

## LANKENAU INSTITUTE FOR MEDICAL RESEARCH

Riddle Memorial Hospital

Bryn Mawr Rehabilitation

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Working Together to Serve the Community

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**ADMINISTRATIVE POLICY AND PROCEDURE MANUAL**  
**MAIN LINE HOSPITALS INSTITUTIONAL REVIEW BOARD**

Part 1

Policy No. XXIX

**Subject: HIPAA-Use of Protected Health Information (PHI) for Research**

**Policy Purpose**

The purpose of this policy is to establish guidelines for the use of Protected Health Information (PHI) and describe under what circumstances *PHI* belonging to Main Line Health, Main Line Hospitals, or other Main Line Health affiliated entity may be used for research<sup>1</sup> purposes.

**Statement of Policy**

Protected health information belonging to Main Line Health, Main Line Hospitals, or other MLH Affiliate<sup>2</sup> may not be used internally or disclosed to any persons or organizations outside MLH for research purposes without prior approval by the Main Line Hospitals Institutional Review Board (MLH IRB) acting as the Privacy Board for research in accordance with this policy.

**I. Definitions**

1. *Health Information (HI)*<sup>3</sup> means any information, including genetic information, whether oral or recorded in any form or medium that is created or received by a health care provider, health plan, public health authority, health care clearinghouse and relates to the past present, or future physical or mental health condition of an individual, the provision of health care to an individual or the payment for provision of health care to an individual.
2. *Individually Identifiable Health Information*<sup>3</sup> is a subset of HI, including demographic information collected from an individual and is created or received by a health care provider, health plan or health care clearinghouse that identifies the individual or for which there is a reasonable basis to believe the information can be used to identify the individual.
3. *Protected Health Information (PHI)*<sup>3</sup> means individually identifiable health information.

**II. Access to PHI for Research**<sup>4</sup>

The use and disclosure of *PHI* for research purposes may be authorized under the following limited circumstances<sup>5</sup>:

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<sup>1</sup> For the purposes of this policy, *research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (Refer to 45 CFR 164.501).

<sup>2</sup> MLH Affiliate is defined to be an entity of which Main Line Health, Inc. (or a Main Line Health subsidiary) is the parent organization.

<sup>3</sup> Complete definitions available at 45 CFR 160.103.

<sup>4</sup> Under the HIPAA rule, Business Associates Agreements are generally not required to share PHI with a researcher but may be employed as required by other MLH Policy.

<sup>5</sup> Special rules apply to the use and/or disclosure of psychotherapy notes for research purposes. (Refer to section III. Procedures).

1. Preparatory to Research
2. Limited Data Sets with a Data Use Agreement
3. Subject Authorization for Research
4. Use/Disclosure with an Approved Waiver of Authorization
5. Research on Protected Health Information of Decedents
6. Accounting of Disclosures of PHI for Research

### **III. Procedures**<sup>6</sup>

All requests for *PHI* for research purposes must be made and reviewed in accordance with the procedures explained below.<sup>7</sup>

#### **1. Reviews Preparatory to Research**

The MLH IRB may allow the use and disclosure of *PHI* (*except* psychotherapy notes) to develop a research protocol or for similar purposes preparatory to research. Researchers should be aware that this exception does not permit the continued use or disclosure of the *PHI* once the researcher has determined to go forward with the study.

The MLH IRB may approve the use of *PHI* preparatory to research when the researcher certifies<sup>8</sup> to the following:

1. Use or disclosure is sought solely to review *PHI* as necessary to prepare a research protocol or for similar purposes preparatory to research;
2. No *PHI* may be removed from Main Line Health, Main Line Hospitals, or other MLH Affiliate by the researcher in the course of the review; and
3. The *PHI* sought is necessary for the research purpose.

During the preparatory review, those granted access may only record *HI* in a form that is “de-identified.” Researchers may not take any other notes or take away any *PHI* from the location where information is stored. [Appendix A](#) describes the information that must be removed to constitute de-identified *HI*.

Limited information is available to researchers without MLH IRB approval. Statistical information such as the number and type of procedures performed, the number of patients assigned a particular diagnosis code and other data of a similar nature can be requested by a researcher as part of the work preparatory to developing a research proposal. To access such data, the researcher must submit a request to Information Services.

#### **2. Limited Data Sets with a Data Use Agreement**

MLH IRB may allow Main Line Health, Main Line Hospitals, or other Main Line Health affiliated entity to use or disclose *PHI* contained in a “limited data set” for research purposes when use or disclosure is conducted as part of an IRB approved protocol as required. The recipient of the *PHI* must enter into a data use agreement through which the recipient researcher agrees to protect the privacy of the data received and agrees to use the data in accordance with an IRB approved protocol.

A limited data set for research purposes excludes the following direct identifiers of the individual or of relatives, employers, or household members of the subject:

- a. names
- b. postal address information, other than town or city, state and zip code
- c. telephone numbers
- d. fax numbers

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<sup>6</sup> Any request involving *PHI* may require review by the Chief Privacy Officer for MLH.

<sup>7</sup> Users are prohibited under any circumstance to use personal electronic equipment to access MLH proprietary data or download PHI. Refer to [Information Systems Policy: Personal Electronic Equipment](#)

<sup>8</sup> Certification is not required for preparatory activities conducted by non-employee researchers on private medical records/charts (i.e. *PHI* which has not been collected, stored or maintained by Main Line Health, Main Line Hospitals, or other MLH Affiliate).

- e. e-mail addresses
- f. social security numbers
- g. medical record numbers
- h. health plan beneficiary numbers
- i. account numbers
- j. certificates or license numbers
- k. vehicle identifiers and serial numbers including license plate numbers
- l. device identifiers and serial numbers
- m. web universal resource locators (URLs)
- n. internet protocol (IP) address numbers
- o. biometric identifiers, including finger and voice prints
- p. full face photographic images and any comparable images

A data use agreement must:

- a. establish that the recipient will only use and disclose the limited set information for purposes of research, public health or health care operations
- b. establish who is permitted to use or receive the limited data set
- c. provide that the recipient will
  - i. not use or disclose the limited data set information other than as permitted by the data use agreement or other applicable laws
  - ii. use the appropriate safeguards to prevent use or disclosure of the limited data set information other than as provided for by the data use agreement
  - iii. report to MLH IRB any use or disclosure of the limited data set information than provided for in the data use agreement
  - iv. ensure that any agents including a subcontractor to whom the recipient provides the limited data set information agrees to the same restrictions and conditions that apply to the recipient
  - v. not identify the limited data set information or contact subjects

A code or other means of record identification may be assigned to allow a limited data set to be re-identified provided that the code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated as to identify an individual. The code can not be used or disclosed for any purpose nor can the mechanism for re-identification be disclosed. Some data sets may be considered de-identified for the purpose of accounting of disclosures (see Section 6) and may be considered de-identified for research purposes ([see Appendix B](#)).

### 3. Subject Authorization for Research

*PHI* for research purposes may be used or disclosed in accordance with the terms of a valid authorization approved by the MLH IRB and signed by the research subject. Permissible uses and disclosures are limited to those described in the authorization. No one may be enrolled in any study without signing a research Authorization form. The use and disclosure of psychotherapy notes for research is permissible only if the subject signs an authorization *specifically authorizing the use of psychotherapy notes*. Authorizations must include the following core elements:

- a. description of *PHI* to be used or disclosed as part of the study
- b. who may use or disclosure the information
- c. who may receive the information
- d. purpose of each use or disclosure
- e. expiration date
- f. right to revoke authorization in writing and how to do it
- g. a statement that re-disclosures of *PHI* may no longer be protected
- h. signature of the subject and date (if the legally authorized representative signs the Authorization, a description of the representative's authority to act for the individual must also be provided)

An authorization may be a separate document or combined (except for psychotherapy notes) in an MLH IRB approved Informed Consent or any other type of written permission for the same or another research study and may be combined with an authorization for the creation or maintenance of a research database or repository. Psychotherapy notes require specific authorization and may not be combined with any other authorizations. A correction and/or an amendment of *PHI* in the conduct of research requires a new authorization to be approved by the MLH IRB and authorized by the research subject.

Compound authorizations which contain research-related treatment conditioned on the provision of one of the authorizations must clearly differentiate between the conditioned and unconditioned<sup>9</sup> components and provide the individual with an opportunity to “opt in”<sup>10</sup> to the research activities described in the unconditioned authorization.

Authorizations for future research uses and disclosures are permitted when adequately described in the authorization such that it would be reasonable for subjects to expect that their *PHI* could be used or disclosed for such future research. The Authorization for future research must contain each of the core elements stated above and describe the purpose for the use and disclosure of *PHI* such that it would be reasonable for a subject to expect that *PHI* could be used or disclosed for future research purposes.

#### 4. Use/Disclosure with an Approved Waiver of Authorization

The MLH IRB may grant an IRB approved waiver or authorization to allow the use and disclosure of *PHI* (except psychotherapy notes) for research purposes, without subject authorization, when the researcher provides a description of the *PHI* to be used and requests a waiver as part of an IRB approved protocol. The MLH IRB must document that the requested waiver satisfies each of the following criteria:

1. the use or disclosure involves no more than minimal risk to the privacy of the individuals because:
  - there is an adequate plan to protect the identifiers from improper use and disclosure
  - there is an adequate plan to destroy the identifiers at the earliest opportunity, unless there is a health or research justification for retaining the identifiers or their retention is required by law; and
  - there are adequate written assurances that the *PHI* will not be reused or disclosed to any other person or entity, except (1) as required by law, (2) for authorized oversight of the research project, or (3) for other research for which the use or disclosure of *PHI* is otherwise permissible under this policy.
2. the research could not practicably be conducted without the waiver; and
3. the research could not practicably be conducted without access to and use of the *PHI*. (Note: If a researcher can practicably use de-identified health information or a limited data set for a research study, a waiver of authorization is not required and not subject to accounting of disclosures)

A waiver of individual authorization under this policy is not a waiver of the requirements of informed consent for participation in the study or of any other requirement in any other policy. Disclosures of *PHI* pursuant to a waiver must be tracked according to the requirements outlined in **Section III.6**.

#### 5. Research on Protected Health Information of Decedents<sup>11</sup>

The MLH IRB may permit the use of *PHI* of decedents for research purposes, without an authorization, when the researcher certifies that:

1. representation that the use or disclosure sought is solely for research on *PHI* of decedents (i.e. researchers may not request a decedent’s medical history to obtain health information about a decedent’s living relative

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<sup>9</sup> For example, an optional sub-study involving collection of additional blood/tissue samples for banking.

<sup>10</sup> A combined authorization that only allows the individual the option to “opt out” of the unconditioned research activities (e.g., “check here if you do NOT want your data provided to the biospecimen bank”) is not permitted.

<sup>11</sup> *PHI* of a deceased individual is protected for a period of 50 years following the death of the individual.

2. documentation, at the request of MLH IRB, of the death of such individuals
3. representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

## 6. Accounting of Disclosures of PHI for Research

The Privacy Rule gives individuals the right to receive an accounting of certain disclosures (not “uses”) including research involving *PHI* that occurred during the six years prior to the individual’s request for an accounting. Accounting of disclosures of *PHI* is required in 1) connection with a protocol for which the MLH IRB approved a waiver/alteration of authorization, 2) research on decedents’ information and 3) reviews preparatory to research. The types of disclosures that are exempt from this accounting requirement are:

- a. research disclosure made under an authorization
- b. research disclosures of limited data sets under a data use agreement
- c. research disclosures of de-identified information
- d. exempt research when information recorded cannot be identified, directly or through identifiers linked to subjects.

Research related *PHI* disclosures subject to accounting will follow the process outlined in the MLH Compliance Office: [HIPAA – Patient’s Right to Full Accounting of Disclosures Policy](#).

When the records of 50 or fewer individuals are disclosed, the researcher is responsible for providing MLH Information Management with the following information:

- a. date of disclosure;
- b. name of the recipient, and address if known;
- c. brief description of the PHI disclosed;
- d. brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for disclosure, or a copy of the request for the disclosure.

When more than 50 records of individuals are disclosed, the researcher is responsible for providing Health Information Management with the following information:

- a. the name of the protocol or other research activity;
- b. a brief description of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
- c. a brief description of the type of PHI that was disclosed;
- d. the date or period of time during which disclosures occurred;
- e. the name, address and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and
- f. a statement that the PHI of the individual may or may not have been disclosed for a particular protocol or other research activity.

**References:** Health Insurance Portability and Accountability of 1996 Act (HIPAA), as amended 2013

**Origination Date:** 01/03

**Revision Date:** 08/13

## Appendix A

### **De-Identified Health Information**

Health information is de-identified when one of the following two conditions are met.

1. The following identifiers of the individual or of relatives, employers, or household members of the individual are removed:
  - Names
  - 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 Census:
    - the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
    - the initial three digits of a zip code for a all such geographic units containing 20,000 or fewer people is changed to 000.
  - All elements of dates (except year) directly relating 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 for ages and elements aggregated into a single category of age 90 or older.
  - Telephone numbers
  - Fax numbers
  - Email addresses
  - 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 finger prints and voice prints
  - Full face photographic images or any other comparable images
  - Any other unique identifying numbers, characteristics or codes (other than unique codes assigned to code the data).

**Note that any codes used to replace identifiers in data sets cannot be derived from any information relating to the individual and the master codes, nor can the method to derive the codes be disclosed.**

**Although the use of codes is recommended as a means of reducing risk, if a researcher has the ability to link coded data to identifiable information, the coded data will be considered to be identifiable, (i.e., PHI or individually identifiable health information).** Only when the researcher has no access to the de-identified information, the coded data will be considered de-identified and not *PHI* or individually identifiable health information.

2. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable (de-identified) determines that the risk is very small that the information could be used alone or in combination with other reasonable available information by an anticipated recipient to identify a subject and documents the methods and results of the analysis that justify the determination.

## Appendix B

### De-Identified Data Review Requirements

OHRP<sup>12</sup> considers private information<sup>13</sup> or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. For example, OHRP does not consider research involving **only** coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:

- a. the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
- b. the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
  1. the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
  2. there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
  3. there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

This interpretation applies to existing private information and specimens, as well as to private information and specimens to be collected in the future for purposes other than the currently proposed research. The following are examples of private information or specimens that will be collected in the future for purposes other than the currently proposed research: (1) medical records; and (2) ongoing collection of specimens for a tissue repository.

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<sup>12</sup> Office of Human Research Protection which oversees the protection of human subjects in research. Complete guidance available at: <http://www.hhs.gov/ohrp/policy/cdebiol.html>

<sup>13</sup> Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.