Policy for University of Mississippi Medical Center

Honest Broker Process Related to the Distribution of Health Information for Research Purposes and Other Duties/Responsibilities of an Honest Broker

Policy

It is the policy of the University of Mississippi Medical Center (UMMC) to maintain the privacy, confidentiality and security of patient information, including personally identifiable information and Protected Health Information (PHI) used and disclosed in accordance with the provisions of the Health Insurance Portability and Accountability Act (HIPAA).

Purpose

This policy describes the process for the Honest Broker to provide de-identified data sets and data sets that contain PHI within the UMMC Enterprise Data Warehouse and Data Marts to approved requestors.

Scope

UMMC employees, potential research collaborators, and external data requestors participating in research.

Definitions

**Business Associate** is a person or entity who is not a UMMC employee, and who performs or assists in the performance of a function or activity for or on behalf of UMMC 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 UMMC and a data set recipient which establishes the permitted uses and disclosures of such information and certain administrative, physical and technical safeguards to protect the information.

**Data Marts** are subsets of the Enterprise Data Warehouse gathered from outside sources.

**Data Security Plan** is a plan described in the Data Use Agreement, including where the requestor will store the data, who will have access to the data, and how the data will be protected physically and electronically.

**De-Identified Information** is de-identified using the safe-harbor method. The “Safe-Harbor” method or Expert Determination Method, as defined by the Department of Health and Human Services (DHHS), require that each of the below identifiers be removed from the dataset and there is no reasonable basis to believe that the information can be used to identify an individual. UMMC 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 UMMC 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.
• Any other unique identifying number, characteristic, or code, except a code to permit re-identification of the de-identified data by the Honest Broker.

Disclosure is the release, transfer, provision of access to, or divulging of information in any manner by UMMC to persons outside of UMMC.

External Data Requestor is a person or entity who is not a UMMC employee, and submits a request to the External Requests Review Committee for UMMC data.

External Request Review Committee (ERRC) is a committee who will review the impact and appropriateness of all requests from external requestors to use UMMC data, samples, intellectual property, constituents and/or other work products of UMMC.

Federated Database Structure is a collection of multiple databases that are autonomous yet participate in a federation to allow partial and controlled sharing of their data.

Honest Broker is an individual, organization or system acting as neutral intermediary for, or on behalf of, the covered entity to collect and provide health information to approved requestors in such a manner whereby it would not be reasonably possible for the approved requestors or others to identify the corresponding participants directly or indirectly. The Honest Broker must be either independent of the research team or identified as the Honest Broker for the research study. The dataset provided to the approved requestors by the Honest Broker will incorporate an assigned participant code that will permit information collation and/or subsequent inquiries (i.e., a “re-identification code”).

Internal Data Set Linking is the process of creating a cohort across multiple disparate datasets prior to de-identification.
Internal Epic Clinical Data Warehouse Code is a randomly generated number by the Epic software that uniquely identifies a patient in Epic. This code is not available in the Epic application.

Institutional Review Board (IRB) is a federally mandated committee composed of scientists, clinicians, non-scientists and non-affiliated community representatives charged with overseeing all research projects involving human volunteers to protect the rights and welfare of the volunteers, certifying that the research is conducted according to the highest scientific and ethical standards.

Limited Data Set is a dataset 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.

Modified Limited Data Sets may include the following if the information is necessary for the research and approved via IRB and Director of Information Security and/or the Privacy Officer or their designee:
- 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

Preparatory for Research is a provision under the Privacy Rule that permits covered entities to use or disclose PHI to a researcher without an individual’s authorization, a waiver or an alteration of authorization, or a data use agreement. However, the covered entity must obtain from a researcher representations that (1) the use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research, (2) the PHI will not be removed from the covered entity in the course of review, and (3) the PHI for which use or access is necessary for the research.

Protected Health Information (PHI) 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 UMMC employees maintained by UMMC in its role as an employer.

**Re-identification Code** is 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. The internal Epic clinical data warehouse code will be used for all re-identification codes involving the Epic clinical data warehouse as a data source. The information linking the identification code to identifiers will be retained by the Honest Broker in order for the Honest Broker to perform subsequent linkages or queries.

**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.

**Enterprise Data Warehouse and Data Marts** are the structured data repositories comprised of multiple federated databases that house institutional data and data from external collaborative organizations.

**UMMC Faculty Sponsor** is a UMMC faculty member who agrees to advise or collaborate on a research study with a potential research collaborator or external data requestor.

**Data Access Procedure**

This Procedure is overseen by the Enterprise Data Warehouse (EDW) Governance Committee. This Committee is comprised of the Associate Vice Chancellor for Research, Chief Health Information Officer, and members from the Office of Integrity and Compliance, Office of Information Security, Human Research Office/IRB, Office of Research, Research Informatics and the Center of Biostatistics and Bioinformatics.

Datasets will be requested through the Honest Broker by completing a University of Mississippi Medical Center electronic data request form. Proper approvals and authorizations must be provided before data will be released to the data requestor. If the data requested contains PHI, the Chief Health Information Officer will review the request.

As our Enterprise Data Warehouse (EDW) has a federated structure, it allows for the amalgamation of data from a number of potential sources including registries, biorepositories, electronic health records, and a variety of other medical information sources and databases. All transfers of data from any of these base sources into the central database will be required to follow the explicit rules and restrictions defined in the contractual relationship between the owner of the database and the University of Mississippi Medical Center. These data transfer regulations will include, but not limited to, those required by HIPAA, OHRP, Institutional Notice of Privacy Practices and any other relevant federal or state regulations and laws. Compliance with these requirements will be overseen by the Honest Broker and EDW Governance Committee and in consultation with the UMMC IRB and Office of Integrity and Compliance.
Honest Broker Responsibilities

- Confirmation of IRB approval, if applicable - The Honest Broker must ensure IRB approval for the research study for which Honest Broker services are requested.
- Adherence to IRB – The Honest Broker must adhere to the policies and procedures specified by the IRB for any research study for which the honest broker will perform services.
- De-identification – The Honest Broker must adhere to the requirements of the Safe-Harbor method or Expert Determination Method, as defined by DHHS, for any research study which the Honest Broker will perform de-identification services.
- Maintenance of disclosures – The Honest Broker providing the data extract shall record the date the extract was provided to the requesting party and shall maintain a copy of the information provided for a minimum of six (6) years from the date of the disclosure.
- Access to requested data – The Honest Broker must have access to the data requested by the requestor.
- Confirmation of Required Authorizations - The Honest Broker must ensure that all required authorizations are obtained for requested data sets. Listed below are the required authorizations:
  - Preparatory for Research
    - Data Use Agreement
    - Representation that (1) the use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research, (2) the PHI will not be removed from the covered entity in the course of review, and (3) the PHI for which use or access is requested is necessary for the research.
  - Decedents (Research Requests)
    - Data Use Agreement
    - Representation that (1) the use and disclosure is sought solely for research on the PHI of the decedents, (2) the PHI for which use or disclosure is sought is necessary for the research purposes, and (3) documentation, at the request of the covered entity, of the death of the individuals whose PHI is sought by the researchers.
  - Limited Dataset
    - Data Use Agreement
    - HIPAA Authorization Waiver/IRB Approval
  - IRB Approved Research
    - Data Use Agreement
- Ensure proper de-identification - The Honest Broker will produce the requested dataset (either Limited Data Set or De-identified (Safe Harbor) Data Set) from the PHI as documented by the requestor and approved by the IRB.
- Creation and validation of datasets – The Honest Broker will be responsible for the creation and validation of internal dataset linking.
- Maintain documentation - The Honest Broker will maintain documentation of the processes and/or systems used to develop de-identified and/or limited datasets from PHI.
- Accounting of Disclosure – The Honest Broker will track the released participants in REDCap.
**Honest Broker Requirements**

The Honest Brokerage process will reside within the Research Informatics structure under the supervision of the Chief Health Information Officer or his/her delegate.

Requirements for the Honest Broker include:

- The Honest Broker must be either completely independent of the research team or identified as the Honest Broker for the research study.
- The 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 including the security plan.
- The Honest Broker must exhibit knowledge of UMMC’s HIPAA Privacy and Security policies including but not limited to the following:
  - Accesses, Uses and Disclosures of PHI
  - Accounting of Disclosures of PHI
  - Disclosure of De-identified PHI
  - Minimum Necessary Uses and Disclosures of PHI
  - Policy on HIPAA Compliant Research
  - Information Policy
- Personnel engaged in an Honest Broker system must complete the following training:
  - CITI Human Subject Research
  - CITI Responsible Conduct of Research
  - CITI Information Privacy and Security
  - HIPAA Privacy and Security Training
  - Safe Harbor Method Education
  - Expert Determination Method Education

The Human Research Office, the Office of Information Security and the Office of Integrity and Compliance must be notified if an individual serving as an honest broker terminates his/her position.

**Audits**

The Office of Integrity and Compliance and the Office of Information Security will conduct audits to ensure that all of the honest broker requirements/duties are met and the conditions of the IRB approval and the data security plan are followed.

**REFERENCES**

HIPAA Privacy Regulations, 45 CFR Parts 160 and 164
UMMC Privacy and Security Policies
DHHS Health Information Privacy Guidance