POLICY

Decatur Memorial Hospital (DMH) is committed to conducting research in compliance with all applicable laws, regulations and Decatur Memorial Hospital policies. As part of this commitment, Decatur Memorial Hospital has adopted a policy to clearly define the circumstances under which Protected Health Information (PHI) may and may not be used internally or disclosed externally in connection with research activities.

This Policy covers all PHI, which is or may be created, used or disclosed by, through or during research activities. This Policy applies to all faculty, staff (including student employees), students, residents, post-doctoral fellows, and non-employees (including visiting faculty, courtesy, affiliate and adjunct faculty, industrial personnel, fellows, etc.) who conduct research, assist in the performance of research, or otherwise use or disclose PHI in connection with research activities at Decatur Memorial Hospital. In most cases, the prior review and approval of the IRB will be required in the implementation of this Policy.

PROCEDURES

1. RESEARCH USE AND DISCLOSURE OF PHI WITH AUTHORIZATION

1.1 As a general rule, a researcher must obtain an Authorization from all participants in research prior to the internal use or external disclosure of PHI for any research-related purpose that is not otherwise permitted or required under this Policy.

1.2 There are two options for the Authorization. It can be submitted to the IRB as a stand-alone document, or it may be embedded in the consent form. The stand-alone document is preferred.

1.3 An additional, separate Authorization will be required if the research involves the use or disclosure of Psychotherapy Notes.

1.4 An Authorization must be written in plain language, and must contain all of the following elements:

1.4.1 A specific and meaningful description of the information to be used or disclosed.

1.4.2 The name or identification of the persons or class of persons authorized to make disclosures of PHI and to use the PHI for research-related purposes.

1.4.3 The name or identification of the persons or class of persons authorized to receive disclosures of the PHI and to use the PHI for research-related purposes.

1.4.4 A description of each purpose of the use or disclosure.

1.4.5 An expiration date or event, or a statement “end of research study” or “none” or similar language, when appropriate.

1.4.6 The individual’s signature (or that of his/her authorized representative as determined by Illinois law) and date. Note: If the Authorization is signed by an authorized representative, it needs to include a description of the representative’s authority under Illinois law to act on behalf of the individual.

1.4.7 A statement that the individual may revoke the Authorization if done in writing to the Principal Investigator; however, the researcher may continue to use and disclose, for research integrity and reporting purposes, any PHI collected from the individual pursuant to such Authorization before it was revoked.

1.4.8 A statement that an individual’s clinical treatment may not be conditioned upon whether or not the individual signs the research Authorization. However, participation in research may be conditioned on a signed Authorization, including treatment protocols.

1.4.9 A statement that information disclosed under the Authorization could potentially be re-disclosed by the recipient and would no longer be protected under HIPAA.

1.5 The research participant must be provided with a copy of the signed Authorization.

2. REMOTE AUTHORIZATION

2.1 The written Authorization form may be sent to the subject or the subject's legally authorized representative by email, by postal mail, or by facsimile prior to (in advance of) the HIPAA interview. It is a requirement that the subject or their legally authorized representative has a copy of the written, study-specific Authorization form to read and follow while the HIPAA interview and discussion takes place. The person who conducts the HIPAA interview needs to be knowledgeable about the study and be able to answer any questions.

2.2 Signature Requirement

2.2.1 Signature of the research participant or the research participant's legally authorized representative. If the potential participant or legally authorized representative agrees to the use and disclosure of protected health information, that individual signs and dates the Authorization form and returns it to the clinical research coordinator or the Investigator (e.g., via text [picture], email, postal mail or facsimile). If postal mail is used, a pre-paid, self-addressed envelope should be provided to the participant or their legally authorized representative to mail the signed Authorization form back to the clinical research coordinator or the Investigator.

2.3 The method used for obtaining the Authorization must be documented by the clinical research coordinator or Investigator in the participant's research records. It must specifically include the interface (e.g., speaker phone, FaceTime, Skype) used for obtaining for the HIPAA interview and discussion, the date of the HIPAA interview, and the date the signed Authorization form was received. For example, "Discussed with [participant or LAR name] via [name the interface used] on [insert date] and received signed Authorization form on [insert date]." Include a brief reason for performing the HIPAA interview and discussion over the speaker phone, FaceTime, Skype, etc.

2.4 The clinical research coordinator or the Investigator must have a signed and dated Authorization form in their possession before PHI is disclosed to a third party.

SIGNING THE AUTHORIZATION

3.1 Adults

3.1.1 A competent individual, 18 years of age or older, must sign the Authorization to use or disclose his/her PHI. A person is competent if he/she has the general ability to understand the concept of release of his/her medical information.

3.1.2 If an individual is competent, but unable to sign the Authorization, it needs to be documented that "Patient unable to sign due to [insert reason]. Patient gave verbal permission." The Authorization must be signed and dated by the individual who noted the patient's inability to sign the Authorization.

3.1.3 If the patient is not conscious, coherent or not competent for whatever reason, a legally recognized proxy must sign the Authorization. Illinois law recognizes the following order of individuals capable to serve as proxies.

3.1.3.1 Court appointed guardian, or proxy designated by durable power of attorney

3.1.3.2 Spouse or civil union partner

3.1.3.3 Any adult son or daughter

3.1.3.4 Either parent

3.1.3.5 Any adult brother or sister; or

3.1.3.6 Any adult grandchild

3.1.3.7 A close friend (requires affidavit)

3.1.3.8 Guardian of the estate; or

3.1.3.9 Temporary custodian appointed under the Juvenile Court Act

3.2 Minors

3.2.1 Any parent may sign for a minor child in his/her legal custody.

3.2.2 Any minor who has been lawfully married and any minor parent or legal custodian of a child may sign for him/herself, his/her child and any child in his/her legal custody.

3.2.3 Any minor may sign for him/herself in case of:

3.2.3.1 Pregnancy, but excluding abortions

3.2.3.2 Venereal disease

3.2.3.3 Drug or substance abuse in accordance with Illinois law.

3.2.4 Any adult standing in loco parentis, whether serving formally or not, may sign for his/her minor charge in case of emergency in accordance with Illinois law.

4. USE AND DISCLOSURE OF PHI FOR IDENTIFYING/CONTACTING POTENTIAL PARTICIPANTS

4.1 Physicians, and other health care providers, may contact their own patients for purposes of recruiting them to participate in a research study without an Authorization.

4.2 Individuals responding to an advertisement regarding participation in a research study may be given an explanation of the study (including, but not limited to, the name of the Principal Investigator and description of the study) prior to obtaining an Authorization.

4.3 An Authorization must be obtained from an individual who has indicated interest in participating in a research study prior to asking the individual any screening questions that involve PHI.

4.4 All other uses and disclosures of PHI for the purpose of identifying and/or contacting potential research participants may require an Authorization or Waiver.

5. WAIVER OF AUTHORIZATION

5.1 In some circumstances, Authorizations otherwise required under this Policy may be waived or altered by the IRB, provided the following criteria are satisfied and documented:

5.1.1 The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on the presence of at least the following elements:

5.1.1.1 An adequate plan to protect the identifiers from improper use and disclosure;

5.1.1.2 An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

5.1.1.3 Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by this Policy;

5.1.2 The research could not practicably be conducted without the waiver; and

5.1.3 The research could not practicably be conducted without access to and use of the PHI.

a. The Waiver of Authorization must be documented in the IRB application. Approval of the Waiver shall be interpreted as such:

i. The date of IRB approval is also the date in which the Waiver is approved;

ii. The IRB approval means that the Waiver satisfied the criteria for waiver;

iii. The IRB approval means that the IRB was provided a brief description of the PHI to be used or accessed;

iv. The IRB approval means the Waiver has been reviewed and approved by either the full IRB at a convened meeting or the IRB Co-Chair using expedited review procedures; and

v. Signed minutes represent documentation for the approval of the Waiver for full board submissions; the electronic signature of the IRB Co-Chair applies to the IRB approval and serves as documentation of the approval for the Waiver under expedited review procedures.

b. Uses or Disclosures of PHI made pursuant to a Waiver are subject to the Minimum Necessary rules.

6. USE AND DISCLOSURE OF PHI PREPARATORY TO RESEARCH

a. Researchers may use or disclose PHI without an Authorization or IRB waiver for the development of a research protocol, provided that the researcher documents that all the following criteria are satisfied:

6.1.1 The use or disclosure of PHI is solely to prepare a research protocol, or to identify prospective research participants for purposes of seeking an Authorization;

6.1.2 The researcher shall not record or remove the PHI from DMH, and

6.1.3 The PHI sought is necessary for the purposes of the research.

b. Uses or Disclosures of PHI preparatory to research are subject to the Minimum Necessary rules.

7. USE AND DISCLOSURE OF DECEDENT'S PHI

a. Researchers may use and disclose a decedent's PHI for research without an Authorization or IRB waiver, provided that the researcher documents that all the following criteria are satisfied:

i. The use will be solely for research on the PHI of a decedent; and

ii. The researcher has documentation of the death of the individual about whom information is being sought; and

iii. The PHI sought is necessary for the purposes of the research.

b. Uses or Disclosures of a decedent's PHI for research purposes are subject to the Minimum Necessary rules.

8. USE AND DISCLOSURE OF "DE-IDENTIFIED" HEALTH INFORMATION

8.1 De-identified health information is exempt from HIPAA and may be used or disclosed for research purposes without an Authorization or Waiver.

8.2 Researchers must provide documentation to the IRB that the health information has been de-identified by one of the following two methods:

8.2.1 Statistical Method. The IRB may determine that health information is de-identified for purposes of this Policy, if an independent, qualified statistician:

8.2.1.1 Determines that the risk of re-identification of the data, alone or in combination with other data, is very small; and

8.2.1.2 Documents the methods and results by which the health information is de-identified, and the expert makes his/her determination of risk. Note: The expert may not be the researcher or anyone directly involved in the research study.

8.2.2 Removal of All Identifiers. Identifiers concerning the individual and the individual's employer, relatives and household members that must be removed include: names; geographic subdivisions smaller than a state; zip codes; dates directly related to an individual; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary identifiers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URL); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images; and any other number, characteristic or code that could be used to identify the individual.

8.3 Re-identification Code. The de-identified information may be assigned a code that can be affixed to the research record that will permit the information to be re-identified, if necessary, provided that the key to such a code is not accessible to the researcher requesting to use or disclose the de-identified health information.

9. LIMITED DATA SET

9.1 A researcher may use or disclose a Limited Data Set for any research purpose without an Authorization or Waiver.

9.2 A "Limited Data Set" is defined as PHI that may include any of the following direct identifiers:

9.2.1 Town, city, state and zip code.

9.2.2 All elements of dates directly related to an individual, including birth date, admission date, discharge date, and date of death.

9.3 A Limited Data Set must exclude all of the following direct identifiers of the individual or of the individual's relatives, employers, or household members of the individual: names; postal address information other than town or city, state, and zip code; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary identifiers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URL); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images and any comparable images; and any other number, characteristic or code that could be used to identify the individual.

9.4 A Limited Data Set may be used or disclosed only if there is a Data Use Agreement between DMH and the recipient of the limited data set. See: Data Use Agreement Template

10. INDIVIDUAL'S ACCESS TO RESEARCH INFORMATION

a. As a general rule, individuals who participate in research have a right to access their own PHI that is maintained in a Designated Record Set. However, individuals participating in research protocols that include treatment (ex: clinical trials) may be denied access to their PHI obtained in connection with that research protocol, provided that:

i. The PHI was obtained in the course of the research;

ii. The individual agreed to the denial of access in the Research Authorization;

iii. The research remains in process; and

iv. The individual's rights to access such PHI are re-instated once the research study has ended and the Authorization has expired.

11. INDIVIDUAL'S REVOCATION OF AUTHORIZAITON

a. As a general rule, an individual may revoke his/her Authorization, in writing to the Principal Investigator, at any time.

11.2 The revocation will be applicable to the protocol or protocols specified by the individual. However, the researcher may continue to use and disclose, for research integrity and reporting purposes, any PHI collected about the individual pursuant to a valid Authorization before it was revoked.

11.3 The Principal Investigator shall forward a copy of the written revocation to the Privacy Officer. The Principal Investigator shall also keep copies of all revocations of Authorizations for a specific protocol, and report them to the IRB at the time of continuing review.

12. ACCOUNTING OF DISCLOSURES

a. As a general rule, an individual must be provided with an accounting of all disclosures of his/her PHI for research purposes, unless such disclosure was made pursuant to an Authorization, or is part of a Limited Data Set.

12.2 The IRB must keep records of all disclosures of PHI in the following circumstances:

12.2.1 Disclosures pursuant to an IRB waiver or partial waiver;

12.2.2 Disclosures of PHI used in preparation of a research protocol; and

12.2.3 Disclosure of a decedent's PHI used for research.

12.3 A simplified accounting procedure may be used if the research use or disclosure involves the PHI of more than 50 people. Under the simplified accounting procedure:

12.3.1 The individual must be provided a list of research protocols in which the individual's PHI may have been used. The list must provide the following:

11.3.1.1 The name of the protocol or other research activity;
11.3.1.2 A description of the purpose of the study and the type of PHI disclosed; and

11.3.1.3 The time-frame during which such disclosures occurred.

12.3.2 Upon request, the Privacy Officer, or his/her designee, will assist the individual in contacting those researchers to whom it is likely that the individual's PHI was actually disclosed.

SCOPE

This SOP applies to all IRB members, the IRB administrator, the DMH Privacy Officer, and members of the research community.