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**PURPOSE**

To establish the policy and procedure for the Michigan Department of Licensing and Regulatory Affairs (LARA) to disclose protected health information (PHI) for research purposes in accordance with applicable Health Portability and Protection 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.

**DEFINITIONS**

Refer to HIPAA Policies and Procedures Definitions Glossary.

**POLICY**

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

- When the PHI has been de-identified
- For research of decedent’s PHI under certain conditions
- When a review of PHI is done in preparation for research
- The PHI contained in a limited data set and data use agreement has been entered
- When LARA approves in whole or in part a waiver of authorization. Another Entity’s IRB or Privacy Board approval may be accepted by LARA, however, LARA reserves the right to review their decision and disapprove a waiver.

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

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

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

Note: When applicable, LARA will use or disclose PHI for purposes of research in

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accordance with other state or federal laws including but not limited to: Medicaid, Substance/Drug Abuse, Public Health Code, HIV/AIDS/STDS and the Mental Health Code. When in doubt, contact LARA Director’s Office

**PROCEDURE**

- Determine if PHI is subject to HIPAA:** This procedure applies to PHI (data) that can be collected by a LARA HIPAA covered component. If the PHI (data) has been collected by a non-HIPAA covered component, see LARA’s Research Activities policy. ALL data requests involving human subjects require approval. See below.
- Determine if 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 Director’s Office. 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 generalized knowledge. CFR 164.501.45, CFR.46. Or, (the definition recommended by the National Board of Bioethics Advisory Committee): “a systematic collection or analysis of data with intent to generate new knowledge.

**Human Subject:** “a living individual whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.” (Includes PHI)

- When using data warehouse to collect PHI, a 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 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 Lara Privacy Officer. If the waiver is approved by an entity other than LARA, the department reserves the right to

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review and accept or deny the waiver. A waiver of authorization decision must be made on the following 3 factors:

- a) The use or disclosure of PHI involves no more than minimal risk to the privacy of individual.
  - b) The research could not practically be done without the wavier or alteration; and
  - c) The research could not practically be done without the access and use of PHI.
- Upon LARA’s approval, the requested data is permitted to be used and disclosed in accordance with the Research Protocol. See requirements below.

**Information required in Research Protocol:** The Research Protocol will include how the PHI will be safeguarded by establishing:

- a) Who is permitted to use or receive data.
- b) That the PHI will not further used or disclosed other than as permitted by the protocol or as otherwise required by law.
- c) That the recipient will use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the research protocol.
- d) That the recipient will report to the covered entity any use or disclosure of information not provided for by the protocol of which it becomes aware.
- e) That any agents or subcontractors involved in the research project will abide by the safeguards and conditions set out in the protocol.
- f) That the recipient will not publish the PHI, unless as approved by
- g) That LARA owns the PHI.
- h) That all identifiable PHI data will be destroyed at the end of the project.

3. **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:**

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<i>De-identified Data</i>	<p>When data has had all individual identifiers removed (see De-identification Policy) then completely de-identified, data is permitted to be used or disclosed without an authorization or LARA review and approval for research purposes.</p>
<i>Data on Decedents</i>	<p>When any amount or type of PHI is requested to perform research on decedents without an authorization:</p> <p>Information is permitted to be disclosed without an authorization if:</p> <ul style="list-style-type: none"> <li>▪ Information sought is solely for research of decedents,</li> <li>▪ Information is necessary for the research, and</li> <li>▪ Requestor has documentation to prove the individual is deceased.</li> </ul> <p>Note: Other applicable laws may further restrict deceased individual's PHI for use or disclosure. Questions should be referred to the Privacy Office.</p>
<i>Limited Data Set:</i>	<p>When a request is made for a limited data set, where all identifiable data has been removed with the exceptions of dates and some demographical data (See Limited Data Set Policy and Procedure) and no authorization has been obtained:</p> <ul style="list-style-type: none"> <li>▪ The Privacy Officer must review and approve the request,</li> <li>▪ A data agreement must be entered into before disclosing PHI without an authorization.</li> </ul>

**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. 330.1749](#)