to serve as an approved honest broker and immediate termination of their business associate agreement with UAMS.

Questions regarding the certification process should be directed to the DBMI Honest Broker Office.

REFERENCES

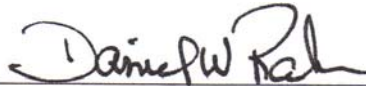
HIPAA Privacy Regulations, [45 CFR Parts 160 & 164](#)

UAMS Administrative Guide, Section 3.1.27: [HIPAA Research Policy](#)

UAMS Administrative Guide, Section 3.1.31: [De-Identification of Protected health Information and Limited Data Set Information](#)

UAMS Administrative Guide, Section 3.1.33: [Business Associate Policy](#)

UAMS Administrative Guide, Section 4.4.02: [Employee Disciplinary Notice](#)

Signature:  _____

Date: February 8, 2012