Allina Health

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

Reference #: SYS–ADMIN-RA-005

Origination Date: May 2016
Next Review Date: November 2026
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Approval Date: November 2023
Approved By: Research Advisory Committee (RAC)

System-wide Policy Ownership Group: Research Integrity

System Policy Information Resource: Director, Research Integrity

Stakeholder Groups
Research Operations
Human Research Protection Program (HRPP)
Compliance & Privacy
Health Information Management
Legal and Risk Services

SCOPE:

Sites, Facilities, Business Units	**Departments, Divisions, Operational Areas**	**People applicable to**
Allina Health Group, Abbott Northwestern Hospital, Abbott Northwestern Hospital – WestHealth, Buffalo Hospital, Cambridge Medical Center, Faribault Medical Center, Mercy Hospital, Mercy Hospital – Unity Campus; New Ulm Medical Center, Owatonna Hospital, River Falls Area Hospital, St. Francis Regional Medical Center, United Hospital, United Hospital – Hastings Regina Campus, Allina Health Emergency Medical Services, Orthopedic Institute Surgery Center at COC; Allina Health Home Care Services; All other patient care business units; System Office	All departments, divisions, and operational areas	All Researchers, Internal or External, performing Research at Allina Health using Allina Health Medical Records

POLICY STATEMENT:

Allina Health (Allina) will abide by all federal and state regulatory requirements concerning the Use and Disclosure of patient Medical (Health) Records and/or 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).

Researchers, Internal and External, conducting Research using Health Records at Allina Health must ensure compliance with both HIPAA and Minnesota law. The Minnesota Health Records Acts (MHRA) requires that patients authorize the release (Disclosure) of their Health Records to External Researchers. This authorization is called the Minnesota Research Authorization (MRA). Both the HIPAA Authorization and MRA requirements must be met to Use and Disclose patient Health Records for Research at Allina Health.

This policy also defines the terms Internal and External Researcher for the purposes of the MRA. These terms apply to individual Researchers, not solely to the Principal Investigator or to the study team in general. Therefore, some Researchers working on a study may be Internal Researchers while others are External Researchers. It is the responsibility of the Principal Investigator to ensure that this policy is followed.

This policy applies to all identifiable and de-identified data from the Medical or Health Records at Allina Health. It does not apply to data that is anonymous (i.e., data that was collected without identifiers without intervention, interaction, or extraction from the Medical Record; data for which there is no way for the Researchers or anyone else to identify the source).

DEFINITIONS:

Data Use Agreement: 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 that establishes the ways in which the information may be used and how it will be protected.

Disclosure: The release, transfer, provision of access to, or divulging of information in any other manner of PHI and/or Individually Identifiable Information outside Allina Health (e.g., to an External Researcher).

External Researcher: A Researcher who is not an Internal Researcher.

Health Record: See Medical Record.

HIPAA Authorization: Written permission by the patient or the patient's personal representative to Use and/or Disclose Protected Health Information about the individual. The requirements of a valid authorization are defined in the HIPAA regulations.

Institutional Review Board (IRB): A committee formally designated by the institution that prospectively reviews and makes determinations concerning all human subjects Research conducted at Allina Health facilities, by its employees or agents, or under its auspices unless an external IRB has been designated to do so.

Internal Researcher: A Researcher who is (1) employed by Allina Health and/or the organizations covered by the Allina Health Notice of Privacy Practices and/or owned by the Allina Health System, (2) credentialed as a member of the Allina Health Medical Staff, (3) affiliated through a direct contract at Allina Health facilities, related sites, and specialty programs, or (4) as designated by the Compliance & Privacy Department.

Limited Data Set (LDS): A dataset of patient health information that excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual, and which may be Used or Disclosed only with a Data Use Agreement for the purposes of Research, public health, or health care operations.

Medical Record: Any documentation of a patient's medical care at Allina Health. This may include records received from other providers or facilities that are incorporated into the Allina Health Record of the patient's medical care, physical or mental condition of the patient, and payment for the provision of medical care to the patient. It may include secondary records and correspondence that documents clinical care. Also referred to as Health Record.

Minnesota Research Authorization (MRA): The requirement to obtain authorization to release a patient's Health Records to an External Researcher solely for the purposes of medical or scientific Research. At Allina Health, patients may provide authorization or decline the Use and Disclosure of their Medical Records for Research purposes when presented with the Release of Information (ROI) form. MRA status must be verified for Research when HIPAA Authorization is not to be obtained (e.g., chart review Research).

MRA-no: An MRA status that denotes that a patient has explicitly declined the Use and Disclosure (release) of their Medical Records for Research purposes on the ROI form (i.e., they checked the box to opt out of records Research and signed the form). If data from Medical Records are to be Used or Disclosed for Research purposes by any Researcher without HIPAA Authorization (e.g., chart review Research), MRA-no must be excluded. An MRA-no status does not mean that a patient will never be contacted about participating in any Research study.

Those with a status of MRA-no can enroll in Research with HIPAA Authorization, however, this enrollment does not change their MRA status for other Research.

MRA-yes: An MRA status that denotes that a patient has provided consent for the Use and Disclosure of their Medical Records for Research purposes on the ROI form (i.e., they did NOT select the box to object to the Use and Disclosure and signed the form). If data from Medical Records are to be Disclosed to an External Researcher, an MRA-yes status must be confirmed prior to the Use and Disclosure of information from the Medical Records for Research purposes. An MRA-yes does not replace HIPAA Authorization for studies that require it.

Preparatory to Research: 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 as allowed under the HIPAA Privacy Rule.

Protected Health Information (PHI): 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: A systematic investigation, including Research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes the development of Research repositories and databases for Research. 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.

Researcher: Anyone who is a member of the Research team including, but not limited to, the Principal Investigator.

Use: With respect to Individually Identifiable Health Information, the sharing, employment, application, utilization, examination, or analysis of such information within the entity or health care component (for hybrid entities) that maintains such information.

Waiver or Alteration of Authorization: The documentation that the covered entity obtains from an investigator or an IRB or a Privacy Board that states that the IRB or Privacy Board has waived or altered the Privacy Rule's requirement that an individual must authorize a covered entity to Use or Disclose the individual's PHI for Research purposes.

PROCEDURES:

1. Requirement to Obtain HIPAA Authorization

1.1. HIPAA Authorization Requirement

Following IRB approval, Researchers will obtain an individual's voluntary and informed HIPAA Authorization before PHI 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 elements (45 CFR §164.508(c)(1)) and required statements (45 CFR § 164.508(c)(2)):

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 study-specific 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.

1.1.7. The Research participant's right to revoke their Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the Research participant may revoke Authorization or (2) reference to the corresponding section(s) of the Allina Health Notice of Privacy Practices.

1.1.8. Notice of Allina Health's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including Research-related treatment, and, if applicable, the consequences of refusing to sign the Authorization.

1.1.9. The potential for the health information (PHI) to be re-Disclosed and that any re-Disclosure is not protected by the Privacy Rule.

1.1.10. Notice that a Research participant may revoke their Authorization at any time and that PHI already collected may continue to be Used and Disclosed.

1.2. Exceptions to the HIPAA Authorization Requirement

In certain instances, Researchers are 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; a patient's Minnesota Research Authorization (MRA) status may still need to be verified (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. The HIPAA Privacy Rule provides

the standards for the de-identification of PHI. 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*), which is compliant with the standards under HIPAA. Data that is de-identified under HIPAA may still be considered human subject data under the Common Rule and/or the FDA regulations and may require IRB review and approval before Research Use. MRA status verification also applies to de-identified data (see Section 2).

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 (health information that excludes 16 specific categories of direct identifiers specified in the HIPAA Privacy Rule). 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 (SYS-PSC-706).* MRA status verification also applies to an LDS (see Section 2).

1.2.4 Research Using Decedents' Information. The HIPAA Privacy Rule protects the identifiable health information about a decedent for 50 years following the date of death of the individual. HIPAA Authorization is not required for the Research-related Use and/or Disclosure of a deceased person's PHI when Allina obtains written attestation 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 investigator certifies these requirements through the submission of the Research Use of Decedents' PHI Attestation to Allina Health's IRB Office. Research using PHI relating to decedents whose date of death is older than 50 years is not subject to HIPAA protections and does not require authorization, nor the written attestation noted above. A Researcher may Disclose a decedent's Medical Records for Research purposes only in accordance with the decedent's MRA status, which prevails after the patient's death.

1.2.5. Activities Preparatory to Research. HIPAA Authorization is not required in instances where PHI is accessed for purposes Preparatory to Research and the PHI is **NOT** removed from the Allina Health System. Instead, Allina must obtain the written Preparatory to Research Attestation from the Researcher 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 Health System) 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 (and MRA status verification).

1.2.6. Disclosure of Protected Health Information for a Public Health Activity. Individual Authorization is not required for Disclosures of PHI 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 Verify Minnesota Research Authorization (MRA) Status

2.1. MRA Requirement

The MRA process requires that Allina Health obtain general authorization from patients seen in their hospitals and clinics or other affiliated Minnesota entities before using their Medical Records for Research in general. The requirements to verify MRA status vary depending on whether the recipient(s) of the Health Records, including PHI, are Internal Researchers or External Researchers. See the Definitions in this Policy for the definitions of these terms. Verification of MRA status only applies in cases where study-specific HIPAA Authorization is not sought.

If a study-specific HIPAA Authorization will be signed, Researchers do not need to verify the subject's MRA status prior to accessing the Medical Record for study purposes, including screening and recruitment purposes. Even if a patient objected to the general Use and Disclosure of their Medical Record (MRA-no), Researchers can still approach these patients for enrollment in studies requiring study-specific HIPAA Authorization. They can also access and Use the Medical Records for the study to which the HIPAA Authorization applies.

Upon the death of a patient, the MRA status they indicated on the Release of Information consent form (ROI) continues to apply, therefore, the MRA status of decedents needs to be verified by Researchers who intend to Disclose Medical Records to an External Researcher.

Researchers can determine if a patient has objected to or authorized the Use or Disclosure of their Medical Records for Research by checking the patient's status in Excellian for "AHC Consent for Use of Records in Research." In general, if the patient's status is listed as "No," (also referred to as MRA-no) the patient has

objected to the Use and Disclosure of their Medical Records for Research purposes. If the patient's status is "Yes," (also referred to as MRA-yes), they have allowed Allina Health to Use and Disclose their Medical Records for Research purposes in general.

2.1.1. Internal Researchers

Internal Researchers may access a patient's Medical Record (i.e., Use Allina Health Records, including PHI) for Research only if:

a) the patient has signed a study-specific HIPAA Authorization and access is covered by that HIPAA Authorization; or

b) the patient (living or deceased) has not objected to the Use of their Medical Records for Research purposes. Any patient with an MRA-no status must be excluded from Research that does not seek study-specific HIPAA Authorization.

Internal Researchers do not need to verify MRA status for Preparatory to Research activities when they have a partial HIPAA waiver for screening and/or recruitment from the IRB or submit and follow the provisions outlined in the Preparatory to Research Attestation.

2.1.2. External Researchers

External Researchers may access a patient's Medical Record (i.e., Use Allina Health Medical Records, including PHI) for Research only if:

a) the patient has signed a study-specific HIPAA Authorization and Use and Disclosure are covered by that HIPAA Authorization, or

b) the patient (living or deceased) has authorized the Use and Disclosure of their Medical Records for Research purposes. Research involving External Researchers must verify an MRA-yes status to Use and Disclose these Health Records for Research purposes.

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 when records have a verified MRA-yes.

For activities Preparatory to Research, External Researchers may only access Medical Records, including PHI, when the PHI does not leave

Allina Health (i.e., PHI may be reviewed by an External Researcher within the confines of Allina Health) following the provisions in the Preparatory to Research Attestation. No MRA status verification is required for this process. If a study has a partial HIPAA waiver for screening and/or recruitment or a submitted Preparatory to Research Attestation, an External Researcher may screen records within the covered entity without MRA status verification.

3, Requirement to Track Disclosures Under HIPAA

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 accounting.

Under HIPAA, Disclosure of PHI outside of the covered entity (i.e., disclosing PHI to an External Researcher) is considered a Disclosure and access to PHI within the covered entity (i.e., 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 Uses PHI and then later Discloses PHI to an External Researcher, such Disclosure must be tracked pursuant to Section 3.2 of this Policy.

3.2 External Researchers

The HIPAA Privacy Rule generally grants individuals the right to a written “Accounting of Disclosures” of their PHI made by a covered entity without the individual’s authorization in the six years prior to their request for an Accounting.

External Researchers are required to record (i.e., track) all access to Allina Health Medical Records, whether the access is to an electronic patient record maintained in Excellian or a paper record. MRA status, as explained in section 2 of this policy, must be verified as applicable to the study for any Disclosures. 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 Compliance & Privacy Department and will be used to respond to patient requests for accounting.

Under HIPAA, 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. MRA status verification would be required for de-identified data.

b) *Disclosure of Limited Data Set*. If a Limited Data Set (LDS) is Disclosed to an External Researcher who has signed a Data Use Agreement, there is no need to track the Disclosure of such information. MRA status verification would be required for an LDS.

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.

3.3 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 multiple 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+ Disclosures:** 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 (See Research Compliance page the form). 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;

FORMS:

See Research Compliance page for the following forms:

- Disclosures of 50+ Patients' PHI for Research Form
- 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 Disclosures - ROI: Documenting and Disclosure of Protected Health Information for Research When a Study-Specific HIPAA Authorization for Research is Not Present, Excellian.net

See Research Compliance page for the 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, HIPAA authorization, preparatory to research, disclosure, PHI

RELATED POLICIES:

Name of Policy	Content ID	Business Unit where Originated
Use and Disclosure of Protected Health Information (PHI)	SYS-PSC-703	Compliance & Privacy
De-Identification of Patient Health Information	SYS-PSC-705	Compliance & Privacy
Limited Data Sets: Patient Health Information	SYS-PSC-706	Compliance & Privacy

POLICIES REPLACING:

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

RESEARCH ON PROTECTED HEALTH INFORMATION OF DECEDENTS ATTESTATION

This form must be submitted to the IRB Office 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 IRB Office at irb@allina.com. Send the completed form to irb@allina.com.

If you cannot make the representations listed below, you need to seek a waiver from the IRB. To contact the IRB Office, 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, the 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)
- If disclosed to an External Researcher, the decedent's MRA status will be verified and those with an MRA-no will be excluded as MRA status prevails after a patient's death.

_____ _____
Signature of Researcher (Principal Investigator) Date

PREPARATORY TO RESEARCH ATTESTATION

This form must be submitted to Clinical Research Informatics and Analytics (CRIA) 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 Office of Research Integrity at ResearchCompliance@allina.com. Send the completed form to **ResearchAnalytics@allina.com**

Preparatory to research means actions taken to prepare for research, such as designing a study, assessing the feasibility of conducting a study, and determining the existence of a 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 research 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

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. An individual's Minnesota Research Authorization (MRA) status must be a verified MRA-yes (see the Policy) to be disclosed to an External Researcher[1].

If you anticipate that you will disclose PHI for 50 or more individuals to an External Researcher[1] (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):

- o **Allina Health Cancer Institute**
- o **Cardiovascular (e.g., MHVI, MHI/F)**
- o **Courage Kenny Rehabilitation Institute**
- o **Mental Health and Addiction Services**
- o **Mother-Baby**
- o **Neuroscience, Spine, and Pain Institute**
- o **Nursing**
- o **Orthopedics**
- o **Penny George Institute for Health and Healing**
- o **Primary Care**
- o **Surgical**
- o **Other: _____**

[1] An "External Researcher" is defined as a Researcher who is not an Internal Researcher. An Internal Researcher is a Researcher who is (1) employed by Allina Health and/or the organizations covered by the Allina Health Notice of Privacy Practices and/or owned by the Allina Health System, (2) credentialed as a member of the Allina Health Medical Staff, (3) affiliated through a direct contract at Allina Health facilities, related sites, and specialty programs, or (4) as designated by the Compliance & Privacy Department. See the policy *Use and Disclosure of Protected Health Information for Research.*

Type of PHI disclosed (select all that apply):

- **Demographic**
- **Clinical**
- **Billing**
- **Other: _____**

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