



System-wide Policy: **Use and Disclosure of Protected Health Information for Research**

Reference #: SYS-ADMIN-RA-005

Origination Date: May 2016
 Next Review Date: July 2022
 Effective Date: July 2019

Approval Date: July 2019
Approved By: Research Oversight Committee

System-wide Policy Ownership Group: Research Administration

System Policy Information Resource: Director, Research Compliance

Stakeholder Groups
Research Administration
Human Research Protections Program (HRPP)
Compliance / Privacy Office
Health Information Privacy and Security (HIPS) Committee
Health Information Management
Legal and Risk Services

SCOPE:

Sites, Facilities, Business Units	Departments, Divisions, Operational Areas	People applicable to
Abbott Northwestern Hospital, Buffalo Hospital, Cambridge Medical Center, District One Hospital, Mercy Hospital, New Ulm Medical Center, Owatonna Hospital, Phillips Eye Institute, River Falls Area Hospital, Regina Hospital, St. Francis Regional Medical Center, United Hospital, Unity Hospital; WestHealth Inc.; Orthopedic Institute Surgery Center at COC; Allina Health Group; Allina Health Home Care Services; All other patient care business units; System Office	All departments, divisions, and operational areas	All persons performing research at Allina Health using Allina Health patient data

POLICY STATEMENT:

Allina Health (Allina) will abide by all federal and state regulatory requirements concerning the use and disclosure of protected health information (PHI) for research purposes, and will track the disclosure of PHI as required by the Health Information Portability and Accountability Act (HIPAA).

Minnesota law (the Minnesota Health Records Act) contains restrictions on access to PHI that are more protective of patient rights than HIPAA and therefore must be followed. Researchers must ensure compliance with both HIPAA and Minnesota law. To avoid confusion, throughout this policy we will refer to the “HIPAA Authorization” requirements, which are driven by HIPAA, and the “Minnesota Research Authorization” requirements, which are driven by the Minnesota Health Records Act. Both the HIPAA Authorization and Minnesota Research Authorization requirements must be met in order to use PHI for research purposes.

1. Requirement to Obtain HIPAA Authorization

1.1. HIPAA Authorization Requirement

Allina will obtain an individual’s voluntary and informed HIPAA Authorization before protected health information about that individual is used and/or disclosed for research purposes. This standard does not apply where HIPAA provides an exception to the HIPAA Authorization requirement (see Section 1.2 below for Exceptions to the HIPAA Authorization Requirement).

The research HIPAA Authorization is study-specific (i.e., each research study will have a separate Authorization) and must include the following criteria:

- 1.1.1. A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner;
- 1.1.2. The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure;
- 1.1.3. The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure;
- 1.1.4. A description of each purpose of the requested use or disclosure;
- 1.1.5. Authorization expiration date or expiration event that relates to the individual or to the purposes of the use or disclosure (“end of the



research study” or “there is no expiration” are permitted, including for the creation and maintenance of a research database or repository);

- 1.1.6. The signature of the research participant and date. If the individual’s legally authorized representative signs the Authorization, a description of the representative’s authority to act for the individual must also be provided.

1.2. Exceptions to the HIPAA Authorization Requirement

In certain instances, Allina is not required to obtain a signed HIPAA Authorization from the patient prior to the use and/or disclosure of PHI for research. Note that these exceptions apply only to the HIPAA Authorization requirement; patients may still need to provide a Minnesota Research Authorization (See Section 2).

Exceptions to the HIPAA Authorization requirement include:

- 1.2.1. Partial or Complete Waiver or Alteration of HIPAA Authorization Requirement. An Allina-designated IRB may act upon requests for a partial or complete waiver or alteration of the HIPAA Authorization requirement for certain studies that could not otherwise practicably be conducted.
- 1.2.2. De-identified Health Information. HIPAA Authorization is not required for the use or disclosure of de-identified health information for research, provided the data has been de-identified in accordance with Allina’s procedure *De-Identification of Patient Health Information (304-P-13)*.
- 1.2.3. Limited Data Set (LDS). HIPAA Authorization is not required to use or disclose health information, provided the health information is used or disclosed for research purposes and meets the criteria for a limited data set. A signed data use agreement must be in place between the recipient and Allina in accordance with Allina’s procedure *Limited Data Sets: Patient Health Information (304-P-14)*.
- 1.2.4. Research Using Decedent’s Information. HIPAA Authorization is not required for the research-related use and/or disclosure of a deceased person’s protected health information, provided Allina obtains written representation from the investigator stating that: (A) the use or disclosure sought is solely for research on the PHI of decedents; (B) documentation of the death of such individuals is available upon Allina’s request; and (C) the PHI for which use or disclosure is sought is necessary for the research purposes. The



HIPAA Privacy Rule protects PHI about a decedent for 50 years following the date of death of the individual. Research using PHI relating to decedents whose date of death is older than 50 years does not require authorization or the written representation noted above.

1.2.5. Activities Preparatory to Research. HIPAA Authorization is not required in instances where protected health information is accessed for purposes preparatory to research, and the PHI is **NOT** removed from Allina. Instead, Allina must obtain a written representation from the investigator stating that: (A) the use or disclosure of the PHI 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 the covered entity (Allina) by the researchers in the course of the review; and (C) the PHI for which use or access is sought is necessary for the research purpose. If the above representations are not met (e.g., PHI is being removed from Allina), the researcher must obtain a complete or partial waiver of the HIPAA Authorization requirement from the IRB.

1.2.6. Disclosure of Protected Health Information for a Public Health Activity. Individual Authorization is not required for disclosures of protected health information for a public health activity related to research, including disclosures to the FDA, so long as such disclosure is consistent with 42 CFR 164.512(b).

2. Requirement to Obtain Minnesota Research Authorization (MRA)

The requirements to obtain a Minnesota Research Authorization (MRA) vary depending on whether the recipient(s) of the PHI are Internal Researchers or External Researchers. See the Definitions in this Policy for the definitions of these terms.

2.1. Internal Researchers

Internal Researchers may access a patient's medical record (i.e., use PHI) for research or preparatory to research activities only if:

- a) the patient has signed a study-specific HIPAA Authorization and access is covered by that HIPAA Authorization; or
- b) the patient has not objected to the use of his/her medical records for research purposes.

2.2. External Researchers

External Researchers may access a patient's medical record (i.e., use PHI) for research or preparatory to research activities only if:

- a) the patient has signed a study-specific HIPAA Authorization and access is covered by that HIPAA Authorization, or
- b) the patient has authorized the use of his/her medical records for research purposes (e.g., signed the MRA).

3. Requirement to Track Disclosures

HIPAA offers patients an opportunity to request an accounting of all disclosures of their PHI. Therefore, disclosures of PHI to External Researchers must be tracked so that Allina can respond to such requests for an accounting.

Under HIPAA, access to PHI by an External Researcher or sharing PHI with an External Researcher is considered a "disclosure," and access to PHI by an Internal Researcher is considered a "use." When a patient requests an accounting, Allina is required to provide a list of all "disclosures;" there is no obligation to provide a list of all "uses."

3.1. Internal Researchers

If PHI will be accessed solely by Internal Researchers, such use need not be tracked for accounting purposes. If an Internal Researcher accesses PHI and then later discloses PHI to an External Researcher, such disclosure must be tracked pursuant to Section 2.2 of this Policy.

3.2. External Researchers

Tracking of disclosures to External Researchers is required unless one of the following **exceptions** applies:

- a) *Disclosure of De-Identified Data.* If PHI has been de-identified, there is no need to track the disclosure of such information.
- b) *Disclosure of Limited Data Set.* If a Limited Data Set is disclosed to an External Researcher who has signed a Data Use Agreement, there is no need to track the disclosure of such information.
- c) *Study-Specific Authorization.* If the patient has already signed a study-specific HIPAA authorization, and the disclosure to the External Researcher occurs in the context of that authorization, the disclosure need not be tracked.

- d) *Treatment purposes.* If PHI is being disclosed to a clinician (such as a physician, nurse practitioner, or physician assistant) for the purpose of obtaining treatment from that clinician, the disclosure need not be tracked. In this situation there should already be an established treatment relationship between the patient and the clinician, or the patient's physician must have requested a consultation from the clinician.

PROCEDURES:

Pursuant to the Allina policy stated above, Researchers must comply with both HIPAA and Minnesota law (MRA) when accessing protected health information for research purposes.

1. Satisfying the HIPAA Authorization Requirement

1.1. Authorization Requirement

Unless an exception applies, Researchers must obtain an individual's HIPAA Authorization. The Allina-designated IRB verifies that the Allina template HIPAA Authorization, or an alternate HIPAA Authorization, is properly used.

1.2. Exceptions to the HIPAA Authorization Requirement

1.2.1. Partial or Complete Waiver or Alteration of HIPAA Authorization Requirement.

Any researcher conducting research at Allina may request a partial or complete waiver or alteration of the Authorization requirement from an Allina-designated IRB.

1.2.2. De-identified Health Information. Use of de-identified health information for research purposes must comply with Allina's procedure *De-Identification of Patient Health Information (304-P-13)*.

1.2.3. Limited Data Set (LDS). Use of limited data sets for research must comply with Allina's procedure *Limited Data Sets: Patient Health Information (304-P-14)*.

1.2.4. Use and Disclosure of a Deceased Person's Protected Health Information for Research. When research includes PHI from decedents only, PHI may be used without an authorization or



waiver if the researcher submits a [research use of decedents' PHI attestation](#) to Allina's Health Information Management (HIM).

1.2.5. Use and Disclosure of Protected Health Information Preparatory to Research. PHI may be used for preparatory to research activities by submitting a [preparatory to research attestation](#) to Allina's Health Information Management (HIM).

2. Satisfying the Requirement to Obtain Minnesota Research Authorization (MRA)

Patient authorization that meets the requirements of the Minnesota Health Records Act can either be obtained through a HIPAA Authorization, which meets the standards of an MRA, or through the Consent for Release of Information, which is obtained through the patient registration process. The portion of the Consent for Release of Information relating to research is often referred to as the "MRA."

3. Special Rules for Internal Researchers

3.1. General Guidance. The term "Internal Researcher" is defined narrowly in the Definitions section of this policy. The term applies to an individual person, not to a particular study. Some individuals working on a study may be considered Internal Researchers, others may be External Researchers. It is important that individuals understand the status of others working with them on a research study, and ensure that this policy is complied with if disclosures are made to External Researchers working on the study. If individuals have questions regarding whether an individual is an Internal Researcher or an External Researcher, please contact the System Policy Information Resource listed above.

3.2. Requirement to Obtain Patient's Authorization under the Minnesota Health Records Act. Prior to reviewing a patient's medical record for preparatory to research activities or research, Internal Researchers will ensure that the patient has provided the required authorization. Internal Researchers may access a patient's medical record (i.e., use PHI) for research or preparatory to research activities only if: (a) the patient has signed a study-specific HIPAA Authorization and access is covered by that HIPAA Authorization; or (b) the patient has not objected to the use of his/her medical records for research purposes.

a) Study-specific HIPAA Authorization. If a patient has signed a study-specific HIPAA Authorization, researchers do not need to check the MRA status of the patient prior to accessing the patient's medical record for that study. Even if a patient

objected to the general use of his/her medical record (i.e., status under “AHC Consent for Use of Records in Research is “No”), researchers can still access and use the medical record for the study to which the HIPAA Authorization applies.

- b) *Patient has not objected to the use of his/her medical records for research purposes.* If a patient has objected to the use of medical records for research purposes, an Internal Researcher will not access the patient’s medical record unless the patient has signed a study-specific HIPAA Authorization and access is covered by that HIPAA Authorization.

In general, Internal Researchers can determine if a patient has objected to the use of his/her medical records for research by checking the patient’s status in Excellian for “AHC Consent for Use of Records in Research.” If the patient’s status is “No,” the patient has objected to the use of his/her medical records for research purposes. Guidance for determining whether a patient has objected to the use of their records for research purposes is provided in an Excellian tip sheet “Documenting Access to or Disclosure of Protected Health Information for Research when a Research Authorization is Not Present.”

If the study involves older records maintained only in paper form, the researcher may consult Allina HIM for guidance on how to confirm that the patient has not objected on his/her MRA.

3.3. *Tracking Access to Medical Records.* There is no requirement for Internal Researchers to track their access to a patient’s medical record. If PHI is accessed by or disclosed to an External Researcher, the disclosure must be tracked in accordance with the Section 4.3 below.

4. Special Rules for External Researchers

4.1. General Guidance. The term “External Researcher” is defined in the Definitions section of this policy. The term applies to an individual person, not to a particular study. Some individuals working on a study may be considered Internal Researchers, others may be External Researchers. It is important that individuals understand the status of others working with them on a research study, and ensure that this policy is complied with if disclosures are made to External Researchers working on the study. A physician who is on the hospital’s medical staff but is not employed by Allina is generally considered an External Researcher, not an Internal Researcher. If individuals have questions regarding whether an individual is an Internal Researcher or an External Researcher, please contact the System Policy Information Resource listed above.

4.2. Requirement to Obtain Patient's Consent under the Minnesota Health Records Act. Prior to reviewing a patient's medical record, External Researchers must determine whether a patient has consented to the use of their medical records for research purposes. External Researchers may access a patient's medical record (i.e., use PHI) for research or preparatory to research activities only if: (a) the patient has signed a study-specific HIPAA Authorization and access is covered by that HIPAA Authorization; or (b) the patient has consented to the use of his/her medical records for research purposes.

- a) Study-specific HIPAA Authorization. If a patient has signed a study-specific HIPAA Authorization, researchers do not need to check the MRA status of the patient prior to accessing the patient's medical record for that study. Even if a patient objected to the general use of his/her medical record (i.e., status under "AHC Consent for Use of Records in Research is "No"), researchers can still access and use the medical record for the study to which the HIPAA Authorization applies.
- b) Patient has consented to the use of his/her medical records for research purposes. External Researchers may access a patient's medical record for research if the patient has consented the use of his/her medical record for research.

If the study involves older records maintained only in paper form, the researcher may consult Allina HIM for guidance on where to find the consent form addressing the MRA requirement.

- c) Limited Data Sets and De-identified Data Sets. External Researchers may be provided with de-identified data or data contained in a Limited Data Set for those patients who have either 1.) consented to the use of their medical record for research (i.e., MRA status is yes); or 2.) not objected to the use of their medical records for research (i.e., MRA status is blank).
- d) Checking for a Patient's Consent. In general, External Researchers can determine if a patient has objected to the use of his/her medical records for research by checking the patient's status in Excellian for "AHC Consent for Use of Records in Research." If the patient's status is "No," the patient has objected to the use of his/her medical records for research purposes. Guidance for determining whether a patient has objected to the use of their records for research purposes is

provided in an Excellian tip sheet “Documenting Access to or Disclosure of Protected Health Information for Research when a Research Authorization is Not Present” and in the “MRA Decision Tree.”

4.3. Tracking Access to Medical Records.

HIPAA offers patients an opportunity to request an accounting of all disclosures of their PHI. Therefore, disclosures of PHI to External Researchers must be tracked so that Allina can respond to such requests for an accounting.

External Researchers are required to make a record of (i.e. track) all access to Allina medical records, whether the access is to an electronic patient record maintained in Excellian, or a paper record. HIPAA gives patients the right to request an accounting from a covered entity, like Allina, that identifies any individual or entity to whom their records were disclosed. The record that results from this tracking requirement will be maintained by Allina’s Health Information Management (HIM) department, and will be used to respond to patient requests for an accounting.

The requirement for External Researchers to track access to medical records exists whether or not the access was preparatory to research or part of a clinical study. The requirement also applies even if the research site has obtained a waiver or partial waiver of the authorization requirement from a Privacy Board or IRB.

4.3.1. Determine whether tracking is required.

Tracking is not required if one of the following **exceptions** applies:

- a) *Disclosure of De-Identified Data.* If PHI has been de-identified, there is no need to track the disclosure of such information.
- b) *Disclosure of Limited Data Set.* If a Limited Data Set is disclosed to an External Researcher who has signed a Data Use Agreement, there is no need to track the disclosure of such information.
- c) *Study-Specific Authorization.* If the patient has already signed a study-specific HIPAA authorization, and the disclosure to the External Research occurs in the context of that authorization, the disclosure need not be tracked.
- d) *Treatment purposes.* If PHI is being disclosed to a clinician (such as a physician, nurse practitioner, or physician assistant) for the purpose of obtaining treatment from that clinician, the

disclosure need not be tracked. In this situation there should already be an established treatment relationship between the patient and the clinician, or the patient's physician must have requested a consultation from the clinician.

4.3.2. Process for tracking disclosures

There are two methods for tracking access to a patient's medical record for research purposes.

- a) *Chart-by-Chart*. Tracking access to a patient's medical record for research purposes is contained in an HIM tip sheet entitled "Documenting Access to or Disclosure of Protected Health Information for Research when a Research Authorization is Not Present." If a number of records are to be accessed, HIM can design a template for use with a particular study that makes the information required by the form auto populate when used while reviewing a specific record.
- b) *50 or More*. If there are disclosures to an External Researcher for 50 or more individuals, HIPAA permits an abbreviated tracking procedure. Rather than tracking disclosures on a patient-by patient basis, research sites may submit a "[Disclosures of 50+ Patients' PHI for Research Form](#)" in accordance with the instructions on the form (click [here](#) for a form that does not require AKN Access). No further tracking is required. The form shall include the following information:
 - The name of the protocol or other research activity;
 - A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
 - A brief description of the type of PHI that was disclosed
 - The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period; and
 - The name, address, and telephone number of the entity that sponsored the research and of the External Researcher to whom the information was disclosed;

DEFINITIONS:



The definitions of the **underlined terms** can be found in the [Privacy & Security Glossary of Terms](#). Since this policy applies to individuals who may not have access to the Privacy & Security Glossary of Terms (on the AKN), the definition of certain key terms have been restated below. To the extent that the definitions of underlined terms below conflict with the definitions in the Glossary, the definitions in the Glossary shall control.

Alteration of the HIPAA Authorization requirement occurs when the IRB approves an alteration to the requirements for an authorization. For example, the IRB could allow an HIPAA Authorization to be provided verbally rather than in writing.

Data Use Agreement means a written agreement between Allina and a person or entity, that meets certain requirements, which permits the use and disclosure of protected health information in a Limited Data Set for research, health care operations, or public health purposes.

Disclosure means the release, transfer, and provision of access to, or divulging of protected health information to an External Researcher.

Electronic health record (EHR) means the patient's Medical Record that is maintained in electronic form.

External Researcher means a researcher who is not an Internal Researcher.

Healthcare provider refers to individuals and entities engaged in the delivery of medical or health care to individuals, including providers (for example, physicians, dentists, psychologists, chiropractors, nursing homes, pharmacies, hospitals and clinics) and, any other person or entity who furnishes, bills, or is paid for health care in the normal course of business.

HIPAA Authorization is written permission for a research subject (or his/her legally authorized representative) allowing the use and disclosure of his or her health information for research purposes. In this policy, "Study Specific HIPAA Authorization" refers to authorizations that relate to a single study, as well as authorizations that relate to a category of studies (including future use).

Institutional Review Board (IRB) is a committee formally designated by an institution to review research involving human subjects. The Institutional Review Board approves the initiation of new research and conducts reviews of ongoing research, and has sole discretion to approve an alteration to or waiver, in whole or in part, of the individual Authorization required by the Privacy rule.

Internal Researcher means employees of Allina Health and other individuals designated as Internal Researchers by the Compliance Department.

Limited Data Set (LDS) means a set of patient health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual, and which may be used or disclosed with a Data Use Agreement for the purposes of research, public health, or health care operations:

- (i) Names;
- (ii) Postal address information, other than town or city, State, and zip code;
- (iii) Telephone numbers;
- (iv) Fax numbers;
- (v) Electronic mail addresses;
- (vi) Social security numbers;
- (vii) Medical record numbers;
- (viii) Health plan beneficiary numbers;
- (ix) Account numbers;
- (x) Certificate/license numbers;
- (xi) Vehicle identifiers and serial numbers, including license plate numbers;
- (xii) Device identifiers and serial numbers;
- (xiii) Web Universal Resource Locators (URLs);
- (xiv) Internet Protocol (IP) address numbers;
- (xv) Biometric identifiers, including finger and voice prints; and
- (xvi) Full face photographic images and any comparable images.

Medical Record means the documentation of the patient's medical care at Allina Health. This may include records received from other providers or facilities that are incorporated into Allina Health record of the patient's medical care. It may include secondary records and correspondence that documents the clinical care.

Minnesota Research Authorization (MRA) refers to the written consent of a patient or a patient's legal representative allowing the release of health records to a researcher.

Patient is defined as a person who has received health care services from a provider for treatment or examination of a medical, psychiatric, or mental condition.

Preparatory to research means actions taken to prepare for research such as designing a research study, assessing the feasibility of conducting a study, determining if the population base needed for the research exists, or identifying potential subjects.

Protected health information means health information, including demographic information, that is individually identifiable (i.e., contains patient-specific information) and that is created, maintained, received, used or disclosed by or for an Allina Business Unit or other covered entity. More specifically, the term refers to information that:

- (i) identifies or could reasonably be used to identify the individual; and
- (ii) related to:
 - a. the past, present or future physical or mental health or condition of an individual;
 - b. the provision of health care to an individual; or
 - c. the past, present, or future payment for health care provided to an individual

PHI excludes information in education records, in employment records held by a covered entity in its role as employer; and regarding a person who has been deceased for more than 50 years.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research also means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Research staff refers to anyone who is a member of the research team.

Waiver, Complete of the HIPAA Authorization requirement occurs when the IRB determines that no authorization will be required before PHI is used or disclosed for research purposes by an Internal or External Researcher.

Waiver, Partial of the HIPAA Authorization requirement occurs when the IRB determines that Allina does not need an HIPAA Authorization for all PHI uses and disclosures for research purposes. For example, the IRB could determine that an Authorization is not necessary if PHI is being reviewed for research recruitment purposes, but is necessary if the patient enrolls in the research.

FORMS:

[Disclosures of 50+ Patients' PHI for Research Form](#)
(click [here](#) for a form that does not require AKN Access).

[Preparatory to Research Attestation](#)

[Research on Protected Health Information of Decedents Attestation](#)

ADDENDA: Not applicable.

REFERENCES:

Scanning procedures (Ambulatory, Hospitals) – [Excellian Tip Sheet](#),
Excellian.net

Documenting Access to or Disclosure of Protected Health Information for
Research when a Research Authorization is Not Present, [MRA Decision Tree](#)

Related Regulation and Laws: 45 CFR 164.501, 164.508, 164.512(i),
164.528; Minn. Stat. § 144.295; GDPR: Regulation (EU) 2016/679 of the
European Parliament and of the Council of 27 April 2016 on the protection of
natural persons with regard to the processing of personal data and on the free
movement of such data, and repealing Directive 95/46/EC (General Data
Protection Regulation)

Alternate Search Terms: MRA, research authorization, preparatory to
research

RELATED POLICIES:

Name of Policy	Content ID	Business Unit where Originated
Use and Disclosure of Protected Health Information (PHI)	SYS-PSC-703	
De-Identification of Patient Health Information	304-P-13	
Limited Data Sets: Patient Health Information	304-P-14	

POLICIES REPLACING:

Name of Policy	Content ID	Business Unit where Originated
Use and Disclosure of Protected Health Information for Research, Allina Policy PSC-311		

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System-wide Policy

RESEARCH ON PROTECTED HEALTH INFORMATION OF DECEDENTS ATTESTATION

This form must be submitted to Health Information Management (HIM) when accessing Protected Health Information (PHI) for purposes of research when the research is **solely** on the PHI of decedents without a waiver from the IRB. If you have questions about this form and/or the research privacy policies at Allina Health, please contact the Director of Research Compliance at researchcompliance@allina.com. Send the completed form to **Attn: Document Management, Mail Route 20300, 2828 10th Avenue So., Minneapolis, MN 55407.**

If you cannot make the representations listed below, you need to seek a waiver from the IRB. To contact the IRB, please email IRB@allina.com.

PI INFORMATION

Principal Investigator Name

Phone #

Street Address

City/State/Zip

Email Address

Name of Study/Project (use same name as provided in IRBNet if possible): _____

IRBNet# (if applicable): _____

The researcher represents that:

- Use or disclosure sought is solely for research on the protected health information of decedents.
- At the request of Allina Health, researcher will provide documentation of the death of the individuals about whom information is being sought.
- The protected health information for which use or disclosure is sought is necessary for research purposes.
- Researcher will safeguard data to protect it from unauthorized disclosure.
- The protected health information will not be re-used or disclosed to any other person or entity, except as required by law, for the authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Regulation (45 CFR 164.512)

Signature of Researcher (Principal Investigator)

Date

Send the completed form to:

Attn: Document Management, Mail Route 20300, 2828 10th Avenue So., Minneapolis, MN 55407

PREPARATORY TO RESEARCH ATTESTATION

This form must be submitted to Health Information Management (HIM) when accessing to Protected Health Information (PHI) for purposes preparatory to research without a waiver from the IRB. If you have questions about this form and/or the research privacy policies at Allina Health, please contact the Director of Research Compliance at researchcompliance@allina.com. Send the completed form to **Attn: Document Management, Mail Route 20300, 2828 10th Avenue So., Minneapolis, MN 55407.**

Preparatory to research means actions taken to prepare for research, such as designing a study, assessing the feasibility of conducting a study, and determining existence of necessary population base, including chart review. If you cannot make the representations listed below, you need to seek a partial waiver from the IRB. To contact the IRB, please email: irb@allina.com.

PI INFORMATION

Principal Investigator Name

Phone #

Street Address

City/State/Zip

Email Address

Name of Study/Project (use same name as provided in IRBNet if possible): _____

IRBNet#: _____

The researcher represents that:

- Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research.
- No protected health information is to be removed from Allina Health by the researcher in the course of the review;
- The protected health information for which use or access is sought is necessary for research purposes.
- Researcher will safeguard data to protect it from unauthorized disclosure.
- The protected health information will not be re-used or disclosed to any other person or entity, except as required by law, for the authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Regulation (45 CFR 164.512)

Signature of Researcher (Principal Investigator)

Date

Send the completed form to:

Attn: Document Management, Mail Route 20300, 2828 10th Avenue So., Minneapolis, MN 55407

DISCLOSURES OF 50+ PATIENTS' PHI FOR RESEARCH FORM

The Privacy Regulations issued under the Health Insurance Portability and Accountability Act (“HIPAA”) and Allina Health’s policy, *Use and Disclosure of Protected Health Information for Research* (the “Policy”), require that researchers track all disclosures of PHI outside of Allina Health. There are exceptions for disclosures of de-identified data, data in a limited data set, data disclosed pursuant to a study-specific authorization, and disclosures made for purposes of treatment, payment, or operations.

If you anticipate that you will disclose PHI for 50 or more individuals to an External Researcher¹ (as defined in the Policy) for a particular research study, you may submit this form rather than tracking each disclosure individually. The disclosures do not necessarily need to be made to the same External Researcher.

If you do not submit this form but have made disclosures of PHI for research, you must track such disclosures individually consistent with the Policy.

Study Title (as it appears in IRB application): _____

IRBnet (if applicable) #: _____

Name and Email Address of Person Completing this Form: _____

Principal Investigator: _____

Brief description (3-4 sentences) in plain language of this study, including the purpose of the study and the criteria for selecting particular records:

Research site/service line (select best fit):

- Care Delivery
- Cardiovascular (e.g., MHVI, UHVC, MHI/F)
- Integrative Health and Healing (PGIHH)
- Neuroscience (JNNI)
- Nursing
- Oncology (e.g., VPCI)
- Orthopedics and Spine
- Rehabilitation (CKRI)
- Other: _____

Type of PHI disclosed (select all that apply):

- Demographic
- Clinical
- Billing
- Other: _____

¹ In general, “External Researcher” is defined as an individual who is not employed by Allina Health. The term is further defined in the policy *Use and Disclosure of Protected Health Information for Research*.

Date or period of time during which the disclosures are likely to occur: _____ through _____
[calendar date] [calendar date]

Sponsor Name: _____

Sponsor Address: _____

Sponsor Phone: _____

External Researcher Name: _____

External Researcher Address: _____

External Researcher Phone: _____

Notice: Any information provided on this form (including names, addresses and phone numbers) may be provided to patients who request an accounting of their PHI disclosures.

If a patient requests an accounting of his/her disclosures, Allina Health is obligated to identify whether it is reasonably likely that his/her PHI was disclosed for a particular research protocol, and if so, Allina Health must assist the patient in contacting the sponsor or External Researcher. If a patient requests further detail about the study listed above, the individual who filled out the form and/or any member of the study staff may be contacted to help identify whether a particular patient's PHI may have been disclosed in the course of this study.

****Submit this form to researchcompliance@allina.com****