1. POLICY

It is the policy of Maine Medical Center (MMC) 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.

Specific Policies

1.1. Purpose

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

1.2. Background

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

1.2.2. 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.

1.2.3. 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.
1.3. Honest Broker Training and Certification Criteria

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

1.3.1. All honest brokers will be required to receive a training session with the HRPP staff and will be required to complete the following CITI Modules:

- CITI Responsible Conduct of Research (only the following modules required from the RCR course)
  - Introduction to the Responsible Conduct of Research
  - Research Misconduct
  - Data Management
  - Authorship
  - Peer Review
  - Mentorship
  - Conflicts of Interest
  - Collaborative Research

- CITI Health Information Privacy and Security (HIPS) for Clinical Investigators (only required for individuals who are not employed by MaineHealth, Maine Medical Center, or Maine Medical Partners).

- CITI Good Clinical Practice (GCP).

1.3.2. The honest broker must be initially sponsored by investigator(s) who are in good standing with a MMC-recognized IRB of record AND who intend to use the honest broker’s services.

1.3.3. The honest broker/service must submit an application to become an MMC-and IRB-certified honest broker. The application is to be submitted by the investigator/researcher to the IRB. The MMC IRB 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 MMC certification criteria:

1.3.3.1. 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;

1.3.3.2. honest brokers must have written documentation of policies, procedures and controls necessary for:

- compliance with the HIPAA Privacy Rule, the Federal Policy regulations for human subject protections (45 CFR 46) and MMC’s Business Associate Agreement (if applicable);
- security and management of all PHI in the honest broker’s possession during the performance of honest broker functions;
- audits and/or quality checks related to determining the efficacy of de-identification mechanisms;
- security and management of re-identification keys; and
- documentation/maintenance/retention of all work performed (for whom, what was provided, IRB approval info, etc.).

1.3.4. All honest brokers must provide MMC with a written statement assuring that they will abide by all relevant MMC and IRB guidelines, policies and procedures, including continuing adherence to the MMC 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 MMC Business Associate Agreement (if applicable) for honest brokers.

1.4. Duties and Other Requirements of the Honest Broker

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

- All non-MMC certified honest brokers must execute a Business Associate Agreement with MMC, the terms of which will specify the continuing confidentiality requirements, duties and other expectations MMC has of an honest broker service.

- A certified honest broker must ensure that approval of the IRB 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.

- 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.

1.5. Honest Broker Data Requests

1.5.1. If applicable, requests for de-identified data must be documented by filing an Honest Broker Data Request Form with the IRB.

1.5.2. Elements to be recorded for each request include the following information from the investigator initiating the research:
- Name of individual honest broker, whether working alone or as part of an organization or team;
- The purpose of the research;
- The data source(s) to be used;
- The fields required to retrieve the data;
- The method of output for the data;
- Any special conditions, terms or instruction from the IRB;
- Billing information, if applicable

1.6. Non-Compliance

1.6.1. An employee honest broker’s failure to abide by this policy may result in disciplinary action. Other non-employee work force members may be sanctioned in accordance with applicable MMC procedures.

1.6.2. A business associate honest broker’s failure to abide by this policy may result in immediate termination of their MMC certification to serve as an approved honest broker and immediate termination of their business associate agreement with MMC.

1.6.3. Questions regarding this policy should be directed to the MMC Research Compliance Office.

2. APPLICABLE REGULATIONS AND GUIDELINES

- Federal Regulation 45 CFR Parts 160 & 164
- MMC Institutional Policy Uses and Disclosures of Protected Health Information for Research Purposes
- MMC Institutional Policy Uses and Disclosures of De-Identified Health Information and Limited Data Sets

3. OTHER APPLICABLE SOPs

This SOP affects SOP PP 901.

4. ATTACHMENTS

- PP 902-A Honest Broker System Application and Certification Form
- PP 902-B Honest Broker Business Associate Agreement for Honest Brokers
- PP 902-C Honest Broker Agreement and Attestation
- PP 902-D Honest Broker Data Request Form
- PP 902-E Honest Broker FAQs