PURPOSE

To establish the policy and procedure for the Michigan Department of Health and Human Services (MDHHS) to disclose protected health information (PHI) for research purposes in accordance with applicable Health Insurance Portability and Accountability Act (HIPAA) and other federal requirements, and to determine whether disclosure involves the use of human subjects.

This procedure is intended to ensure compliance with the HIPAA privacy rule. There may be additional requirements under the common rule that should be pursued with the administrator of the Institutional Review Board (IRB).

REVISION HISTORY

Reviewed: 01/01/2022.
Next Review: 01/01/2023.

POLICY

MDHHS shall require a valid written authorization from an individual to use or disclose his or her own PHI for purposes of research except:

1. When the health information has been de-identified.
2. For research of decedents' PHI under certain conditions.
3. When a review of PHI is done in preparation to research.
4. The PHI is contained in a limited data set and a data use agreement has been entered into.
5. When MDHHS's IRB approves in whole or in part a waiver of authorization. Another entity's IRB or Privacy Board waiver approval may be accepted by the MDHHS, however, the MDHHS IRB reserves the right to review their decision and disapprove a waiver.

When PHI is disclosed for research, only the minimum necessary will be permitted.

An individual's right to access or obtain an accounting of disclosures for PHI being used for research may be temporarily suspended.

Disclosures of PHI for research purposes must be logged for accounting purposes.

Note: When applicable, MDHHS will use or disclose PHI for purposes of research in accordance with other state or federal laws, including but not limited to: Medicaid, substance abuse, Public Health Code, HIV/AIDS/STDs, and the Mental Health Code. When in doubt, contact the Compliance and Data Governance Bureau or the Legal Affairs Administration for assistance.

PROCEDURE

1. Determine if the PHI is subject to HIPAA: This procedure applies to PHI (data) that has been collected by a MDHHS HIPAA covered component. If the data has been collected by a non-HIPAA-covered component, such as the Bureau of Epidemiology, then see the MDHHS's IRB Research Policy and Procedures. All data requests involving human subjects require IRB approval.

2. Determine if an IRB review and approval is required prior to use or disclosure: Once determination is made that HIPAA is applicable, then determine whether the request or activity requires review and approval by the MDHHS's IRB. IRB approval is required prior to use or disclosure when the research activity involves both research and human subject(s) as defined:

   - Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR §164.501, 45 CFR. 46 **or**, (the definition recommended by the National Bioethics Advisory Commission): "a systematic collection or analysis of data with the intent to generate new knowledge."

   - Human subject: "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." (Includes PHI.)

When using the data warehouse to collect PHI, IRB review is required for research that involves the use of the department's non-public information to identify or contact human research subjects or prospective subjects.

A signed HIPAA compliant authorization is required prior to using or disclosing an individual's PHI for a research project. However, upon request and review, the authorization requirement may be

waived by a privacy board or IRB. If the waiver is approved by an entity other than the MDHHS, the MDHHS reserves the right to review and accept or deny the waiver. A waiver of authorization decision must be made on the following 3 factors:

1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on additional protections as outlined at 45 CFR §164.512(i)(2)(ii)(A) (1-3).

2. The research could not practicably be conducted without the waiver or alteration.

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

Upon IRB or Privacy Board review and the MDHHS's approval, the requested data is permitted to be used and disclosed in accordance with the approved research protocol; see requirements in this item.

Information required in the research protocol. The research protocol will include how the PHI will be safeguarded by establishing:

- Who is permitted to use or receive the data.

- That the PHI will not be further used or disclosed other than as permitted by the protocol or as otherwise required by law.

- That the recipient will use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the research protocol.

- That the recipient will report to the covered entity any use or disclosure of the information not provided for by the protocol of which it becomes aware.

- That any agents or subcontractors involved in the research project will abide by the safeguards and conditions set out in the protocol.

- That the recipient will not publish the PHI unless as approved by MDHHS.

- That MDHHS owns the PHI.

- That all identifiable PHI data will be destroyed at the end of the project.

Determine if PHI is permitted to be used or disclosed for a research project without an IRB review and without the individual's permission (a signed HIPAA compliant authorization) under HIPAA:

De-identified Data

When data has had all individual identifiers removed then completely de-identified, data is permitted to be used and disclosed without an authorization or IRB review and approval for research purposes.

Data on Decedents

When any amount or type of PHI is requested to perform research on decedents without an authorization:

Information is permitted to be disclosed without an authorization if the:

- Information sought is solely for research on decedents.
- Information is necessary for the research.
- Requestor has documentation to prove the individual is deceased.

Note: Other applicable law may further restrict deceased individuals' PHI for use or disclosure. Questions should be referred to the Compliance and Data Governance Bureau.

Limited Data Set

When a request is made for a limited data set, where all identifiable data has been removed with the exception of dates and some demographic data and no authorization has been obtained:

- The Compliance and Data Governance Bureau must review and approve the request.
- A data use agreement must be entered into before disclosing PHI without an authorization.

REFERENCES

45 CFR §164.508, §164.512(i), §164.514(d), §164.514(e), §164.524, §164.528, §164.532, 45 CFR 46,

21 CFR 50 & 56.

CONTACT

For additional information concerning this policy, contact the MDHHS Compliance and Data Governance Bureau at MDHHSPrivacySecurity@michigan.gov.