



POLICY AND PROCEDURE NO. 32

Effective: October 29, 2014

Honest Broker Program

I. POLICY

It is the policy of Tallahassee Memorial HealthCare (TMH) (which includes Tallahassee Memorial Hospital and all TMH entities and locations) to comply with the Health Insurance Portability and Accountability Act (HIPAA); HHS and FDA Protection of Human Subjects Regulations; and related federal or state laws that are not preempted by HIPAA as they pertain to the use and disclosure of protected health information (PHI) and Research. Terms used herein, but not otherwise defined, shall have the same meaning as those terms in the references (*Section XI*) of this policy.

II. PURPOSE / SCOPE

This policy describes the TMH Honest Broker Program and the process used when an Honest Broker is required to abstract research variables requested by a TMH IRB approved study research investigator. The program assures that all data identified or disclosed to include PHI is in accordance with applicable regulations and the research protocol approved by the TMH IRB.

III. BACKGROUND

Protected health information (PHI) may be used and disclosed for research with the patient's written permission in the form of a HIPAA compliant authorization. PHI may be used and disclosed for research without an authorization in limited circumstances. These are: 1) Under a Waiver of the Authorization; 2) As Limited Data Set with a Data Use Agreement; 3) Preparatory to research; and, 4) For research on decedents' information.

IV. DE-IDENTIFICATION or Data Coding

De-identified health information, as described in the Privacy Rule, is not PHI, and therefore is not protected by the Privacy Rule. Health information may be used or disclosed without patient authorization when the information or data are de-identified in accordance with the Privacy Rule. Health information or data may be de-identified by an Honest Broker, who is employed by TMH (a covered entity) or by an Honest Broker who contracted by TMH (a business associate). An Honest Broker is an individual, organization or system acting for, or on behalf of, TMH to collect and provide health information to research investigators in such a manner whereby it would not be reasonably possible for the Honest Broker, investigator or others to identify the corresponding patient's subjects directly or indirectly. The Honest Broker cannot be one of the investigators or part of the research team except when the research is being done by TMH and all

members of the research team are employed by TMH. The role of an individual research study coordinator may further be defined by the Research Council on a case by case basis. Because prior written Authorization from individual patients for the use of de-identified health information for research purposes is not required, this approach would address the regulatory requirements associated with the conduct of retrospective research of existing health information which does not require or contain HIPAA defined identifiers.

The information provided to the investigator(s) by the Honest Broker may be coded using linkage codes to permit the Honest Broker to re-identify the record so that information collation or subsequent inquiries may be made, or to identify patients who meet the research inclusion criteria so that their physician may be notified to determine if they want to participate in the study. This re-identification code linking to the patient's identity must be retained by the Honest Broker and all subsequent inquiries must be conducted through the Honest Broker. Requirements must be met regarding the "codes" that are used. The code cannot be one of the removed identifiers or a derivation of an identifier, such as the initials of the patient's name.

The linkage codes and re-identification process may also be used to identify eligible patients for subsequent recruitment into clinical trials. For example, based on defined variables (inclusion criteria) the researcher would provide to the Honest Broker the codes for records of patients who appear to meet eligibility criteria for the study. The Honest Broker would subsequently provide the names of the identified patients to the patients' primary care physician who would contact the patient to 1) introduce the research study; 2) ascertain their interest in study participation; and 3) instruct the patients to contact the investigators or obtain their written authorization to share their interest in study participation with the investigators. **Note that direct contact with a patient by the Honest Broker is prohibited by the TMH.**

HIPAA specifies the multiple data elements that must be removed from health information in order for the information to no longer be recognized as PHI and to be de-identified. This is the "safe harbor" approach. Fully and completely de-identified data under this approach must meet the following criteria:

- A. The following PHI identifiers that apply to the individual/patient or to relatives, employers, or household members of the individual/patient must be removed:
 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 three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
 - a. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 - b. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people are changed 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, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code; and 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.

B. 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.

C. This process for de-identifying PHI must be followed prior to giving any data to the primary investigator.

Another means to de-identify health information or data is the “statistical” approach (45 CFR sections 164.502 and 164.514).

V. **LIMITED DATA SET**

A. HIPAA will permit, without prior patient authorization, the use and disclosure of health information (for research) in the form of a “Limited Data Set.” Use of Limited Data set must be approved by the TMH IRB. See IRB Guidelines for more information. A Limited Data Set is PHI which excludes all the previously listed direct identifiers of the individual, or of the relatives, employers or household members of the individual except for:

1. Town or city, State and zip code; and
2. 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.

- B. It is important to note that this information is still individual protected health information (PHI) under HIPAA. It is not de-identified information and is still subject to HIPAA regulations. When a Limited Data Set is used, there must be an accompanying Data Use Agreement as defined by HIPAA and TMH Policy. See TMH Privacy P&P 26 De-Identification of PHI and 26A Limited Data Sets.

VI. WAIVER OF AUTHORIZATION or ALTERATION OF AUTHORIZATION

TMH (a covered entity) may use or disclose PHI for research based on a Waiver of Authorization or an Alteration of Authorization.

- A. The Waiver of Authorization or Alteration of Authorization must be approved by the TMH IRB. See IRB Guidelines for more information. TMH (Research Council) must receive documentation of this approval from the TMH IRB which must contain the following:
 - 1. The date on which the waiver or alteration was approved
 - 2. A statement that the IRB has determined that all specified criteria for a waiver or alteration were met (See TMH Privacy P&P 30 Uses and Disclosures of PHI for Research Activities)
 - 3. A brief description of the PHI (IRB Form 4c) for which use or access has been determined by the IRB to be necessary in connection with the specific research activity
 - 4. A statement that the waiver or alteration was reviewed and approved under either normal or expedited review procedures (see IRB Approval Proceedings)
 - 5. The required signature of the IRB chair or the chair's designee
- B. As noted, the IRB's documentation of its approval must describe the PHI for which use or access has been determined to be necessary for the research. This would include stating, for example, that the waiver was limited to only certain information in a patient's medical record, instead of the entire record. Whenever a TMH IRB approved *Waiver of Authorization or Alteration of Waiver* is used, all information and PHI must be acquired through the TMH Honest Broker program. TMH must retain the IRB's approval documentation for at least 6 years from the date the Waiver or Alteration was obtained, or the date when it was last in effect, whichever is later.

VII. TMH IRB FORM 4c-HEALTH INSURANCE PORTABILITY & ACCOUNTABILITY ACT (HIPAA) COMPLIANCE

- A. Whenever the TMH IRB Form 4c indicates that an Authorization to use or disclose PHI will be obtained, and
- B. The research protocol Informed Consent/HIPAA Authorization allows use and disclosure of all the patient's medical record and health information without limitation, then an Honest Broker will not be required. The Honest Broker must provide all the requested data for research studies to the TMH Administrative Liaison who will complete a Data Pull Exit Survey to include auditing of Honest Broker system access and confirmation of data pulled. Upon completion of the Data Pull Exit Survey, the TMH Administrative Liaison will provide

the data to the investigator. All data transactions must be through the TMH Administrative Liaison.

VIII. HONEST BROKER SELECTION PROCESS

The TMH Administrative Liaison will assure that there is approval of the TMH Research Council prior to the assignment of the Honest Broker to a study and initiation of any data collection.

For an individual to be an Honest Broker at TMH, the individual must meet the following criteria:

- A. The applicant must be a TMH employee or credentialed associate and not a part of the study or research team.
- B. The individual must be proficient in the use of the TMH's medical record systems.
- C. Upon the TMH Administrative Liaison certifying the Honest Broker's proficiency, the Honest Broker must complete the Honest Broker Study Agreement (HBSA) (*attachment 1*).
- D. For each study, a Honest Broker Request Form (*attachment 2*) must be completed by the Principle Investigator and TMH Honest Broker. The HBSA is available on the TMH IRB website and should be submitted to the TMH Administrative Liaison who will approve the HBSA and supervise the activity of data abstraction.
- E. The Honest Broker applicant must complete the identified readings (HIPAA and related TMH Privacy and Security policies), education and test, prior to the TMH Administrative Liaison requesting credentials for system access.
- F. All Honest Brokers must provide a written statement assuring that they will abide by all relevant federal regulations and TMH HIPAA Privacy and Security policies and procedures.
- G. Any and all payments made to the TMH Honest Broker Program will be made directly to TMH and submitted to the TMH Administrative Liaison.

IX. NON-COMPLIANCE

A TMH employed Honest Broker's failure to abide by this policy may result in disciplinary action pursuant to TMH Human Resource Policy, 45-301(f/k/a E-2) *Colleague Counseling and Corrective Action*.

A researcher's or research team member's failure to abide by this policy may result in sanctions being imposed by TMH and/or appropriate action by the TMH IRB

The TMH Administrative Liaison and TMH Research Council are responsible for oversight of the TMH Honest Broker Program. Questions regarding this policy should be directed to the TMH Administrative Liaison at (850) 431-2132.

X. RESPONSIBILITIES

The TMH Research Council working with the TMH Administrative Liaison is responsible for implementation and oversight of the Honest Broker Program and this Policy and Procedure.

XI. REFERENCES

- Health Insurance Portability and Accountability Act (HIPAA) 45 CFR Parts 160;162; and 164
- American Recovery and Reinvestment Act of 2009 (ARRA) and HITECH Act
- For guidance on the HIPAA Privacy Rule, see the HHS Office for Civil Rights (OCR) Web site at <http://www.hhs.gov/ocr/hipaa>. For guidance on the interpretation of HHS or FDA Protection of Human Subjects Regulations at 45 CFR part 46 or 21 CFR parts 50 and 56, respectively, visit the Office for Human Research Protections (OHRP) Web site at <http://ohrp.osophs.dhs.gov> or the FDA Web site at <http://www.fda.gov/oc/gcp/>, respectively.
- TMH IRB Guidelines at www.tmh.org/IRB
- TMH HIPAA Privacy Policies Procedures at www.tmh.org/policies/HIPAA
- TMH HIPAA Security Policies Procedures at www.tmh.org/policies/HIPAA

(Attachments can be found on TMH Intranet FORMS/HIPAA Forms or the IRB Website)

Signature on file in Administration/Compliance Office

Andrea Eklund
Privacy Officer

10/29/14

DATE

Policy and Procedure Review and Revision History:

Effective: October 10/29/14

Honest Broker Study Agreement (HBSA)

Name:

Employee/Affiliate Number:

Telephone Number:

1. I am cognizant of and will comply with HIPAA regulations and TMH Privacy and Security policies governing research involving the use of identifiable medical record information.
2. I will ensure that the Honest Broker processes will be implemented and followed in strict accordance with defined policies and procedures.
3. I will request and obtain the approval of the TMH Administrative Liaison for any proposed modifications to this application prior to implementing such modifications.
4. I will only access the requested variables in the patient’s record.
5. I will respond promptly to all requests for information or materials solicited by the TMH Administrative Liaison.
6. I will maintain complete confidentiality and protection of identifiable medical record information during the performance of Honest Broker functions and beyond.
7. I will maintain adequate documentation of all Honest Broker transactions for a period of six years. After six years, the data will be destroyed according to TMH policy.
8. I, under no circumstances, provide the researchers with information that would permit de-identified medical record information or Limited Data Sets of medical record information to be linked to patient identifier
9. I will not provide identifiable medical record information, de-identified medical record information, or Limited Data Sets of medical record information to researchers; this information will only be provided to the TMH Administrative Liaison.
10. I will not intervene or interact with patients in the conduct of Honest Broker functions.
11. I will not allow any member of the research team to access the medical record.

By signing the HBSA I agree to the above terms.

Signature of Honest Broker Applicant

Date

TMH Honest Broker System/Process Application Approval:

TMH Administrative Liaison

Date

Tallahassee Memorial HealthCare

Honest Broker Request

To Review Health Information for Research Purposes

Select all applicable entries where the information is stored:

Tallahassee Memorial Hospital (list site: _____)

Tallahassee Memorial Physician Partners (list site _____)

SECTION I: Requester Information (To be completed by Principal Investigator)

Investigator Name:	Phone or Pager	Fax #:
Email:	Mailing Address:	
Honest Broker Name:	Phone or Pager	Fax #:
Email:	Mailing Address:	

SECTION II: Information Being Reviewed/Accessed/ Collected (To be completed by Principal Investigator)

Title of Protocol: _____

What type of record/chart/database will be accessed for research (check all that apply)?

<input type="checkbox"/> Medical Record/ Chart Review (paper	<input type="checkbox"/> Drug and Alcohol Treatment Records
<input type="checkbox"/> Computer/ Database (electronic record) (spe. _____)	<input type="checkbox"/> HIV Test Results
<input type="checkbox"/> Hospital Administrative/ Billing Records	<input type="checkbox"/> Mental Health Records
<input type="checkbox"/> Quality Improvement Records	<input type="checkbox"/> Psychotherapy Notes
<input type="checkbox"/> Lab and/or Pathology Reports	<input type="checkbox"/> Data previously collected for research purposes
<input type="checkbox"/> Films/ X-rays	<input type="checkbox"/> Other types of records/ schedules

(specify: _____)

Please check any of the following identifiers that will be reviewed/ accessed/ collected by Honest Broker for research:

View	Collec		View	Collec	
<input type="checkbox"/>	<input type="checkbox"/>	Name (including initials)	<input type="checkbox"/>	<input type="checkbox"/>	Patient Health Record Number
<input type="checkbox"/>	<input type="checkbox"/>	Age 90 and over	<input type="checkbox"/>	<input type="checkbox"/>	Health Plan Beneficiary Number
<input type="checkbox"/>	<input type="checkbox"/>	Street Address	<input type="checkbox"/>	<input type="checkbox"/>	Account Number (FIN)
<input type="checkbox"/>	<input type="checkbox"/>	City or State*	<input type="checkbox"/>	<input type="checkbox"/>	Fax Number
<input type="checkbox"/>	<input type="checkbox"/>	Zip Code*	<input type="checkbox"/>	<input type="checkbox"/>	Email Address
<input type="checkbox"/>	<input type="checkbox"/>	Geocode*	<input type="checkbox"/>	<input type="checkbox"/>	Certificate/ License Number
<input type="checkbox"/>	<input type="checkbox"/>	Date of Birth*	<input type="checkbox"/>	<input type="checkbox"/>	Vehicle Identification Number (VIN)
<input type="checkbox"/>	<input type="checkbox"/>	Admission/Discharge Date	<input type="checkbox"/>	<input type="checkbox"/>	Device Identifiers and Serial Numbers
<input type="checkbox"/>	<input type="checkbox"/>	Dates of Service*	<input type="checkbox"/>	<input type="checkbox"/>	Web Universal Resource Locator (URL)
<input type="checkbox"/>	<input type="checkbox"/>	Date of Death*	<input type="checkbox"/>	<input type="checkbox"/>	Internet Protocol (IP) Address Number
<input type="checkbox"/>	<input type="checkbox"/>	Telephone Numbers	<input type="checkbox"/>	<input type="checkbox"/>	Biometric Identifiers, Including Voice and Fingerprint
<input type="checkbox"/>	<input type="checkbox"/>	Social Security Number	<input type="checkbox"/>	<input type="checkbox"/>	Full Face Photographic Images/ Comparable Images

NOTE: PROTECTED HEALTH INFORMATION (PHI)—health information that is directly associated with the identity of the individual through the use of the above identifiers—cannot be disclosed to the investigator by the Honest Broker.

SECTION III: Complete for Access to Protected Health Information of Decedents

Will you be accessing protected health information of decedents? Yes / No

If you indicated YES in this Section III, by signing Section V, you are representing and warranting the following to TMH.

I hereby represent that I am reviewing health information only for the limited purpose of research on decedents' health information, and that review of such health information is necessary for the research the investigator is conducting. At the request of TMH I will promptly provide TMH with documentation of the death of the individual whose health information I will review.

SECTION IV: Protocol Objective and Rationale

A. Provide the objective of this study: _____

B. Provide the rationale for this request: _____

SECTION V: Health Information to be Maintained by Honest Broker

A. List all health information (e.g., diagnoses, procedures, and other data, including age) that will be needed to meet the goals of research: _____

B. Federal regulation requires that only the minimum necessary data be obtained in order to achieve the goals of the research. Please indicate why the data you are obtaining is necessary to achieve the goals of the investigator's research: _____

C. The proposed use of this health information presents no more than minimal risk to the privacy of individuals because the health information will be stored _____

A locked file cabinet in the Honest Broker's office and only the Honest Broker will have access to the cabinet;

On a secured computer or computer file to which access is restricted to the Honest Broker only;

Other (describe): _____

D. How long will the health information be maintained by the Honest Broker? _____

E. Describe your plan for the Honest Broker to destroy subject identification at the earliest opportunity (for example, shredding the PHI after the study has been complete) _____

SECTION VI: Assurance of Compliance (Investigator)

Thereby assure that the de-identified information obtained will only be used for the purposes of this research study. In accordance with Federal regulations [45 CFR 46] and Florida Statute (when applicable), I hereby assure that all information being collected will not be released to a person not connected with the study and that the final product of the de-identification will not reveal information that may serve to identify the subject.

By signing this agreement, I agree that the Honest Broker, under no circumstances, re-identify the protected health information, provide a key to the code, or reveal the identity of a subject. I understand that I am associated with a medical environment that sets high ethical standards of conduct and that I have responsibility to uphold the agreement as set forth in this document. I further agree to comply with the Honest Broker policy set forth in the TMH HIPAA policies and procedures.

Signature of Principal Investigator _____ Print Name _____ Date _____

SECTION VII Assurance of Compliance (Honest Broker)

I have completed Honest Broker certification and training and am certified as an Honest Broker of TMH.

I hereby assure that the information obtained will be used only for the purposes of this research study. In accordance with Federal regulations [45 CFR 46] and Florida Statute (when applicable), I hereby assure that all information being collected will be de-identified prior to release to the investigator or persons name in Section I of this form. The final product of the de-identification will not reveal information that may serve to identify the subject. I understand that I am associated with a medical environment that sets high ethical standards of conduct and that I have a responsibility to protect and uphold the confidentiality of PHI. I understand that I should not read PHI except as required for the purposes of the aforementioned research study. I will not discuss the PHI with anyone as a matter of conversation.

Signature of Honest Broker

Print Name

Date

NOTE: The TMH Administrative Liaison requires original signatures. Notification of approval to begin pulling data will not be sent to the Honest Broker until the TMH Administrative Liaison has received these original signatures on this