

*Overview of HIPAA and its
Impact on Health Services
Research*



Presented by

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TOPICS

- ❖ **HIPAA Components Affecting Health Services Research**
- ❖ **HIPAA Privacy – Core Concepts**
- ❖ **HIPAA Privacy and Research**
- ❖ **Resources**





HIPAA Privacy – Core Concepts

Key Terms

- ❖ Covered Entities: Health plans, clearinghouses, health care providers
- ❖ Protected Health Information (PHI): Individually identifiable information related to the past, present or future health, health care or payment for health services
- ❖ Uses and Disclosures: internal (employees) vs. external access to PHI

Key Terms

- ❖ **Individual identifiers include:**
 - ❖ **Demographic elements (name, birth, admission, discharge, death, and all ages over 89)**
 - ❖ **Geographic subdivision smaller than state (except first 3 zip code digits)**
 - ❖ **Locator elements (telephone, fax, email)**
 - ❖ **IDs (SSN, medical record number, health plan ID, account numbers, certificate/license numbers, vehicle IDs, device IDs, URLs, IP addresses, biometric IDs, full face photographic images, any other unique identification number)**
- ❖ **De-identified data: All identifiers removed or statistician determines very low risk data containing all or some elements identifies an individual**



HIPAA Privacy and Research

Who is Affected by HIPAA Privacy Research Provisions

- ❖ Covered entities conducting internal research
- ❖ Covered entities participating with other entities in joint research
- ❖ Covered entities disclosing PHI to external researchers
- ❖ Any researcher conducting research that involves PHI
- ❖ IRBs that review research protocols

What is Research under HIPAA Privacy?

“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”

45 CFR § 164.501

What Research is Affected under HIPAA

- ❖ **Records research that uses existing PHI, such as research databases and data repositories**
- ❖ **Research that includes treatment of research participants, such as clinical trials**

HIPAA Privacy Research Provisions

- ❖ **Covered Entities may use and disclose PHI for research**
 - ❖ **With individual authorization**
 - ❖ **Without individual authorization in limited circumstances**

HIPAA, the Common Rule and FDA's Human Subject Protection

- ❖ **HIPAA Privacy does not override the Common Rule of FDA's human subject protection regulations**
- ❖ **HIPAA Privacy seeks to extend waiver of informed consent that apply to federally funded research to apply to all research, regardless of source of funding**

Research WITH Patient Authorization

Common Rule/FDA



**IRB Reviews Research
And Informed Consent**

- ❖ **Research participant authorization to use or disclose PHI is required for most clinical trials and records research**
- ❖ **May continue until “end of research study”**
- ❖ **May be combined with informed consent to participate in research**

HIPAA Privacy



**Research must have
valid authorization
form**

Requirements of a HIPAA Patient Authorization

- **Form must include:**
 - **Purpose (title of study)**
 - **What PHI is being used or disclosed**
 - **Who is authorized to receive and use PHI**
 - **Who is authorized to disclose PHI**
 - **Right to refuse to sign and to revoke authorization at any time**
 - **Potential for re-disclosure of PHI**
 - **Expiration date (“end of study”; “never” OK for research databases and repositories)**
 - **Signature**

Research WITHOUT Patient Authorization

Common Rule/FDA



- **IRB Reviews**
- *4 waiver criteria*

HIPAA Privacy



- **IRB/Privacy Board**
- *3 review criteria*
- **Preparat. Research**
- **Research on Deced**
- **Limited data set**

Option 1 - IRB Waiver of Authorization (Criteria)

- 1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of the individual, based on:**
 - An adequate plan to protect the identifiers in the dataset
 - An adequate plan to destroy the identifiers as soon as is possible, unless there is a research reason for not doing it
 - Adequate written assurance that the PHI will not be reused or re-disclosed to any other person or entity (except for oversight of research or as authorized by law)

Option 1 - IRB Waiver of Authorization (Criteria)

- **The research could not be practicably conducted without the waiver of authorization**
- **The research could not be practicably conducted without access to and use of PHI**

Option 2 - Preparatory Research

- ❖ **Obtain representation that the use and disclosure of PHI is necessary to prepare a research protocol or other preparatory research purposes**
- ❖ **PHI must not be removed from covered entity**

Option 3 - Research on Decedents

- ❖ **Obtain representation that the use and disclosure is solely for the purpose of research on decedent's PHI**

Option 4 - Limited data set

- **Limited data set is PHI that has been stripped of specific readily identifiable data elements (such as name, address, phone number, etc), but which still include other identifiable data elements (such as zip code, dates, gender, etc.)**

Option 4 - Limited data set

- **Use and disclosure of a limited data set is permitted:**
 - **For specific purposes, including research, public health and certain health care operations**
 - **With the signing of a data use agreement from the recipient limiting the recipient's use to the specified purposes, limiting who may use or receive data, and establishing that no re-identification or contact the individuals will be attempted.**

DISCLOSURE OF RECORDS FOR RESEARCH PURPOSES

CATEGORY OF RESEARCH DISCLOSURE UNDER HIPAA

Status on Registration Consent for Research	<u>Authorization</u> A patient-signed research authorization is presented.	<u>Waiver of Authorization</u> An IRB-approved, IRB-signed waiver of the research authorization is presented.	<u>Use Preparatory to Research – PHI is not removed</u> Release is for use preparatory to research only and PHI is NOT removed from Allina.	<u>Use Preparatory to Research – PHI is removed</u> Release is for use preparatory to research only and PHI IS removed from Allina.	<u>Use of Decedents' Information</u> Release is for research use of decedents information only.	<u>Limited Data Set</u> Release is for research using a Limited Data Set (LDS) only.
Patient consents to disclosure on registration form "YES"	May release PHI when a patient signed authorization is presented.	May release PHI as indicated in the waiver of the research HIPAA authorization.	May release PHI with required representation from researcher.	May release PHI as indicated in the IRB-approved alteration of the HIPAA research authorization.	May release PHI with required representation from researcher.	May release PHI as indicated in the data use agreement.
Patient does not consent to disclosure on registration form. "NO"	May release PHI as indicated in HIPAA research authorization ONLY if the HIPAA research authorization is signed AFTER the registration form.	May not release PHI	May release PHI with required representation from researcher.	May not release PHI.	May not release PHI.	May release PHI as indicated in data use agreement.
Patient did not complete research section on Registration form OR Data is from pre-1997 "UNKNOWN"	May release PHI as indicated in the HIPAA research authorization.	May not release PHI.	May release PHI with required representation from researcher.	May not release PHI.	May not release PHI.	May release PHI as indicated in data use agreement.

Source: Allina Health System



Other HIPAA Privacy Provisions Affecting Research

Minimum Necessary

- **Covered entities are required under HIPAA Privacy to only use or disclose the minimum amount of PHI needed to achieve the intended purpose of the use or disclosure**
- **This provision applies to research – only the minimum amount of data needed can be used by or disclosed to researchers**
- **Determination is required to be made by covered entity maintaining the data**

Accounting of Disclosures

- **Patients have the right to request an accounting of certain disclosures done of their data (excludes disclosures for treatment, payment and operations and those done with a patient authorization)**
- **Covered entity disclosing protected health information for research purposes without the need to obtain patient authorization must account for the disclosure**

Non-Preemption of More Stringent State Privacy Laws

- **HIPAA Privacy rules do not preempt state laws or regulations that are more stringent (protects more the information, restricts more its use or disclosure, gives more rights to consumers)**
- **Minnesota has one of the more stringent privacy laws in the Nation affecting research**

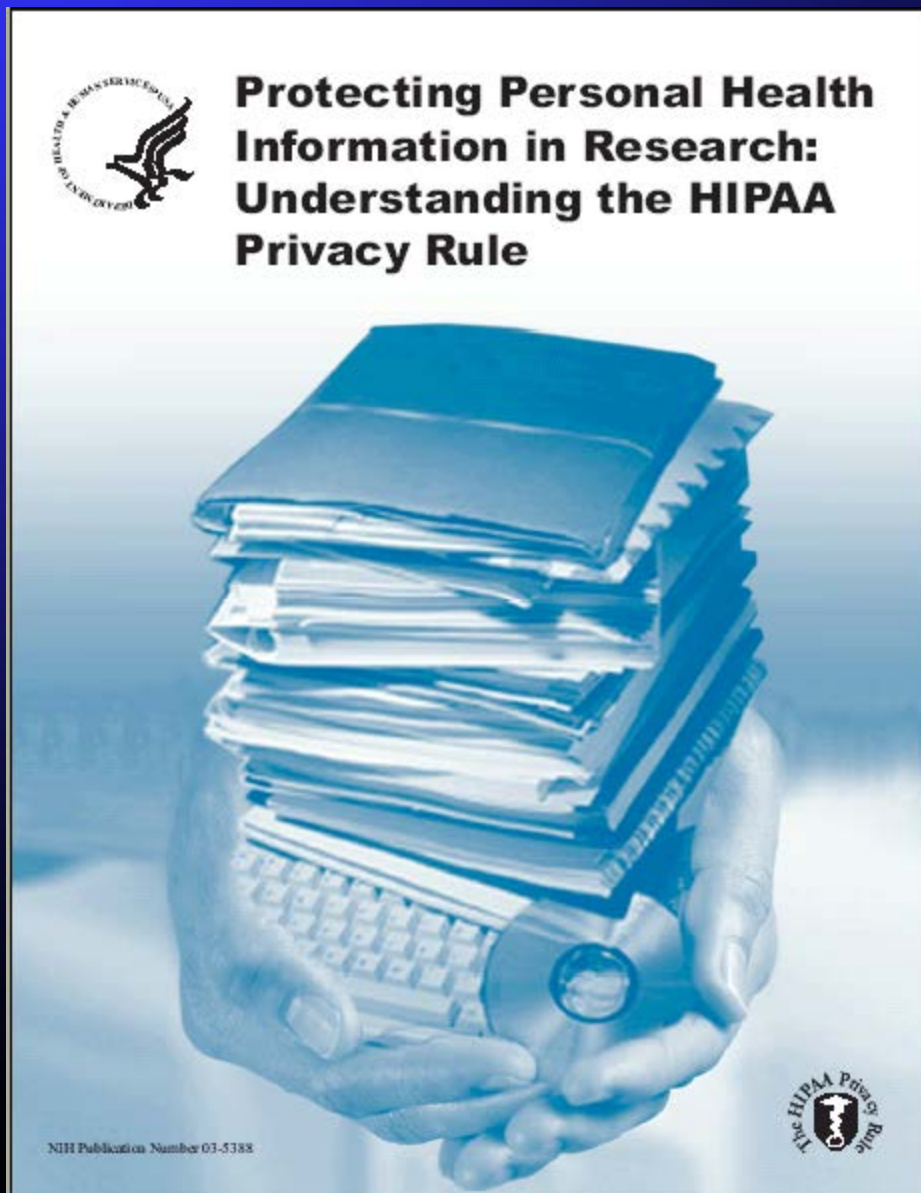
Non-Preemption of More Stringent State Privacy Laws

- **State law allows “a provider or a person who receives health records from a provider to disclose the records to an external researcher for purposes of medical and scientific research, if the provider has:**
 - **Disclosed in writing to the patients currently being treated by the provider that health records may be disclosed and that the patient may object; and**
 - **Used reasonable efforts to obtain the patient’s written general authorization, which does not expire but may be revoked or limited in writing**



HIPAA Resources for Researchers

Resources



<http://privacyruleandresearch.nih.gov/>

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On this page:

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7. [Using Data that is De-Identified](#)

HIPAA Resources

HIPAA-related IRB forms & templates:

- [Authorization Form Template](#)
- [De-Identification Certification Form](#)
- [Data-Use Agreement Template](#)

[FAQ about HIPAA & Research](#)

[University HIPAA Training](#)

[Protecting Personal Health Information in Research](#) (pdf) - NIH Publication

What to do for existing studies approved by the IRB

If your research will enroll or reenroll any subjects for this research AND you are obtaining subjects' protected health information (PHI) in either electronic, faxed or hard copy, subjects are required to sign an authorization form.

The IRB must approve the authorization form before it can be used. Use our [Authorization Form Template](#) and submit it to

<http://www.irb.umn.edu/topics/hipaa/>

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Frequently Asked Questions(FAQ) about HIPAA & Research

PHI & De-Identified Data

- [When is health-related information considered PHI?](#)
- [Am I required to get a signed Authorization Form at the time I get the signed consent form?](#)
- [Are any health records exempted from the definition of PHI?](#)
- [When is data "de-identified"?](#)
- [What identifiers must be removed from a limited-data set?](#)

Authorizations

- [Is the HIPAA Authorization the same as the consent form?](#)
- [How do I qualify for a waiver of authorization?](#)
- [Do minors need to sign a separate HIPAA authorization?](#)
- [Do subjects receive a copy of the Authorization Form as they do a consent form?](#)
- [Can authorization be revoked by the subject?](#)

Other Research Questions

- [What happens to research studies underway or initiated before April 14, 2003?](#)
- [How does HIPAA define research?](#)
- [What about reviews preparatory to research?](#)
- [What does a researcher have to do to assure compliance with the new requirements?](#)

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HIPAA-related IRB Forms & Templates

Authorization Form Template

Customize this template and use in conjunction with a consent form during the consent process with potential subjects. It must be signed and dated by the subject or the subject's authorized representative as a consent for would be. *Use and disclosures of PHI must be described in this document to receive IRB approval.*

Please submit your customized authorization form for IRB approval along with your IRB application.

 [Authorization Form Template](#)

De-Identification Certification Form

Complete and submit this form to the IRB to assure the IRB that data used in your research is de-identified. (see [When is data "de-identified"?](#))

This form is required when applying for an Exemption of IRB Review for studies that will use de-identified data. This form is to be used in conjunction with the IRB's Exempt Screening Application form.

 [De-Identification Certification Form](#)

Data-Use Agreement Template

Customize this template as an agreement that will be signed by the researcher as an agreement for how they will use/disclose the PHI provided to them by a covered entity.

 [Data-Use Agreement Template](#)

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HIPAA Privacy Rule Requirements for Research

REQUIREMENTS

Allina Hospitals & Clinics ("Allina") will abide by all federal and state regulatory requirements concerning the use and/or disclosure of Protected Health Information (PHI) for research purposes. To do so, Allina must abide by:

- (i) regulatory requirements for obtaining patient Authorization prior to the use and/or disclosure of protected health information for research purposes;
- (ii) regulatory requirements pertaining to review by the Institutional Review Board of an Authorization waiver or alteration request;
- (iii) regulatory requirements for documenting the disclosure of protected health information for research purposes;
- (iv) regulatory requirements for patient access to protected health information for research purposes, including allowable restrictions to patient access;

In order to meet these regulatory requirements, policies, procedures, and forms have been developed to assist researchers, business unit personnel, and IRBs in implementing HIPAA.

HIPAA RESEARCH POLICY PC 311



PC311 3.20.03.doc

http://www.allina.com/ahs/research.nsf/page/HIPAA_and_Research

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HIPAA RESEARCH DISCLOSURE FORMS

Facility Disclosure Form - This form must be signed by the research participant and a copy presented to the facility Health Information Department staff when requesting PHI for research purposes.



200-F-13R Facility Authorization.doc

Research Disclosure Request Form - This form must be completed and given to the Health Information Department staff when requesting medical records for research purposes.



311-F-04 ResDiscReqForm.doc

Research Request for PHI - Decedents - This form must be completed and presented to the facility Health Information Department staff when requesting medical records of decedents for research purposes.



311-F-01 Research Request For PHI-Decedents.doc

Research Request for PHI Preparatory to Research - This form must be completed and presented to the facility Health Information Department staff when requesting medical records preparatory to research.



http://www.allina.com/ahs/research.nsf/page/HIPAA_and_Research

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Release of Patient Identifiable Medical Records For Research Purposes Policy Number RES 100.02 (Approved 12/99)

Policy

It is the policy of Allina Health System ("Allina") to consistently and fully comply with state and federal law pertaining to the release of medical records for research purposes. Specifically, and in no way limiting the foregoing, it is Allina's policy to comply with the provisions of Minnesota Statutes 144.335.

<http://www.revisor.leg.state.mn.us/stats/144/335.html>.

Goal

The goal of this policy is to ensure that Allina conducts the internal use and external release of medical records for research purposes in accordance with all applicable law.

Definitions

- **External release of medical records:** The release of medical records to individuals or entities outside of Allina for research purposes. This includes, but is not limited to, the release of medical records to: (a) medical staff members who are not employed or under contract with Allina, (b) study coordinators who request patient records to facilitate their work for such medical staff members, and (c) physicians under contract with Medica to provide health care services to Medica members.
- **Internal access to medical records:** Allina employee and/or medical director access to medical records to facilitate research conducted by such individuals when the scope of such research is consistent with and reasonably related to the individual's duties as an Allina employee or his/her role as a medical director.

Overview

Prior to allowing an external release of medical records for research purposes, Allina shall obtain written consent for such release from the affected patient or his/her authorized representative. Such consent shall apply to the patient's entire medical record held by Allina, and not simply to the portion of the record documenting a particular hospital admission. Additionally, before allowing an external release of medical records, Allina shall confirm with the researcher that the disclosure of records in patient identifiable form is necessary to conduct the research, that the researcher will safeguard the records to protect them from unauthorized disclosure, and that the researcher will not release the records to anyone else without patient consent.

Resources

- **Office for Civil Rights (OCR), Department of Health and Human Services (HHS) - <http://www.hhs.gov/ocr/hipaa>**
- **Agency for Healthcare Research and Quality (AHRQ) - <http://www.ahrq.gov/>**
- **Centers for Disease Control and Prevention (CDC) - <http://www.cdc.gov/nip/registry/hipaa7.htm>**
- **Food and Drug Administration (FDA) - <http://www.fda.gov/>**
- **National Institutes of Health (NIH) - <http://privacyruleandresearch.nih.gov/>**
- **Office for Human Research Protections (OHRP), HHS - <http://ohrp.osophs.dhhs.gov/>**
- **Academic Medical Centers Site - <http://www.amc-hipaa.org/>**
- **Association for the Accreditation of Human Research Protection Programs - <http://www.AAHRPP.org/>**



Summary

In Summary...

- ◆ **The core components of HIPAA (EDI, code sets, identifiers, privacy and security) will affect researchers in important ways**
- ◆ **Privacy will have a major effect on the ability of researchers to obtain patient health information**
- ◆ **Providers and other covered entities who maintain PHI will be much more cautious as to when and how they will use and disclose to researchers PHI**
- ◆ **Minnesota laws add more stringent requirements to the HIPAA privacy law, will not be preempted and will need to be followed by providers and researchers**

In Summary...

- ◆ **In using and disclosing PHI for research purposes, providers will need to only use/disclose the minimum necessary amount of data needed for the research purpose**
- ◆ **There will be cost implications as to the procedures needed to be done to accomplish the release of PHI, and the accounting of those disclosures**
- ◆ **The HIPAA rules have created a limited data set that can be disclosed to researchers without patient consent, but with the need to have a data use agreement**

In Summary...

- ◆ **Providers and health plans will need to develop and implement procedures for using and disclosing PHI for research purposes**
- ◆ **Researchers (who receive or access PHI) will need to understand their new responsibilities as to the use they will give to the PHI and the safeguards they need to implement to protect this data**

Contact Information

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