

## USE AND DISCLOSURE OF PHI FOR RESEARCH PURPOSES

**Policy Number:** [Enter]

**Effective Date:** [Enter]

### **I. Policy:**

#### **A. Purpose**

This policy establishes guidelines for [Organization]'s workforce to follow regarding the use or disclosure of PHI for research purposes.

#### **B. Policy Implementation**

##### **1. Overview: Authorization generally required**

The use/disclosure of PHI and health records for research purposes is subject to HIPAA and the Minnesota Health Records Act (the "MHRA"). Other requirements may also be relevant, depending on the type of information at issue. For example, if [Organization] maintains patient identifying information relating to substance use disorders, the federal Part 2 requirements will apply. See Policy Number [Insert], "Am I subject to 42 C.F.R. Part 2?" for additional information on Part 2.

Except as otherwise provided, HIPAA and this policy require [Organization] to obtain an individual's authorization prior to use or disclosure of that individual's PHI for research. Such authorization must be a signed document that meets the requirements of Policy Number [insert] regarding authorizations. The exceptions to this authorization requirement are outlined in Section I.B.4 of this policy. The MHRA does not require consent for [Organization] to use health records for [Organization]'s internal research. However, even in situations where HIPAA does not require a patient's authorization for disclosures of PHI for research, the MHRA generally requires [Organization] to obtain a specific form of consent from the patient prior to release of his or her health records to an external researcher. Finally, different rules will apply if the research involves information that meets the definition of a "limited data set" or "de-identified information." [Organization] may use and/or disclose a limited data set and de-identified data for research as permitted by Section I.B.9 of this policy.

##### **2. "Research" defined**

HIPAA defines *research* to mean a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Conducting quality assessment and improvement activities, including outcomes evaluation and the development of clinical guidelines is not "research" if the primary purpose of any studies resulting from such activities is not to obtain "generalizable knowledge." Such activities are "health care operations," for which [Organization] may use or disclose PHI as provided in Policy Number [insert].

### 3. Minimum necessary

[Organization] must limit its use and disclosure of PHI pursuant to this policy to the minimum necessary to accomplish the intended purpose of the use or disclosure, unless the minimum necessary requirement does not apply to the use/disclosure at issue or [Organization] is permitted to rely on a requested disclosure as meeting the minimum necessary standard. For example, the minimum necessary rule does not apply to uses and disclosures made pursuant to a valid authorization. Likewise, [Organization] is permitted to rely on a researcher's documentation of an IRB waiver of authorization (that meets the requirements below) that a requested disclosure satisfies the minimum necessary rule, assuming [Organization]'s reliance is reasonable under the circumstances. For information regarding the requirements of the minimum necessary rule and its various exceptions, refer to policy number [Insert], Minimum Necessary Requests for, or Uses or Disclosures of PHI.

### 4. Exceptions to HIPAA authorization requirement

[Organization] may use or disclose PHI for research without obtaining the individual's authorization only if any of the following are true:

- (a) Board Approval of Waiver of Authorization. [Organization] obtains documentation—that meets the requirements of Appendix A of this policy—that an alteration to or waiver, in whole or in part, of the individual authorization required by this policy has been approved by either:
  - a. An Institutional Review Board ("IRB") that meets the requirements of applicable law, including those stated in 45 C.F.R. § 164.512(i); or
  - b. A privacy board that:
    - i. Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;
    - ii. Includes at least one member who is not affiliated with [Organization], not affiliated with any entity sponsoring the research, and not related to any person who is affiliated with any of such entities; and
    - iii. Does not have any member participating in a review of any project in which the member has a conflict of interest.
- (b) Reviews Preparatory to Research. [Organization] obtains from the researcher representations that:

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- a. Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
- b. No PHI is to be removed from [Organization] by the researcher in the course of the review; and
- c. The PHI for which use or access is sought is necessary for the research purposes.

(c) Research on Decedent's Information. [Organization] obtains from the researcher:

- a. Representation that the use or disclosure sought is solely for research on the PHI of decedents;
- b. Documentation, at the request of [Organization], of the death of such individuals; and
- c. Representation that the PHI for which use or disclosure is sought is necessary for the research purposes.

**The MHRA generally requires [Organization] to obtain signed and dated patient consent prior to releasing health records. However, the MHRA has additional requirements that apply to research disclosures. If the disclosure is to an external researcher solely for purposes of medical or scientific research, [Organization] should refer to the MHRA requirements for consent described in Section I.B.5 of this policy even where [Organization] qualifies for an exception to HIPAA's authorization requirement. In addition, in making a release of health records to an external researcher, the MHRA indicates that providers are to make a reasonable effort to determine that:**

- (a) The use or disclosure does not violate any limitations under which the record was collected;**
- (b) The use or disclosure in individually identifiable form is necessary to accomplish the research or statistical purpose for which the use or disclosure is to be made;**
- (c) The recipient has established and maintains adequate safeguards to protect the records from unauthorized disclosure, including a procedure for removal or destruction of information that identifies the patient; and**
- (d) Further use or release of the records in individually identifiable form to a person other than the patient without the patient's consent is prohibited.**

**The MHRA does not dictate how these matters are to be ascertained or documented.**

**In addition, the MHRA does not provide that any form of patient consent is required for [Organization] to use health records within [Organization] for research. This is different than HIPAA, which requires authorization (or compliance with one of the exceptions to the authorization requirement) even if the activity is solely the internal use of PHI for research purposes and no external “disclosure” will occur.**

**In addition, if [Organization] is subject to 42 C.F.R. Part 2, it may only disclose patient identifying substance use disorder information for the purpose of conducting scientific research if consistent with Section I.B.7 of this policy.**

#### **5. Minnesota law requires consent prior to release of health records to an external researcher**

The MHRA requires providers to obtain consent that meets certain requirements to release health records to an external researcher solely for purposes of medical or scientific research. If [Organization] obtains a valid authorization to use or disclose PHI for research as required by Section I.B.1 of this policy, the authorization should be able to satisfy the MHRA requirement regarding consent to release the patient’s health records to an external researcher. [Organization] will also need to address compliance with the provision in subparagraph (c), noted below, which relates to advising the patient of certain information about the research.

Alternatively, if [Organization] does not obtain a HIPAA authorization, but meets one of the exceptions to HIPAA’s authorization requirements (stated in Section I.B.4), then [Organization] may release health records to an external researcher as long as [Organization] obtains consent as follows:

- (a) [Organization] must disclose in writing to patients currently being treated by the provider that health records, regardless of when generated, may be released and that the patient may object, in which case the records will not be released; and
- (b) [Organization] must use reasonable efforts to obtain the patient’s written general authorization that describes the release of health records for external research; and
- (c) [Organization] must advise the patient that, at the request of the patient, [Organization] will provide information on how the patient may contact an external researcher to whom the health record was released and the date it was released.

The patient’s consent described in this Section I.B.5 does not expire but may be revoked or limited in writing at any time by the patient or the patient’s authorized representative.

If [Organization] meets one of the exceptions to the HIPAA authorization requirement in Section I.B.4 and desires to release health records to an external

researcher as described above, one option for addressing the MHRA requirements is by including a provision in *[Organization's]* standard consent form that meets these requirements. This could include an “opt out” provision under which the patient will consent to the research disclosures unless he or she affirmatively opts out of that disclosure. Alternatively, *[Organization]* could seek separate consent from the patient for the release.

#### **6. Exceptions to Minnesota consent requirement for external research**

If one of the exceptions stated in Section I.B.4 applies, *[Organization]* may release PHI for research purposes without the patient’s authorization or consent, if:

- (a) The health records were generated before January 1, 1997 and the patient has not, at any time, objected to their release; or
- (b) *[Organization]* mailed a request for the patient’s written general authorization at least two times to the patient’s last known address with a postage prepaid return envelope and a conspicuous notice that the patient’s medical records may be released if the patient does not object, and at least 60 days have expired since the second notice was sent.

#### **7. Substance Use Disorder Patient Records**

If *[Organization]* is subject to 42 C.F.R. Part 2, *[Organization]* must comply with this Section I.B.7 and 42 C.F.R. § 2.52. For guidance on Part 2 and what constitutes “patient identifying information,” please see Policy Number *[Insert]*, “Am I subject to 42 C.F.R. Part 2?” and 42 C.F.R. § 2.11.

- (a) *[Organization]* may disclose patient identifying information for the purpose of conducting scientific research if the *[Organization]* [director] [chief executive officer] or their designee makes a determination that the recipient of patient information:
  - i. If a HIPAA-covered entity or business associate: has obtained and documented HIPAA authorization from the patient, or a waiver or alteration of authorization, as applicable.
  - ii. If subject to the HHS regulations regarding the protection of human subjects (45 CFR part 46): either provides documentation that the researcher is in compliance with the requirements of the HHS regulations, including the requirements related to informed consent or a waiver of consent (found in 45 CFR 46.111 and 46.116), or that the research qualifies for exemption under the HHS regulations (found in 45 CFR 46.101(b)) and any successor regulations.

- iii. If subject to both HIPAA and the HHS regulations regarding the protection of human subjects: has met the requirements for both (a) and (b) above.
- iv. If subject to neither HIPAA nor the HHS regulations regarding the protection of human subjects: these rules governing disclosure of Part 2 data for research (42 CFR § 2.52) do not apply.

A person conducting research may disclose individual identifying information obtained under this policy only back to [Organization] and may not identify any individual in any report of that research or otherwise disclose an individual's identity.

(b) An individual or entity conducting research using patient identifying information obtained under paragraph (a) of this section:

- i. Is fully bound by Part 2 and, if necessary, must resist in judicial proceedings any efforts to obtain access to substance use disorder patient records except as permitted by Part 2.
- ii. Must not re-disclose patient identifying information except back to [Organization].
- iii. May include part 2 data in research reports only in aggregate form in which patient identifying information has been rendered non-identifiable such that the information cannot be re-identified and serve as an unauthorized means to identify a patient, directly or indirectly, as having or having had a substance use disorder.
- iv. Must maintain and destroy patient identifying information in accordance with the security policies and procedures established under 42 CFR § 2.16.
- v. Must retain records in compliance with applicable federal, state, and local record retention laws.

## 8. Other special rules: Data Linkages and Substance Use Disorder Records

Researchers and Data repositories must comply with the following rules relating to data linkages.

- (a) Researchers: Any individual or entity conducting scientific research using patient identifying information obtained under Section I.B.7(a) that requests linkages to data sets from a data repository holding patient identifying information must:
  - i. Have their request reviewed and approved by an Institutional Review Board registered with Department of Health and Human Services and the Office for Human Research Protections, in accordance with 45 CFR part 46; and

- ii. Ensure that patient identifying information is not provided to law enforcement agencies or officials.

A researcher may not redisclose patient identifying information for data linkages purposes except as permitted by Part 2.

- (b) Data Repositories: Data repositories are fully bound by Part 2 upon receipt of patient identifying data. Data repositories must:

- i. After providing the researcher with the linked data, destroy or delete the linked data from its records, including sanitizing any associated hard copy or electronic media, to render the patient identifying information non-retrievable; and
- ii. Ensure that patient identifying information is not provided to law enforcement agencies or officials.

## 9. Other special rules: Psychotherapy notes

Certain types of particularly sensitive PHI may be subject to special rules. For example, except as provided in 45 C.F.R. § 164.508(a)(2), [Organization] may not use or disclose psychotherapy notes without the patient's authorization. This means that [Organization] would not be permitted to rely on the exceptions to authorization described in Section I.B.4 to use/disclose psychotherapy notes for research. Rather, [Organization] would need to obtain the appropriate type of authorization for a use/disclosure of psychotherapy notes for research.

## 10. Limited data set and de-identified health information

- (a) If consistent with Minnesota law and this section, [Organization] may use or disclose a "limited data set" for research purposes. A "limited data set" is defined in 45 C.F.R. § 164.514(e)(2) as PHI which excludes certain direct identifiers. Disclosures of a limited data set must be pursuant to a data use agreement substantially similar to [Organization]'s template data use agreement. See policy number [Insert], Template Data Use Agreement. [Organization] is not required to obtain HIPAA authorization for uses and disclosures of limited data sets that meet the requirements of 45 C.F.R. § 164.514(e).
- (b) If consistent with Minnesota law, [Organization] may use or disclose information that qualifies as "de-identified" information, as provided in 45 C.F.R. § 164.514(a)-(c). [Organization] is not required to obtain HIPAA authorization for uses and disclosures of de-identified information that meets the requirements of 45 C.F.R. § 164.514(a)-(c).

**Minnesota Law.** A limited data set, although devoid of direct identifiers, is still PHI and arguably would still qualify as “health records” under the MHRA. De-identified information likely does not qualify as “health records” under the MHRA. Minnesota law generally requires [Organization] to obtain signed and dated patient consent prior to releasing health records and, as discussed in Section I.B.5, specific requirements exist for disclosures of health records to external researchers. A consent that meets the requirements of Section I.B.5 would be sufficient to establish consent to release a limited data set for research purposes.

## 11. Other considerations.

There are a number of other federal guidelines that may interact with the privacy requirements described in this policy, depending on how [Organization] operates. For example, the U.S. Department of Health and Human Services “Common Rule” (See 45 C.F.R. Part 46) outlines standards for the protection of human subjects in federally funded research. Likewise, U.S. Food and Drug Administration regulations set forth certain requirements for human research involving FDA-regulated products (See 21 C.F.R. Parts 50, 56). These regulations impose their own standards related to research, including the type of patient permission necessary for research and alternatives when patient permission is not available. A discussion of these guidelines is beyond the scope of this policy. However, for helpful tools to use in understanding how HIPAA relates to these other federal laws, please see: <https://privacyruleandresearch.nih.gov/default.asp>.

## II. Procedure:

Prior to using or disclosing PHI for research, [Organization] staff should do the following:

- A. Determine whether the information is (1) de-identified information; (2) a limited data set; (3) substance use disorder records; (4) psychotherapy notes; or (5) PHI that does not include information in categories (2), (3) or (4). Follow the procedures for each set forth below:
- B. Note that depending on the scope of the research and the parties involved, other requirements may apply. For example, if [Organization] is using a business associate to create de-identified information or a limited data set for use by a third party researcher, [Organization]’s business associate agreement with the business associate will need to address the de-identification/limited data set.
- C. De-identified Information:
  - 1. Confirm that information meets the definition of de-identified information at 45 C.F.R. § 164.514(b).
  - 2. Confirm that [Organization] meets HIPAA’s requirements with respect to re-identification of de-identified information.



**D. Limited Data Set:**

1. Confirm that information meets the definition of a limited data set as outlined at 45 C.F.R. § 164.514(e)(2).
2. Confirm that [Organization] has a data use agreement with the recipient of the limited data set. *See* policy number [Insert], Template Data Use Agreement.
3. Confirm that the requirements of MHRA are met with respect to the limited data set.

**E. Substance Use Disorder Records:**

1. Determine if Part 2 applies to [Organization].
2. If Part 2 applies, confirm that the recipient of any patient identifying information meets the requirements of Section I.B.7 of this policy.

**F. Psychotherapy Notes:**

1. Confirm that a HIPAA compliant authorization exists to permit the use or disclosure of psychotherapy notes. *See* policy number [Insert], Use and Disclosure of Mental Health Records.
2. Confirm compliance with HIPAA compound authorization rule pursuant to which an authorization for use or disclosure of psychotherapy notes may only be combined with another authorization for use or disclosure of psychotherapy notes. Additional information can be found at 45 C.F.R. § 164.508(b)(3).

**G. Other Categories of PHI:**

1. Determine whether the activity is a use or disclosure of PHI for research.
2. If the activity is a use of PHI for research, confirm that a HIPAA-compliant authorization exists or that one of the exceptions outlined in Section I.B.4 is satisfied.
3. If the activity is a disclosure of PHI to an external researcher solely for purposes of medical or scientific research, confirm that a HIPAA-compliant authorization exists or that one of the exceptions outlined in Section I.B.4 is satisfied.
4. If the activity is a disclosure of PHI to an external researcher solely for purposes of medical or scientific research and [Organization] is relying on one of the exceptions outlined in Section I.B.4, confirm that a valid consent exists under the MHRA (as

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described in Section I.B.5) or that one of the exceptions to consent under the MHRA (as outlined in Section I.B.6) is met.

- H.** [Organization]’s Privacy Official or designee will comply with the above stated policy and ensure the compliance of other Workforce members.
- I.** [Organization]’s Privacy Official or designee will document any uses or releases pursuant to this policy in a manner that will allow [Organization] to provide an accounting of disclosures to patients (as may be required under applicable law). For example, an accounting of disclosures is not required for research disclosures made pursuant to an authorization or disclosures of a limited data set that occur in accordance with this policy.
- J.** [Organization]’s Privacy Official will confirm that [Organization] maintains documentation of IRB or Privacy Board alteration or waiver of authorization as required by this Policy (and described in Appendix A).

## Appendix A

### Documentation requirements for IRB or Privacy Board's alternation or waiver of authorization requirement

For a use or disclosure to be permitted by section I.B.4(a) of this policy, the documentation must include *all of the following*:

- (a) Identification and Date of Action. A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;
- (b) Waiver Criteria. A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:
  - a. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of 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 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
    - iii. Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule;
  - b. The research could not practicably be conducted without the waiver or alteration; and
  - c. The research could not practicably be conducted without access to and use of the PHI.
- (c) PHI Needed. A brief description of the PHI for which use or access has been determined to be necessary by the IRB or privacy board.
- (d) Review and Approval Procedures. A statement that the alteration or waiver of authorization has been reviewed and approved under either the normal or expedited review procedures, as follows:

- a. An IRB must follow the requirements of the “Common Rule.” *See, e.g.*, 45 C.F.R. §§ 46.108(b) & 46.110.
  - b. A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who is not affiliated with [Organization] or any entity sponsoring the research, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting unless the privacy board elects to use the “expedited review procedure” discussed directly below.
  - c. A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the PHI for which use or disclosure is being sought. If the privacy board elects to use this expedited review procedure, the review and approval of the alteration or waiver of the authorization may be carried out by the chair of the privacy board or one or more designated members of the privacy board.
- (e) Required Signature. The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or privacy board, as applicable.