



Privacy and Recruitment Updates

Presented to: Northwestern University

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Presented by: NMHC Office of Research, Corporate Compliance and Integrity,
and Feinberg School of Medicine

Privacy and Recruitment Updates

Agenda

- Overview of Applicable State and Federal Laws
- Access to NMHC Patient Information
- Recruitment Guidelines
- Research Information Documented in NMHC Electronic Medical Records
- Questions





State and Federal Laws

Overview of State and Federal Law

Applicable Laws

- **Health Insurance Portability and Accountability Act (HIPAA):** Federal law among other things governing privacy of health information. See details on future slides.
- **Illinois Mental Health and Developmental Disabilities Confidentiality Act (IMHCCDA):** State law protecting the confidentiality and accuracy of records related to mental health and developmental disabilities. This pertains to mental health, genetic counseling, and developmental disabilities information.
- **Confidentiality of Substance Use Disorder Patient Records (42 CFR Part 2 or Part 2):** Federal law applicable to alcohol and drug abuse programs to protect the confidentiality of patient's information.

Overview of State and Federal Law

HIPAA Definitions

- **Covered Entities:** HIPAA applies to Covered Entities, which generally include healthcare providers, such as Northwestern Memorial HealthCare entities. Northwestern University is not a Covered Entity.
- **Protected Health Information (PHI):** individually identifiable health information maintained by a Covered Entity. PHI can be maintained in electronic, written, or oral form.
- **Business Associate:** an individual or company, per written agreement, performing an activity on behalf of a Covered Entity.
- **Authorization:** generally included within a research consent document, but could be a stand alone document, this contains specific provisions required under HIPAA. This portion of the NU IRB consent template should be modified only as directed in the help text and not otherwise edited.

Overview of State and Federal Law

HIPAA: What is protected health information?

There are 18 elements of PHI and if any of the following are present, it constitutes identifiable information

- Name
- Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
- All elements (except years) of dates related to an individual (**including but not limited to birthdate, admission date, discharge date, date of death, and exact age if over 89**)
- Telephone numbers
- Fax number
- Email address
- Social Security Number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate or license number
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URL
- Internet Protocol (IP) Address
- Finger or voice print
- Photographic image - Photographic images are not limited to images of the face.
- **Any other characteristic that could uniquely identify the individual**

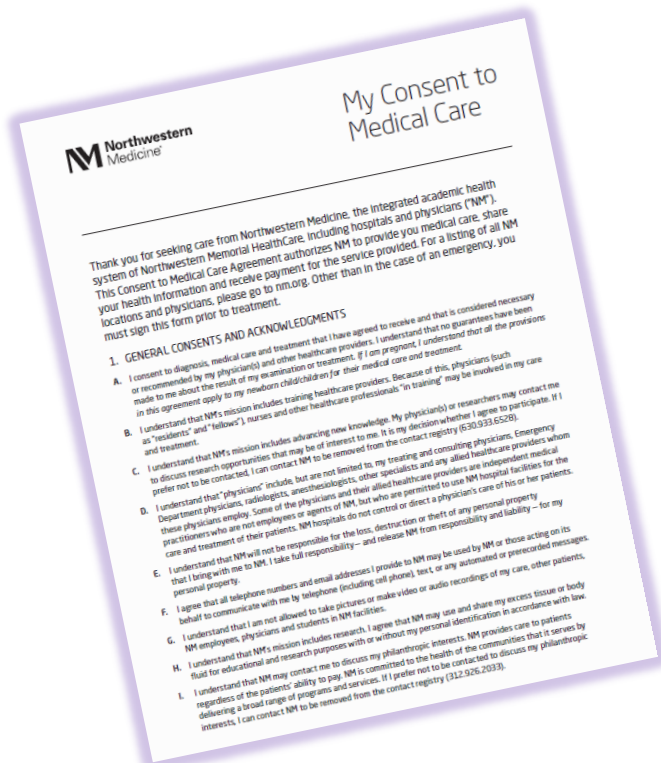
Overview of State and Federal Law

Sensitive Information

- Substance Use Disorder Treatment (42 CFR Part 2)
 - This pertains only to substance use disorder treatment obtained at a “Part 2” program. Northwestern Memorial HealthCare has several programs within its system including, but not limited to Behavioral Health Service at Central DuPage Hospital and Stone Mental Health Center at Northwestern Memorial Hospital.
- Illinois Mental Health and Developmental Disabilities (IMHCCDA)
 - Mental health or developmental disabilities information includes records kept in the course of providing mental health or developmental disabilities services to a patient. The provider could include a psychiatrist, physician, psychologist, social worker, nurse or any other person not prohibited by law to provide these services.
 - This law also includes protections for records of genetic counseling.

Overview of State and Federal Law

NM's My Consent to Medical Care



NM implemented a standard general consent, “My Consent to Medical Care.”

- **Dates of implementation vary by Region.**
- **Obtains patient permission for NM to use and share certain “sensitive” information in the same way that HIPAA allows NM to use and share non-sensitive information.**
- **Obtains the consent, where needed, to use certain “sensitive” information for research purposes.**

Overview of State and Federal Law

Sensitive Information

Type of Information	Can Authorization be Waived?	Special Handling
HIV/AIDS Related Information	Yes	Same as other PHI under HIPAA
Genetic Testing Information	Yes	Same as other PHI under HIPAA
Genetic Counseling Information	Yes, only if patient signed a “My Consent to Medical Care”*	Authorization must contain expiration date, right to inspect and copy, and witness signature
Developmental Disabilities Information	Yes, only if patient signed a “My Consent to Medical Care”*	Authorization must contain expiration date, right to inspect and copy, and witness signature
Mental Health Information	Yes, only if patient signed a “My Consent to Medical Care”*	Authorization must contain expiration date, right to inspect and copy, and witness signature
Substance Abuse Disorder	Yes	Authorization must contain statement on unauthorized disclosure

HIPAA Pathways for Research

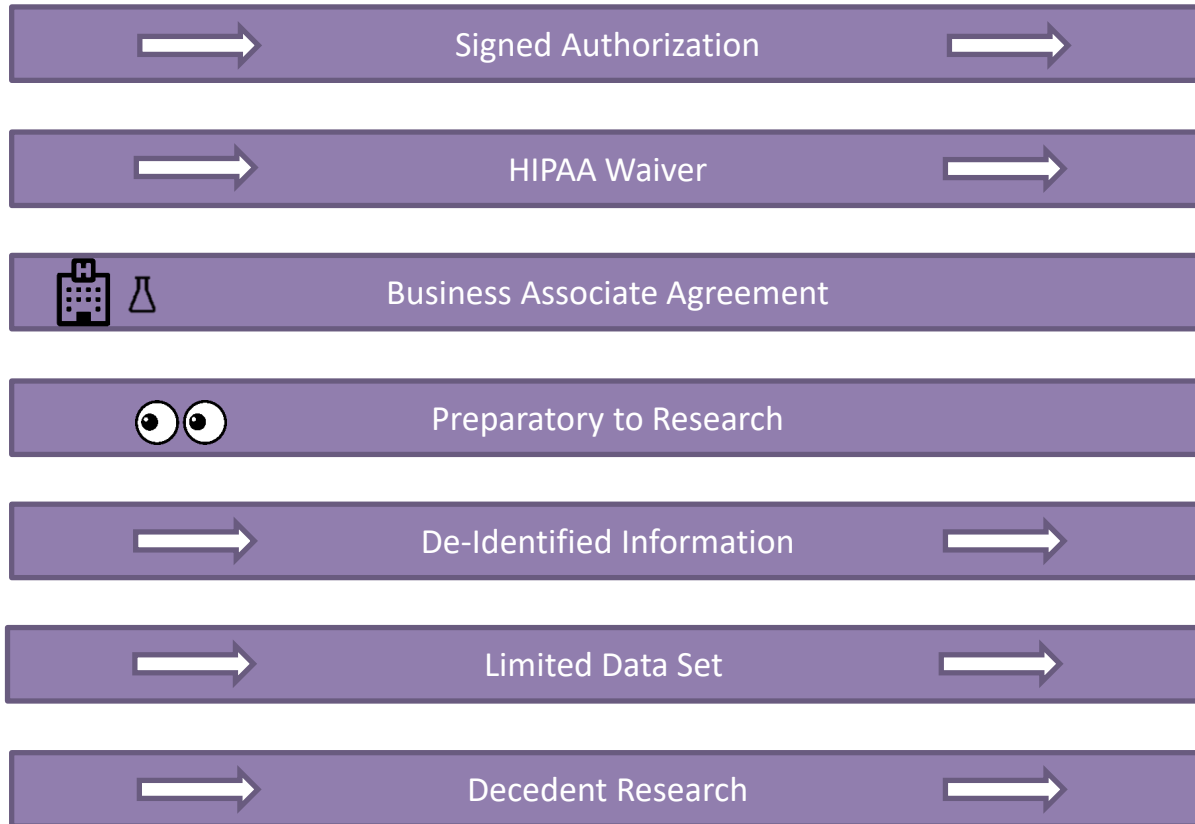
Covered Entity

NMHC



Researcher

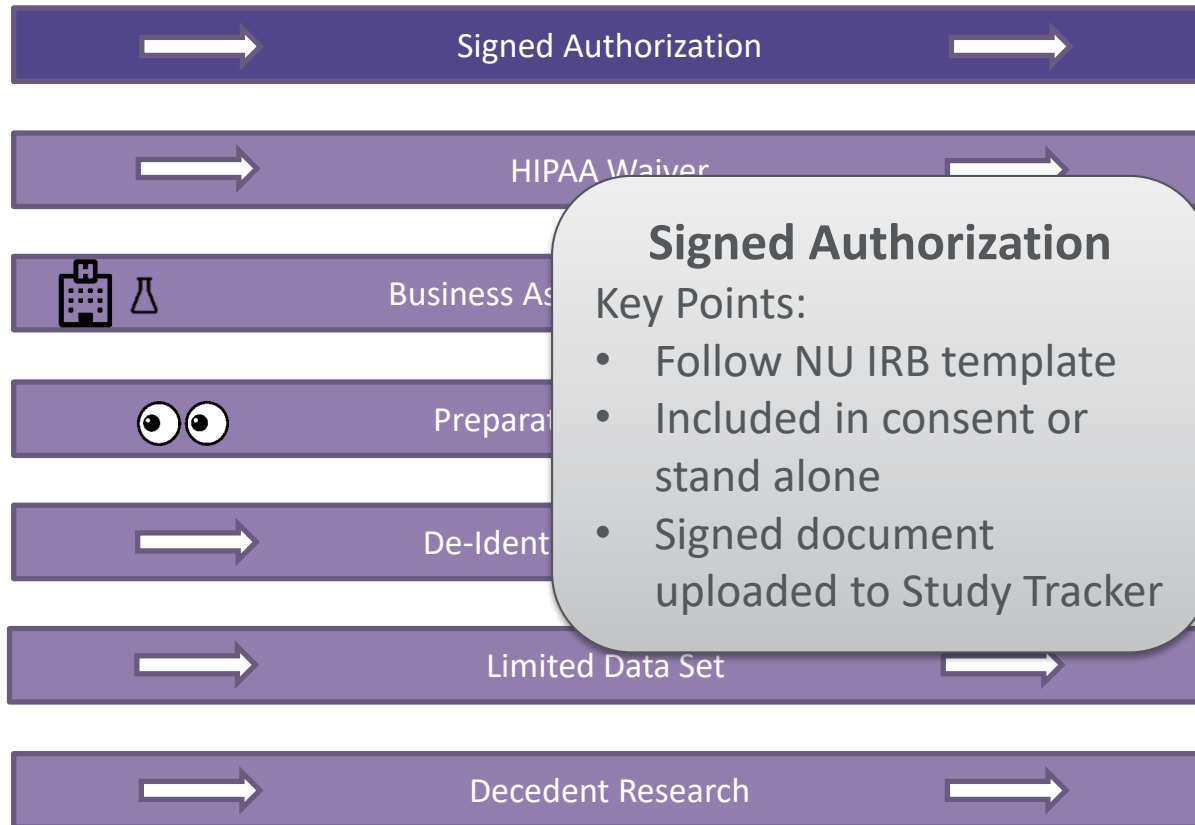
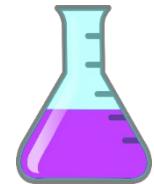
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HIPAA Pathways for Research

Covered Entity

Researcher



Signed Authorization

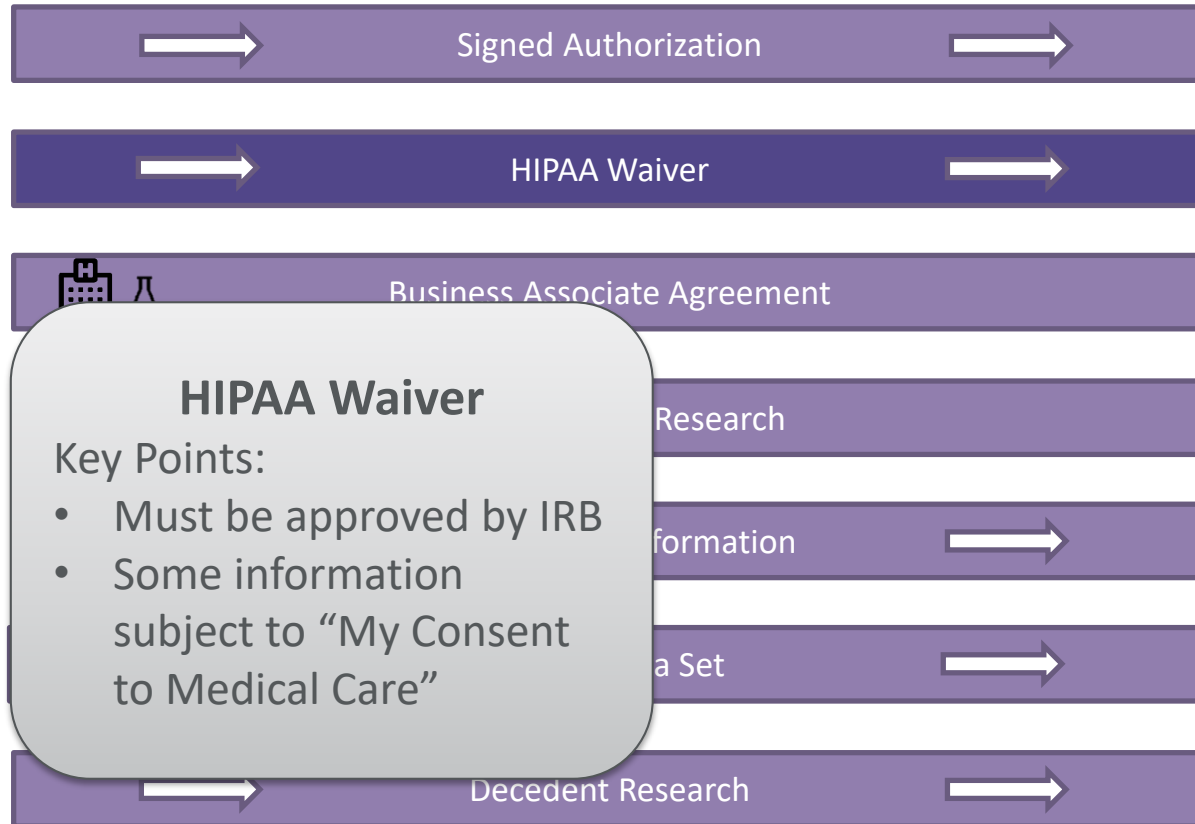
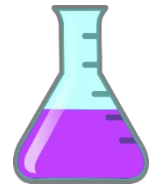
Key Points:

- Follow NU IRB template
- Included in consent or stand alone
- Signed document uploaded to Study Tracker

HIPAA Pathways for Research

Covered Entity

Researcher



HIPAA Waiver

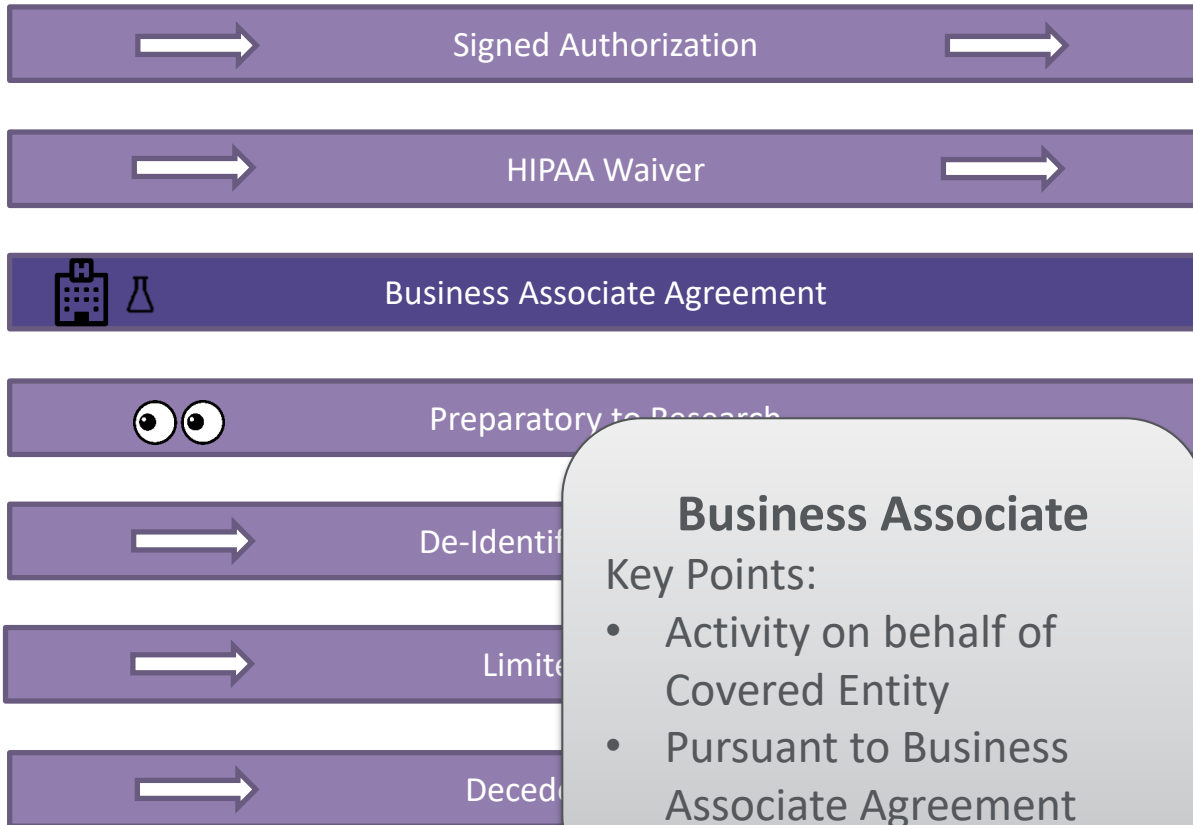
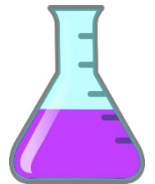
Key Points:

- Must be approved by IRB
- Some information subject to “My Consent to Medical Care”

HIPAA Pathways for Research

Covered Entity

Researcher



Business Associate
Key Points:

- Activity on behalf of Covered Entity
- Pursuant to Business Associate Agreement

HIPAA Pathways for Research

Covered Entity

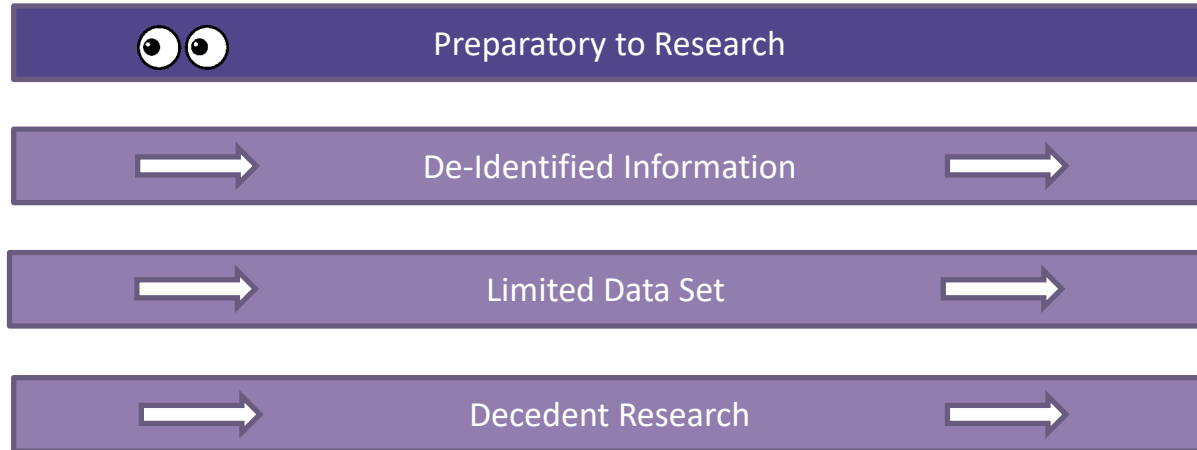
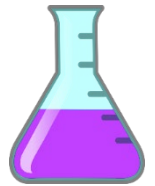


Prep to Research

Key Points:

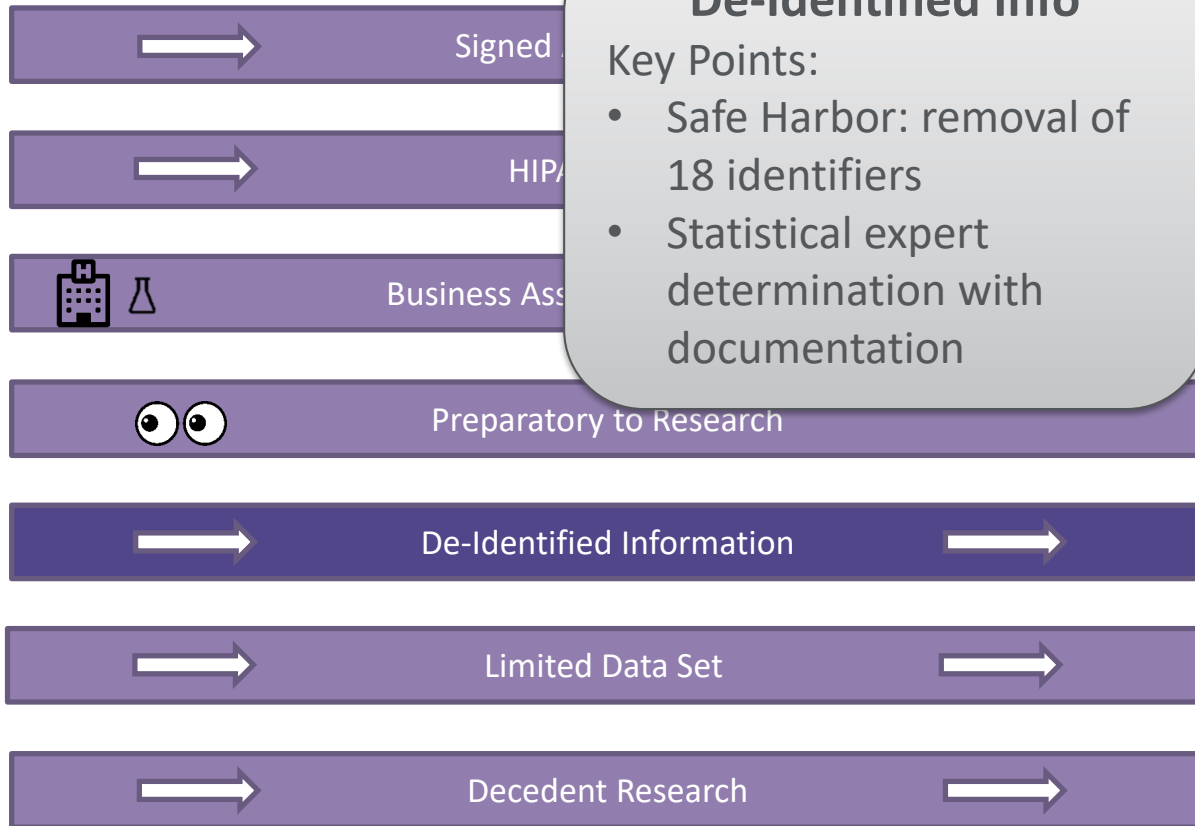
- Info cannot leave Covered Entity
- Use in preparing a research study

Researcher

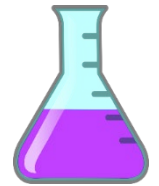


HIPAA Pathways for Research

Covered Entity



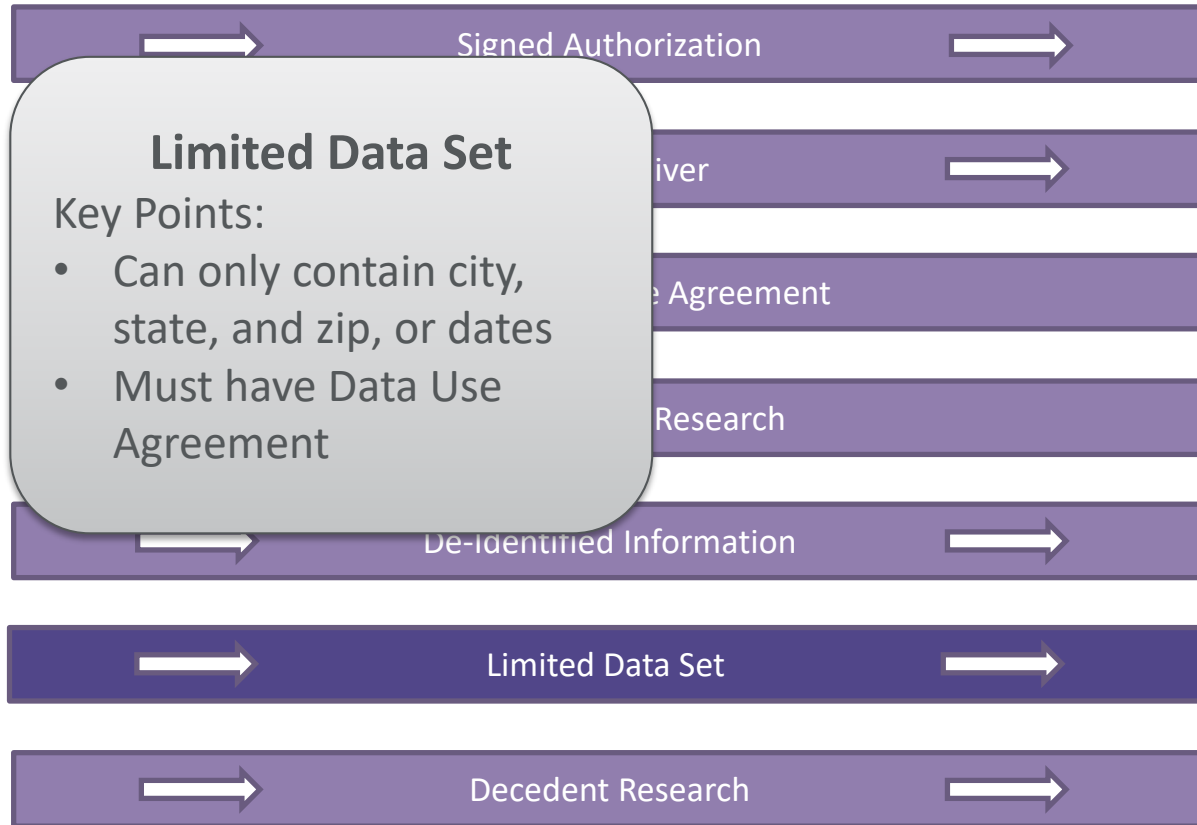
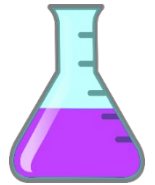
Researcher



HIPAA Pathways for Research

Covered Entity

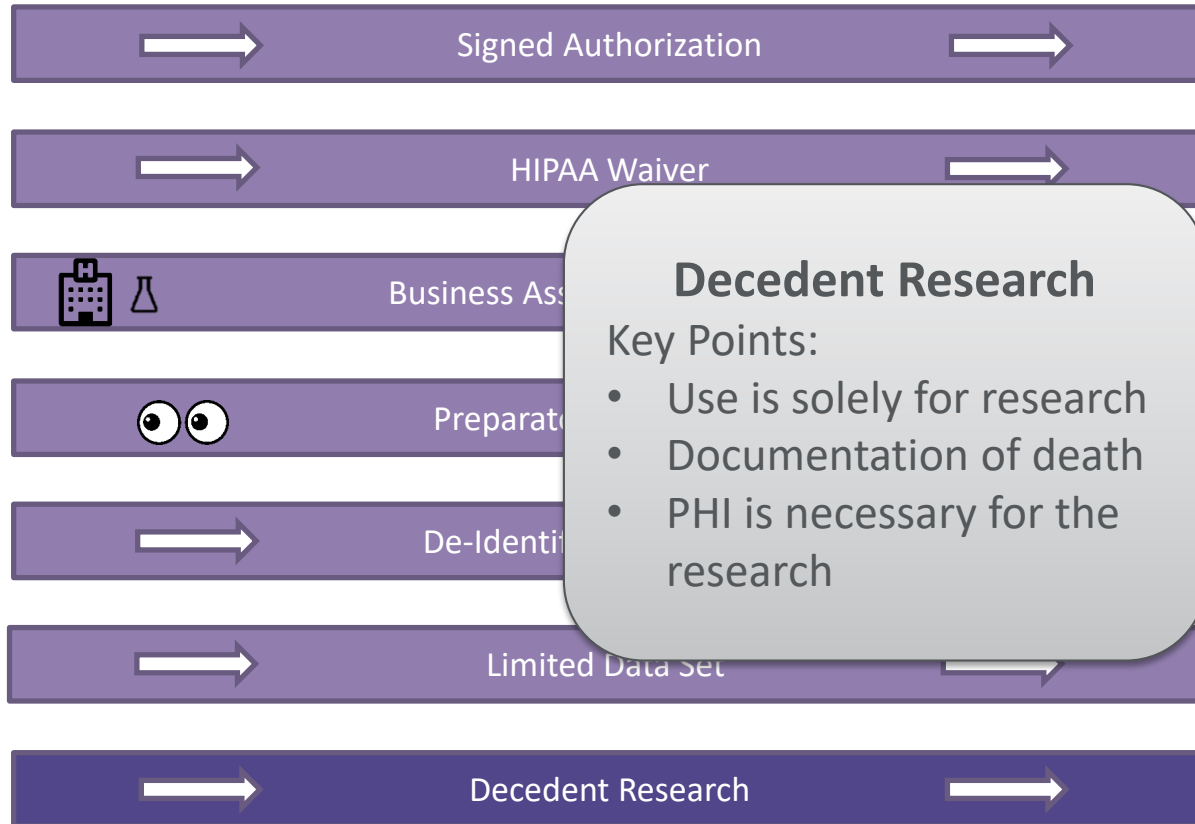
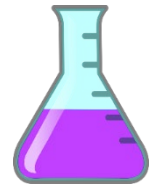
Researcher



HIPAA Pathways for Research

Covered Entity

Researcher



Decedent Research

Key Points:

- Use is solely for research
- Documentation of death
- PHI is necessary for the research



Access to Northwestern Memorial HealthCare Patient Information



Access to NMHC Patient Information

Obtaining Information

- Both NMHC and NU FSM policy require that studies including NMHC patient information, obtain this through the NM Enterprise Data Warehouse (EDW).
- In seeking to obtain the patient information through the EDW, if the EDW (based on standards set forth by the FSM IT Security Committee) determines the necessary information cannot be obtained via the EDW, an exception will be granted to provide direct access to the electronic medical record.
- NU researchers, who do not otherwise have access to NMHC systems (e.g., NMG physicians), and are granted an exception to access the medical record directly, must also gain access through the NMHC Office of Research Access Program process.



Recruitment Guidelines



Recruitment Guidelines

Identifying Eligible Patients

Treatment Relationship

- When the researcher has a current treatment relationship with the patient the researcher may:
 - Access information via the EDW or directly from the medical record to assess eligibility and obtain contact information
 - Contact the patient to obtain consent and authorization face-to-face, electronically (i.e. via email or MyChart), over the phone, or via letter

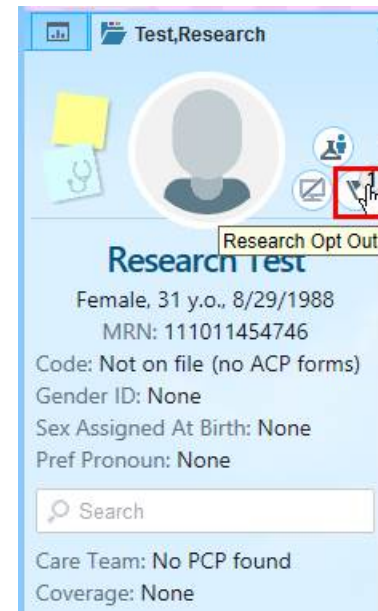
No Treatment Relationship (Cold Recruitment)

- When the researcher doesn't have a treatment relationship with the patient the researcher may:
 - Access a list of eligible patients from the EDW with contact information
 - If not available via EDW, an exception is provided and researcher can access medical record directly, but must determine opt out status prior to contact
 - Contact the patient to obtain consent and authorization face-to-face or via cold contact (i.e. electronically, phone, letter)
 - Prior permission from treating physician no longer required

Opt Out of Research Contact

Obtaining Patient Information for Recruitment

- My Consent to Medical Care permits patients to opt out of contact via cold recruitment
- Cold contact is when a researcher without a treatment relationship to the patient contacts a patient by means other than face-to-face to invite the patient to participate in research.
- A flag is placed on a patient record in Epic when the patient indicates they are “Opting Out” of being cold contacted.
- If a researcher cold contacts a patient for recruitment and the patient indicates they don’t want to be cold contacted for research again, the researcher should either direct the patient to call 630-933-6528 to be “opted out” or the researcher can call this number and make the request on the patient’s behalf.



Recruitment Guidelines

Contact Standards

- Face-to-face recruitment:
 - Researchers recruiting from outside of their own clinical area should work with the NMHC leadership responsible for the area in order to coordinate
 - Follow template included in Recruitment Guidelines document for approaching the patient
- Recruitment in writing and via phone, as applicable, should follow the letter template included in the Recruitment Guidelines, which includes:
 - Noting that contact to the patient by the researchers is “on behalf of Northwestern Medicine” as recruitment is covered under a Business Associate function
 - Emails shall be sent via an nm.org email address. NU staff that don’t have one, can get this by contacting accesspr@nm.org
 - Letters need to be on NM letterhead, download from NMI or contact research@nm.org to obtain
 - Language should not suggest or imply that a patient has a specific diagnosis or condition

Recruitment Guidelines

Privacy Violations

- A privacy violation is when health information received from a Covered Entity for the purposes of recruitment is used or disclosed to an unauthorized person. For example:
 - Your computer with the information is lost or stolen.
 - You email recruitment information to the wrong patient.
 - You email recruitment information to a patient and include unintended others on the communication.
- If you become aware of or suspect a privacy violation this must be reported immediately to FSMIT-Policy@northwestern.edu.



Research Records
Documented in NMHC
Electronic Medical Records



Research Records Documented in NM's EMR(s)

- Research information that is documented in NM's medical record, kept electronically on Epic, is included in NM's designated record set and becomes part of the patient's medical record.
- Northwestern University has provided guidance to researchers with respect to research information that can be documented in Epic.