	MOREHOUSE SCHOOL OF MEDICINE POLICIES AND PROCEDURES	POLICY NUMBER EFFECTIVE	Insert Here 5/1/2015
	SUBJECT **Use and Disclosure of Protected Health Information for Research Purposes**	PAGES	5

SECTION 1: PURPOSE

To provide governing principles and standards on the use or disclosure of protected health information ("PHI") for research purposes at Morehouse School of Medicine, Morehouse Healthcare, Inc. and its related entities (Collectively referred to herein as, "MSM").

SECTION 2: POLICY STATEMENT

This policy establishes the requirements for the use or disclosure of PHI for research purposes in accordance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") in furtherance of the rights of privacy of research subjects with respect to their health information. The use or disclosure of PHI is prohibited for research purposes until Authorizations and/or Institutional Review Board ("IRB") approvals are obtained.

SECTION 3: SCOPE OF POLICY

The requirements of this policy apply to all medical staff, faculty, staff, residents, interns, students, agents and consultants, and other individuals involved in research conducted by or overseen at MSM. The scope extends to the following research activities:

1.) Research using or creating PHI about living individuals
2.) Activities Preparatory to Research
3.) Research using a Limited Data Set
4.) Research using De-Identified Data
5.) Research on Decedents
6.) Recruitment Activities
7.) Transnational Research

The Principal Investigator for the research is responsible for compliance with HIPAA by its investigators and other individuals involved in the research.

SECTION 4: DEFINITIONS

Authorization – Is an individual's written permission to allow the use or disclosure of their specified PHI for a particular purpose. Except as otherwise permitted by the Privacy Rule, MSM may not use or disclose PHI for research purposes without a valid Authorization.

Data Use Agreement - An agreement by which the covered entity obtains assurances that the recipient of the Limited Data Set will use or disclose the PHI in the data set only for specified purposes.

De-identified Data – Health information that does not identify an individual and which there is no reasonable basis to believe that information can be used to identify an individual. For information to be considered de-identified, all 18 identifiers (defined under PHI below) must be removed. PHI may be permanently de-identified, or the code linking identifiers may be maintained by the institution disclosure accounting purposes, but may not be provided to the researchers.

Institutional Review Board ("IRB") – Is a standing committee of the Academic Policy Council of Morehouse School of Medicine that provides the primary review of all human subject research protocols and has the authority to approve, require modification, or disapprove all research activities, including proposed changes in previously approved human subject research.

Limited Data Set - A limited data set is a De-identified Data Set, except that the following data elements are permitted: zip code, city, and state, date of birth and other dates. If a limited data set is to be used a Data Use Agreement is required.

Principal Investigator (*"PI"*)– Individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct and oversee the scientific and technical aspect of a grant and the day-to-day management of the research. (*Investigator – Individual(s) who conducts scientific and technical aspects of a research project/program/activity.*)

Privacy Rule – Sets national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patient's rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections.

Protected Health Information ("PHI") – Individually identifiable health information created or received by MSM. Health information includes any information, whether oral or recorded in any form (including electronic), that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment of health care to an individual.

PHI is identifiable if it contains one or more of the following 18 identifiers:

1. Names
2. All geographic subdivisions smaller than a State, including:
    - street address
    - city
    - county
    - precinct
    - zip codes 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 the Census: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. Telephone numbers
4. Fax numbers
5. E-mail addresses
6. Social Security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. All elements of dates (except year) for dates related to an individual, including:
    - birth date
    - admission date
    - discharge date
    - date of death
    - 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 age 90 or older
11. Certificate/license numbers
12 Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying numbers, characteristics, or codes

Research – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Waiver or Alteration of Authorization - The documentation that MSM obtains from a researcher or the IRB that states that the IRB has waived or altered the Privacy Rule's requirement that an individual must authorize MSM to use or disclose the individual's PHI for research purposes.

SECTION 5: POLICY

The MSM may use or disclose protected health information ("PHI") for Research purposes. In such cases, a Research subject generally must sign a valid Authorization giving permission for the use and disclosure of PHI for the specific Research project. PHI may not be used or disclosed in connection with any Research purpose until the appropriate Authorizations and/or Institutional Review Board ("IRB") approvals are obtained.

In limited circumstances the IRB with oversight responsibility for the Research project may waive or alter this Authorization requirement.

Authorization, or a Waiver or Alteration of Authorization is not required, but IRB approval and permission is required:

- if the PHI is part of a Limited Data Set subject to a Data Use Agreement (see *De-Identification of Protected Health Information Policy*); and for
- Research solely using decedent information.

For Activities Preparatory to Research, Authorization, or a Waiver or Alteration of Authorization is not required, but additional MSM procedures apply. Activities Preparatory to Research include, but are not limited to:

- preparing a research protocol,
- developing a hypothesis,
- determining feasibility of a study and eligibility criteria, and
- reviewing PHI in paper or electronic medical records to identify prospective research participants.

The requirement to obtain an Authorization for Research from a Research subject is separate from the requirement to obtain a signed informed consent form for the same Research. However, the informed consent and Authorization for Research may be combined into a single document.

This Policy does not apply to uses or disclosures for treatment purposes. For example, a treating clinician does not need to obtain a signed Authorization in order to discuss the option of enrolling in a clinical trial with his or her patient. A treating clinician does not need to obtain a signed Authorization in order to provide de-identified clinical information about a patient to an Investigator to determine a patient's eligibility for a particular trial. Authorization is required, however, to include the patient's PHI in a clinical research recruitment database.

Procedure

ALL PROPOSED RESEARCH REQUIRES REVIEW BY THE IRB TO DETERMINE IF RESEARCH IS EXEMPT OR QUALIFIES FOR EXPEDITED OR FULL REVIEW, AND TO DETERMINE WHETHER THE REQUIREMENTS FOR HIPAA AUTHORIZATION MAY BE WAIVED OR ALTERED.

All Investigators requesting to use or disclose PHI for Research related purposes must do so in one of the following ways:

1a. Unless otherwise permitted by this Policy, the Investigator must obtain a signed Authorization from each Research subject, prior to the use and disclosure of PHI for Research purposes. *or;*

1b. Obtain a Waiver or Alteration of Authorization, if appropriate, from the IRB.

- Investigators must submit a completed MSM Application for Waiver or Alteration of Informed Consent Requirements and/or Application For Waiver of HIPAA Authorization, as applicable.
- The IRB will review and approve or deny the application. *or;*

1c. If Authorization is not required, follow the applicable additional procedures in accordance with this policy to obtain IRB approval and permission.

Investigators must also:

2. Document disclosures of PHI in order to account for disclosures of PHI.

3. Retain all supporting documentation for the Research project (e.g., Authorizations, Application for Waiver or Alteration of Informed Consent Requirements for a period of at least six (6) years).

Activities Preparatory to Research

Investigators who plan to engage in Activities Preparatory to Research must:

1. Certify that:
   - the use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
   - no PHI will be removed from MSM premises; and
   - the PHI is necessary for the Research purpose.

2. Consult with the IRB to determine if a waiver of consent is required by the Common Rule

Research using a Limited Data Set

Investigators who plan to engage in Research using a Limited Data Set must obtain approval and permission from the IRB, pursuant to the *De-Identification of Protected Health Information Policy*.

Research using a De-identified Data

Research using data that are de-identified, and for which the research team does not possess any code or other information that would enable re-identification, does not require a HIPAA authorization as long as all 18 identifiers have been removed. The PI is responsible for obtaining a prior written determination from the IRB that the research is "exempt."

Research using Decedent Information

Investigators who plan to engage in Research solely using decedent PHI must obtain permission for the use of decedent PHI on those decedents who have been deceased less than 50 years. The Investigator to represent:

- that the use or disclosure is solely for Research on the PHI of decedents;
  - for example, the Investigator is not looking for PHI about living persons that may be contained in the decedent's records;
- that the Investigator can provide documentation of the death of such individuals, if the IRB so requests, and
- that the PHI is necessary for the Research purpose.

Recruitment Activities

The rules governing activities preparatory to research also apply to recruitment activities. This provision would allow a PI to identify prospective research subjects for purposes of seeking their authorization to use or disclose

PHI for a research study. PIs and providers may discuss the option of enrolling in a study without first obtaining a HIPAA Authorization, and without IRB waiver of the authorization.

Transnational Research

Research using data that contains PHI from studies conducted at clinical facilities outside of the U.S. are not governed by HIPAA until that data is transferred to MSM. Once the data is transferred to MSM, all HIPAA regulations apply.

When an Investigator knows or has a reasonable basis to know that identifiable data will be brought back to MSM, Investigators should obtain HIPAA Authorizations in order to reduce the need to account for subsequent disclosure(s) of the PHI. However, if consent was not granted or confirmed at the time the research was conducted outside of the U.S. in accordance with the laws of that country, Investigators in any event must get Authorization prior to transferring identifiable data to MSM. In some cases, Investigators can bring the relevant data to MSM either stripped of all 18 HIPAA identifiers, with or without a code maintained at the non-U.S collection site, or as a Limited Data Set with an accompanying Data Use Agreement.

SECTION 6: RELATED POLICIES

Related Documents

Application for Waiver or Alteration of Informed Consent Requirements
De-Identification of Protected Health Information
Use and Disclosure of Protected Health Information
Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule (HHS-NIH)
Morehouse School of Medicine Human Research Protection Program Policy
IRB Guidelines, Policies & Procedures for the Protection of Human Subjects
Research Conflicts of Interest Policy, No. 01.01.03

Legal Reference

21 C.F.R. §50 & 56
45 C.F.R. §46
45 C.F.R. §160 and 162
45 C.F.R. §164.501
45 C.F.R. §164.502
45 C.F.R. §164.508
45 C.F.R. §164.512(i)
45 C.F.R. §164.514 (a)-(c)
45 C.F.R. §164.524(a) (2) (iii)

SECTION 7: REPORTING AND SANCTIONS

Improper access to or disclosure of patient information may result in the loss of access to PHI and may result in disciplinary action, up to and including termination and/or revocation of clinical privileges and faculty appointment.

Call your institution's Privacy Officer if you suspect that PHI might have been lost, stolen, or improperly accessed or disclosed.

SECTION 8: CONTACT INFORMATION

Privacy Officer, Keith L. Henderson, khenderson@msm.edu