Health Insurance Portability and Accountability Act (HIPAA) Research Policy

Statement of Policy
University of Missouri Columbia, Health Sciences Institutional Review Boards (IRB’s) are committed to conducting research in compliance with all applicable laws, regulations, and University of Missouri policies. As part of this commitment, the Health Sciences IRB has adopted a policy to clearly define the circumstances under which protected health information (PHI) may or may not be either used internally, or externally disclosed, in connection with research. This policy applies to the following covered components and the employees within them and anyone receiving PHI from one of these entities;

Health Sciences Center
  Children’s Hospital
  Ellis Fischel Cancer Center
  Howard A. Rusk Rehabilitation Center
  Missouri Rehabilitation Center
  University Hospitals and Clinics
  University Physicians
Columbia Regional Hospital
School of Medicine
School of Health Professions
Charles and Josie Smith Sinclair School of Nursing
Missouri Institute of Mental Health
Student Health Center
Psychological Science
Education & Counseling Psychology

Scope of Policy
This policy covers all PHI, which is used or disclosed, which is or may be created, through and/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 the University of Missouri- Columbia.

Policy

A. Research Use or Disclosure of PHI with Authorization

  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.

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See Authorization Form

2. The researcher must complete the Authorization Form and submit it to the IRB for its prior review and approval.

3. An authorization must be in plain language and must contain all of the following elements:
   a. A specific and meaningful description of the information to be used or disclosed;
   b. The name or identification of the persons or class of persons authorized to make disclosures of PHI and to use PHI for research related purposes;
   c. 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;
   d. A description of each purpose of the use or disclosure;
   e. An expiration date or event, or a statement ‘end of research study’ or ‘none’ when appropriate;
   f. The individual’s signature (or that of his/her authorized representative as determined by Missouri Law) and date;
   g. 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;
   h. 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;
   i. A statement that information disclosed under the Authorization could potentially be redisclosed by the recipient and would no longer be protected under HIPAA;
   j. The individual must be provided with a copy of the signed Authorization.

4. Signing an Authorization
   a. Adults
      i. A competent individual, 18 years of age or older, should always sign the authorization to use or disclose his/her PHI.
      ii. If the individual is competent but unable to sign the authorization, the person witnessing the form may write in “Patient unable to sign due to ______________. Patient gave verbal permission.” The authorization must be witnessed.
      iii. If the patient is not conscious, coherent, or not competent for whatever reason, a legally recognized proxy must sign the Authorization. Missouri law recognizes the following order of individuals capable to serve as proxies for incompetent individuals being treated at or by MU Healthcare:
         ▪ Court appointed Guardian, or Proxy designated by Durable Power of Attorney
- Spouse
- Adult son or daughter
- Either parent
- Adult sibling
- Adult relative by blood or marriage.

5. Authorizations will be reviewed for the required elements and the receipt of the authorization will be acknowledged by HS IRB.

B. Waiver of Authorization by the IRB

1. In some circumstances, Research Authorizations, otherwise required under this policy, may be waived or altered by the IRB provided the following criteria are satisfied and documented:
   a. 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:
      i. An adequate plan to protect the identifiers from improper use and disclosure;
      ii. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law and;
      iii. 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.
   b. The research could not practicably be conducted without the waiver; and
   c. The research could not practicably be conducted without access to and use of the PHI.

2. A request for Waiver of Authorization must be completed by the researcher and submitted to the IRB for prior review and approval.

3. The IRB will maintain the following documentation about the waiver;
   a. A statement identifying the IRB and the date on which the waiver request was approved;
   b. A statement that the IRB determined that the waiver satisfied the criteria for waiver;
   c. A statement that the waiver has been reviewed and approved under either normal (full board) or expedited review procedures; and
   d. The documentation is signed by the IRB chair or his/her designee.

See Waiver of Authorization Form

C. Use and Disclosure of PHI Without Authorization Preparatory to Research

May, 5, 2003, Revised: July 12, 2005
1. Physicians, and other healthcare providers, may contact their own patients for purposes of recruiting them to participate in a research study without an Authorization.
2. Individuals responding to an advertisement regarding participation in a research study may be given an explanation of the study prior to obtaining an Authorization.
3. An investigator (employed by MU healthcare) may use and disclose PHI without authorization ‘preparatory to research’ to identify potentially qualifying subjects. Any contact with subjects must be through their own treatment provider and authorization obtained from the investigator prior to obtaining PHI from the subject.
4. An Authorization must be obtained from an individual who has indicated interest in participating in a study prior to asking the individual any screening questions that involve PHI.
5. Researchers may use or disclose PHI without an Authorization or IRB waiver of Authorization for the development of a research protocol, provided that the researcher documents that all the following criteria are satisfied;
   a. 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;
   b. The researcher shall not record or remove the PHI from the covered entity (MU Healthcare); and
   c. The PHI sought is necessary for the purpose of the research.
   The researcher will provide documentation to the IRB Office that all the above criteria are met.

See Review Preparatory to Research Form

D. Use and Disclosure of Decedent’s PHI Without Authorization
   1. Researchers may use and disclose a decedent’s PHI for research without an Authorization or IRB waiver, provided the researcher documents that all the following criteria are satisfied:
      a. The use will be solely for research on the PHI of a decedent;
      b. The researcher has documentation of the death of the individual about whom information is being sought; and
      c. The PHI sought is necessary for the purpose of the research.
   2. The researcher will provide documentation to the IRB Office that all the above criteria are met.

See Use and Disclosure of Decedent’s Information

E. Use or Disclosure of De-Identified Health Information
   1. De-Identified health information is exempt from HIPAA and may be used or disclosed for research purposes without Authorization or IRB waiver.
   2. Researchers must provide documentation to the IRB Office that the health information has been de-identified by one of the following two methods:

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

   i. Determines that the risk of re-identification of the data, alone or in combination with other data, is very small;
   
   ii. Documents the methods and results by which the health information is de-identified, and the expert makes his/her determination of risk. THE EXPERT MAY NOT BE THE RESEARCHER OR ANYONE DIRECTLY INVOLVED IN THE RESEARCH STUDY.

b. **Removal of All Identifiers:** Identifiers concerning the individual, the individual’s employer, relatives, and household members that must be removed include:

<table>
<thead>
<tr>
<th>Identifier Type</th>
<th>Examples</th>
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<tbody>
<tr>
<td>Name</td>
<td></td>
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<tr>
<td>Social Security number</td>
<td></td>
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<tr>
<td>Account numbers</td>
<td></td>
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<tr>
<td>Geographic information smaller than state</td>
<td></td>
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<tr>
<td>Electronic mail address</td>
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<tr>
<td>Certificate or license numbers</td>
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<tr>
<td>Elements of dates including birth date, admission date, date of death, and all ages &gt;89 years of age</td>
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<tr>
<td>Fax numbers</td>
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<tr>
<td>Vehicle identifiers and serial numbers including license plate</td>
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<tr>
<td>Telephone numbers</td>
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<tr>
<td>Health plan beneficiary number</td>
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<tr>
<td>Device identifiers and serial numbers</td>
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<tr>
<td>Medical Record number</td>
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<tr>
<td>Full face photographic images and comparable images</td>
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<tr>
<td>Web Universal Resource Locators (URL’s)</td>
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<tr>
<td>Internet Protocol (IP) address numbers</td>
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<tr>
<td>Biometric identifiers, including finger and voice prints</td>
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<tr>
<td>Any other unique identifying number, characteristic, or code</td>
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</tbody>
</table>

3. **Re-Identification:** 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.

   *See De-Identification Form*

**F. Limited Data Set**

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

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

   a. Town, city, State, and zip code;
   
   b. All elements of dates directly related to an individual, including birth date, admission date, discharge date, and date of death.

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3. A Limited Data Set must exclude all of the direct identifiers listed in E. 2 b above except those allowed in #2 of this section, related to the individual, the individual’s employer, relatives or household members of the individual.

4. A Limited Data Set may be used or disclosed only if there is a Data Use Agreement between the University and the recipient of the limited data set.

See Data Use Agreement, External, Internal

G. Accounting of Disclosures

1. As a general rule, an individual has the right to 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.

2. Records of disclosures of PHI must be kept in the following circumstances:
   a. Disclosures pursuant to an IRB waiver.
   b. Disclosures of PHI used in preparation of a research protocol.
   c. Disclosures of a decedent’s PHI used for research.

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 procedure:
   a. The individual must be provided a list of research protocols in which the individual’s PHI may have been used.
   b. The list must provide the following:
      i. The name of the protocol or other research activity;
      ii. A description of the purpose of the study and the type of PHI disclosed; and
      iii. The timeframe during which such disclosures occurred.
   c. The Privacy Officer will be notified and may assist the individual in contacting those researchers to whom it is likely that the individual’s PHI was actually disclosed.

H. Notice of Privacy Practices

1. A notice of Privacy Practices must be provided to a research participant when an Authorization is signed. This may be obtained through docushare https://docs.hsc.missouri.edu or on the MU Healthcare website.