

Using and Disclosing Patient Information for Research

2026

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Presented by:

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Attendance Reminder

Agenda

- ▶ **Basics about patient information and HIPAA**
- ▶ **Types of Data Sets**
 - ▶ De-Identified Data Sets
 - ▶ Limited Data Sets
 - ▶ Full Data Sets
- ▶ **Use and Disclosure of Patient Information in Research**
 - ▶ Subject Authorization
 - ▶ Waiver of HIPAA Authorization
 - ▶ Preparatory to Research
 - ▶ Research on Decedents
 - ▶ Limited and De-Identified Data Sets
- ▶ **Appendices (other information)**

Basics About Patient Information and HIPAA

Privacy – HIPAA Basics

- ▶ Health Insurance Portability and Accountability Act of 1996
- ▶ Federal Regulations (45 C.F.R. Parts 160-164)
- ▶ Applies to “covered entities”:
 - ▶ **Health Care Providers who transmit electronic health information (UVM Health)**
 - ▶ Health Plans (e.g., commercial insurers, Medicare, Medicaid)
 - ▶ Health Care Clearinghouses (middlemen between providers and payers)



What is Protected Health Information (PHI)?

Protected Health Information (PHI) is all individually identifiable health information (verbal, written, and electronic) that relates to:

- ▶ Past, present, or future physical or mental condition of a patient
- ▶ Provision of healthcare
- ▶ Past, present, or future payment for the provision of healthcare to a patient



Examples of PHI include:

- ▶ Discussions between staff about patients, discussions between staff and patients/patient's family members, telephone conversations with patients.
- ▶ Sign-in sheets, clinic schedules, clinician's handwritten notes, printed AVSs and discharge instructions, and patient identification bracelets.
- ▶ Tracking boards, information in Epic, media devices that contain PHI, emails that contain PHI, and any patient information or data appearing on a computer monitor.

18 Identifiers HIPAA Identifiers

1. Names
2. All geographic subdivisions smaller than a state
 - ▶ Includes cities, counties, street addresses, precinct, geocodes, etc.
 - ▶ Specific exemption for certain zip codes
3. All elements of dates (except year) for dates that are directly related to an individual
 - ▶ Including birth date, admission date, discharge date, death date, and
 - ▶ all ages over 89 must be aggregated into a single category of age 90 or older
4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. URLs
15. IP addresses
16. Biometric identifiers, including finger and voice prints
17. Full-face photographs and any comparable images
18. Any other unique identifying number, characteristic, or code
 - ▶ Unique tattoo, birthmark, feature
 - ▶ Clinical trial subject number

HIPAA Rules for Research

- ▶ **General Rule:** Without an individual patient's written permission, UVM Health cannot access (use) or share (disclose) the patient's PHI unless HIPAA makes an explicit exception for it.
- ▶ **Six HIPAA Pathways for Research:** One of these MUST be satisfied before anyone on the study team may access patient information for research purposes. **IRB approval alone is not sufficient, one of these pathways must be met.**
 - ▶ Patient consent/authorization
 - ▶ Waiver (or partial waiver) of HIPAA Authorization
 - ▶ Preparatory to Research
 - ▶ Research on Decedents
 - ▶ Data Use Agreement for Limited Data Set
 - ▶ Deidentified Data Sets



Use v. Disclosure of Patient Information

USE	DISCLOSURE
<p>Patient information is used and stored within the HIPAA Covered Entity that generated the information (UVM Health).</p>	<p>Patient information is removed from and/or stored outside the HIPAA Covered Entity that generated the information.</p>
<p>Examples:</p> <ul style="list-style-type: none">• Patient information is accessed and reviewed in Epic and not transferred or transcribed.• Patient information stored on the S Drive.• Patient information stored on UVM Health's Sharepoint site.• Patient information stored on other UVMH-approved systems.	<p>Examples:</p> <ul style="list-style-type: none">• Excel spreadsheet containing patient information stored on L: or L:Secure.• Patient information transcribed into REDCap.• Patient information transferred to co-investigators at another research site.• Patient information transferred to a study sponsor.• Data set from DMO with patient data stored on UVM systems

Let's pause for some questions!



Types of Data Sets

Types of HIPAA Data Sets

- ▶ **De-Identified Data Set:** Data set contains **NO IDENTIFIERS** or has **RECEIVED AN EXPERT DETERMINATION** of very low chance of reidentification.

- ▶ **Limited Data Sets:** Data set contains **INDIRECT IDENTIFIERS ONLY** and no direct identifiers.

		Variables					
		Gender (M/F)	Age	Weight (lbs.)	Height (in.)	Smoking (0=No, 1=Yes)	Race
Individuals	Patient #1	M	59	175	69	0	White
	Patient #2	F	67	140	62	1	Black
	Patient #3	F	73	155	59	0	Asian

	Patient #75	M	48	190	72	0	White

- ▶ **Full Data Sets:** Data set contains **DIRECT IDENTIFIERS.**

Types of Identifiers

DIRECT	INDIRECT
<p>Information that can be used by itself to identify a specific person.</p>	<p>Information that links to multiple people but could be used in combination with other information to identify a specific person.</p>
<p>Examples:</p> <ul style="list-style-type: none">• Name• Social security number• Medical record number• Email address• Phone number• Medical device number• Epic encounter number	<p>Examples:</p> <ul style="list-style-type: none">• <u>Study subject number</u>• Dates of birth and death• Dates of treatment, results, prescription, admission, discharge• Patient zip code• Patient city of residence, birth, etc.• Patient county of residence, birth, etc.

Minimum Necessary Standard

HIPAA requires that only the *minimum amount of patient information necessary* to accomplish the purpose be accessed/used/disclosed.

Examples

- ▶ Limited data set should be used if research does not require link between subject data and patient's medical record.
- ▶ Age of patient in years should be used if research does not require patient's date of birth.
- ▶ MRN should be used if research needs to be linked to a patient's medical record but does not require the patient's name.

Let's pause for some questions!



Use and Disclosure of Patient Information for Research

6 HIPAA Paths for Use/Disclosure of Patient Information for Research

- ▶ **Authorization/consent** from the research participant/subject
- ▶ **Waiver of HIPAA Authorization** issued by IRB/Privacy Board
- ▶ **PHI preparatory to research** (PHI cannot be shared outside of UVMHN)
- ▶ Research on **PHI belonging to decedents**
- ▶ Limited data set + **HIPAA-compliant Data Use Agreement**
- ▶ **De-identified Data Sets**



Participant Authorization/Consent

- ▶ Similar to the requirements for a standard HIPAA authorization (but may be combined with consent document).
- ▶ Patient information being used/disclosed **MUST** be listed in the consent.
- ▶ Researchers/recipients using/disclosing patient information **MUST** be identified in the consent.
- ▶ Authorization/consent **MUST be approved by IRB.**
- ▶ **REQUIRED:** Researcher must have signed authorization before accessing patient records
 - ▶ If the research team is accessing records for recruiting there **MUST** be another HIPAA path.

Example Language

What health information will be used and disclosed for this follow-up?

The health information we plan to collect is listed below.

- Medical history and examinations
- Your year of birth
- Estimated and actual date of delivery
- After the baby is born:
 - Your baby's birth weight and length
 - Your baby's sex
 - Whether there were any complications during the pregnancy or delivery
 - Whether your baby had any birth defects

Who is disclosing your health information for this follow-up?

- The University of Vermont Health Network
- Other doctors where medical care is sought during pregnancy and delivery

Who might use and give out information about you and your baby? |

- The study doctor and the study staff.
- The sponsor of the study – Monopar Therapeutics Inc. "Sponsor" means any people and companies that
 - are working for the sponsor,
 - are working with the sponsor, or
 - are owned by the sponsor.

Your information might also be seen by:


- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- The University of Vermont Health Network
- The University of Vermont and its Committees on Human Research

Your health information is protected by a federal law called the Health Information Portability and Accountability Act (HIPAA). Once your health information is shared outside of the University of Vermont Medical Center, we cannot guarantee that these laws will continue to apply. As a result, your health information could be further disclosed for other purposes. In the absence of a Certificate of Confidentiality, it is also possible for a court or other government official to order the release of study data. The confidentiality of your health information cannot be guaranteed if you agree it may be used in this study.

Waiver of HIPAA Authorization

- ▶ Must be **issued by IRB or “Privacy Board.”**
- ▶ Requirements for the waiver are set forth in HIPAA.
- ▶ **Can** be used to disclose full PHI.
- ▶ Document must contain a “brief description” of the data covered by the waiver.
- ▶ Requested via CLICK submission
- ▶ Even if research is secondary and **exempt** (under (4)(iii), **waiver of HIPAA authorization is still required.**

Example Language

 **UNIVERSITY OF VERMONT**
Committee on Human Subjects
Serving the University of Vermont
and the UVM Medical Center

RESEARCH PROTECTIONS OFFICE
213 Waterman Building
85 South Prospect Street
Burlington, Vermont 05405
(802)245-5243 jh
www.uvm.edu/irb

Waiver of HIPAA Authorization under 45 CFR 164.512(j)(2)(i)

The issuing CHSMB board has determined, via expedited review conducted by the author of this certification and waiver, that the waiver satisfies the following criteria:

- The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 1. An adequate plan to protect the identifiers from improper use and disclosure;
 2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 3. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for purposes of oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subject;
- The research could not practically be conducted without the waiver or alteration; and
- The research could not practically be conducted without access to and use of the protected health information.

Brief Description of PHI under the Waiver

Constipation is a very common and potentially debilitating non-motor symptom of Parkinson disease, and there is no clear consensus on management. The goal of this project is to evaluate a cohort of patients with Parkinson disease who are treated by subspecialists at the UVM/MC Movement Disorders clinic, to better understand the prevalence of constipation and approaches to management. We will also explore if involving a gastroenterology specialist affects the management of constipation in this patient population.

All protected health information (PHI) that will be accessed under the waiver (for example, specific tests, medical histories, diagnosis)

• de Parkinson disease

- Constipation
- Provider
- Patient name
- Patient DOB
- Patient MRN
- Patient sex
- Patient race
- Patient ethnicity
- Medication name and dose at most recent clinic visit; any use of medications to treat constipation from 2009 to present
- Gastroenterology evaluation: Notes from any gastroenterology evaluation 2009 to present- specifically assessment and plan / recommendations
- Past medical history: Any past medical history noted in the most recent clinic note, including diagnosis
- Past surgical history: Any past surgical history noted in the most recent clinic note, including surgery name and surgery location
- Allergies
- Procedures: Any gastrointestinal procedure, including endoscopy, colonoscopy - from 2009 to present - specifically for the indication of the procedure
- Symptom onset: Review in any clinic note from 2009 to present of the year of symptom onset
- Year of PD diagnosis: Review in any clinic note from 2009 to present of the year of PD diagnosis
- Imaging: Any brain imaging (MRI, CT, NM DAT SPECT, PET CT) from 2009 to present; any GI imaging (MRI, CT, X-ray) from 2009 to present
- Hospital admissions: Review any hospital admission from 2009 to present to see if constipation or Parkinson disease was an admission diagnosis; no dates will be recorded
- ED encounters: Review any ED visits from 2009 to present to see if constipation or Parkinson disease was an admission diagnosis; no dates will be recorded

Start and Stop Dates for the Collection Period(s) of Interest

1/1/2009 8/10/2021

Number of Records Needed for This Protocol

1343

Partial Waiver of HIPAA Authorization

- ▶ Used to access and disclose PHI for **purposes of recruiting** (before obtaining the participant's authorization)
- ▶ Required if:
 - ▶ PI is not employed by UVM Health **or**
 - ▶ Patient information will be removed and stored outside of UVM Health (e.g., disclosed)

Note: if the PI **IS employed by UVM Health** and the patient information is NOT LEAVING UVM Health, you can use a partial waiver **OR** the preparation for research pathway.

Frequently Asked Questions

- Q: If I am recruiting patients that the PI treats at UVM Health, do I need a waiver?
A: No. If the PI has a treating relationship, the HIPAA path to access the patient's information is treatment.
- Q. If there is a partial waiver, can the study team approach the patient without permission of the care team?
A. Technically yes, but always good to keep the care team in the loop, if possible.
- Q. If I ask the treatment team's permission, do I still need a waiver?
A. Yes. Always good to keep the treatment team in the loop, but the **waiver is the HIPAA path.** (The treatment team cannot authorize the access).

Preparatory to Research

- ▶ May use PHI in preparation for research
- ▶ Researcher must certify that:
 - ▶ The purpose is solely to prepare a research protocol (or for similar purposes);
 - ▶ The researcher will not remove the PHI from the covered entity;
 - ▶ The access is necessary for the research purpose.
- ▶ Complete form and submit to DMO
(DataGovernance@UVMHealth.org)
Form: <https://www.uvm.edu/rpo/uvmclick-irb-forms-library>

Examples

- ▶ **Recruiting**: May be used for subject recruiting if (1) PI is UVM Health employee & (2) patient information will not be removed from UVM Health systems
- ▶ **Study design**: May be used to access patient information to assess study feasibility (e.g., do we have enough patients with this condition) or to design study/draft protocol (we have X number of patients so sample size should be Y)

Research on Decedents

- ▶ HIPAA protects a person's PHI for 50 years after the person dies.
- ▶ Researcher must certify that:
 - ▶ The use or disclosure is solely for the purpose of research on the PHI of the decedents;
 - ▶ The PHI being sought is necessary for the research; and
 - ▶ If requested by the covered entity, the researcher can provide documentation that the individuals whose information is being sought is deceased.
- ▶ Complete form and submit to DMO
(DataGovernance@UVMHealth.org)
Form: <https://www.uvm.edu/rpo/uvmclick-irb-forms-library>

Key Information

- ▶ PI must know that all participants are deceased **before** accessing the PHI (e.g., study population of patients who died from COVID)
- ▶ Patient information **may be disclosed** (not just used) under this pathway. But **be aware** of accounting of disclosure requirements.

Limited Data Sets & Deidentified Data Sets

- ▶ **Deidentified data sets:** As long as the data set meets one of HIPAA's two deidentification standards (Safe Harbor or Expert Determination), data is not considered patient information, so can be used and disclosed without further requirements.
 - ▶ But be aware of institutional contracting requirements related to data sharing and transfer agreements.
- ▶ **Limited data sets:** As long as the data set does not contain direct identifiers (see Appendix), the data may be used and disclosed via **data use agreement that meets HIPAA requirements** (see Appendix).

Let's pause for some questions!



Attendance Reminder

Please contact me at
lynn.combs@uvmhealth.org with
any questions!

Additional Resources

Limited Data Set Requirements

Limited Data Sets may not contain direct identifiers.
The following must be removed:

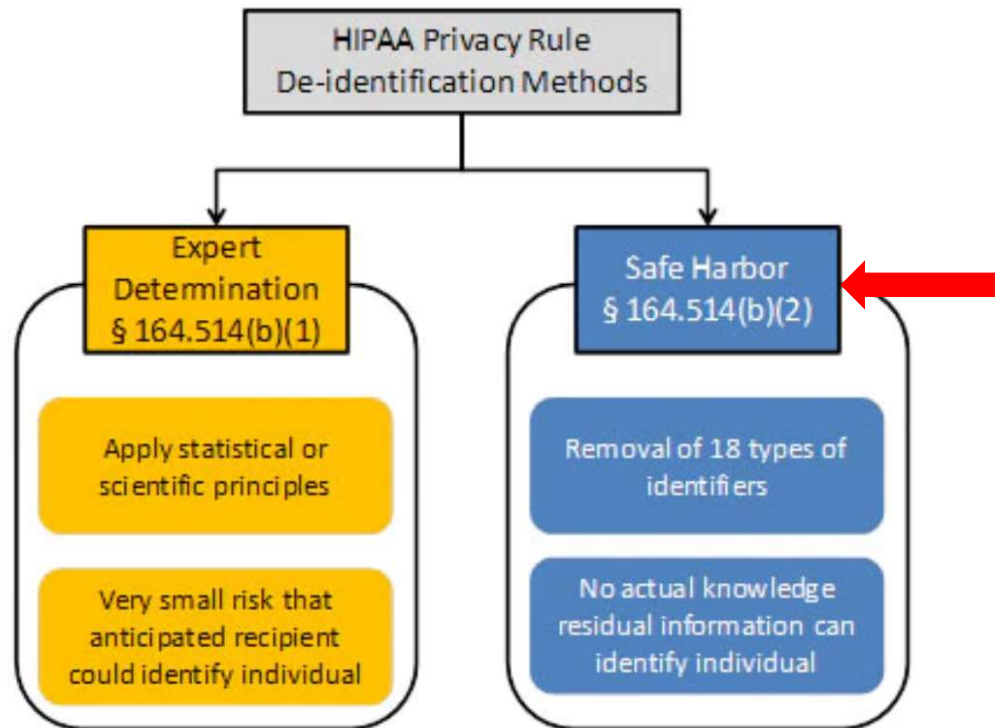
- ▶ Names
- ▶ Postal address information, other than town or city, State, and zip code
- ▶ Telephone numbers
- ▶ Fax numbers
- ▶ Electronic mail addresses
- ▶ Social security numbers
- ▶ Medical record numbers
- ▶ Health plan beneficiary numbers
- ▶ Account numbers
- ▶ Certificate/license numbers
- ▶ Vehicle identifiers and serial numbers, including license plate numbers
- ▶ Device identifiers and serial numbers;
- ▶ URLs
- ▶ IP addresses
- ▶ Biometric identifiers, including finger and voice prints
- ▶ Full face photographic images and any comparable images.

Data Use Agreement Requirements (Defined by HIPAA)

- ▶ State the purpose of the data use/disclosure
- ▶ Define the data being used/disclosed
- ▶ Define permitted uses and disclosures of the data by the limited data set recipient.
- ▶ Define who may receive the data
- ▶ The data recipients must agree:
 - ▶ Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law
 - ▶ Use appropriate safeguards to prevent improper use or disclosure of the
 - ▶ Report to the covered entity any inappropriate use or disclosure
 - ▶ Bind any of the recipients' agents who may get the data to the same restrictions and conditions that apply to the recipient
 - ▶ Not identify the information or contact the individuals

De-Identified (Under HIPAA) Data Sets

Under HIPAA, “de-identified” data sets do not contain patient information but must satisfy one of the HIPAA standards for de-identification.



HIPAA Safe Harbor Provision for Deidentification

Remove All Identifiers (for patient and relatives, employers, household members)

18 Identifiers HIPAA Identifiers

1. Names
2. All geographic subdivisions smaller than a state
 - Includes cities, counties, street addresses, precinct, geocodes, etc.
 - Specific exemption for certain zip codes
3. All elements of dates (except year) for dates that are directly related to an individual
 - Including birth date, admission date, discharge date, death date, and
 - all ages over 89 must be aggregated into a single category of age 90 or older
4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. URLs
15. IP addresses
16. Biometric identifiers, including finger and voice prints
17. Full-face photographs and any comparable images
18. Any other unique identifying number, characteristic, or code
 - Unique tattoo, birthmark, feature
 - Clinical trial subject number

+

No actual knowledge that the information could be used **alone or in combination with other information** to identify an individual who is a subject of the information.

Requirements for Waiver of HIPAA Authorization

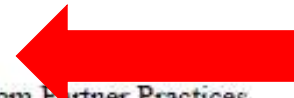
45 CFR 164.512(i)(2)(ii)

- ▶ The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 - ▶ An adequate plan to protect the identifiers from improper use and disclosure;
 - ▶ An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - ▶ Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
- ▶ The research could not practicably be conducted without the waiver or alteration; and
- ▶ The research could not practicably be conducted without access to and use of the protected health information.

Example of INVALID Waiver

Notes:

-Consent waived per 45 CFR 46.116(d).
-Authorization waived per 45 CFR 164.512(i)(2)(ii).
-Partner Practices are not engaged in the research. Data from Partner Practices will be extracted and coded using a unique Study ID. The Master Code Key will be stored at Partner Practices and will not be accessible by the Dartmouth College Research Team.



Note: Approval by CPHS is based on the study's appropriate balance of risk and benefit to subjects, a study design in which risks to subjects are minimized, and a determination that the criteria for approval at 45 CFR 46.111 and 21 CFR 56.111 as satisfied as appropriate.

Approved:

- 31355_Data & Specimens Research Protocol_2-22-2022.docx
- MORE Study Administrative Measures_REVISIED__1-15-2021.pdf
- ChartFilterSpecificationDocument_CVMC.docx