Research at UNE: What's HIPAA got to do with it?

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BRIEF ANNOUNCEMENTS

1. Today's presentation is being recorded
    - Visit the UNE Responsible Conduct of Research Training website to access the recording and download the slide deck (PDF)
2. Please hold all questions until the end of the presentation
3. Content is applicable to all UNE faculty, staff, and students regardless of college affiliation

TOPICS OF DISCUSSION

1. What is the HIPAA Privacy Rule and how does it apply to research?
2. What is protected health information (PHI)?
3. Difference between PHI and research health information (RHI)
4. Clinical access to medical records ≠ access for research purposes
5. Avenues that permit PHI to be accessed for research purposes

What is the HIPAA Privacy Rule?

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (1996)

- HIPAA is a federal law that applies to health care providers, health plans, and health care clearinghouses. These are covered entities.
- Protects sensitive patient health information from being disclosed
- UNE is a hybrid covered entity with both covered and non-covered functions.

UNE – HYBRID ENTITY

- Hybrid Entity – has both covered and non-covered functions
  - The non-covered functions fall under FERPA (Family Educational Rights and Privacy Act)

- UNE's covered entity components
  - Oral Health Center
  - Coleman Dental Hygiene Clinic
  - Student Health Center
  - MatureCare

HIPAA PRIVACY RULE

- Establishes national standards to protect…
  - Individuals' medical records
  - Individually identifiable health information (Protected Health Information - "PHI") held by a covered entity
- Applies to…
  - Health plans
  - Health care clearinghouses
  - Heath care providers that conduct health care transactions electronically
- The HIPAA Privacy Rule also…
  - Requires appropriate safeguards to protect the privacy of PHI
  - Gives individuals rights over their PHI

What is protected health information (PHI)?

PROTECTED HEALTH INFORMATION (PHI)

- Health information
  - Pertaining to an individual's past, present, or future:
    - Physical or mental health
    - Diagnosis and/or treatment
    - Payment for health care
  - Includes **personal identifiers**, and
  - Is **created, used, or disclosed** by a covered entity

PHI INCLUDES 18 IDENTIFIERS:

1. Name
2. Address (all geographic subdivisions smaller than a state, including street address, city, county and zip code)
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 and all elements of dates (including year) indicative of such age, except that such ages and elements may 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. Web universal resource locators (URLs)
15. Internet protocol (IP) address
16. Biometric identifiers, including fingerprints and voiceprints
17. Photographic images – including full facial photographs and other comparable images
18. Any other unique identifying number, characteristic, or code that could identify an individual

What's the difference between PHI & research health information (RHI)?

PHI VS RHI

PHI

- Individually identifiable health information held by a covered entity and subject to the HIPAA Privacy Rule
- Obtained or generated as part of a health care service within the covered entity
- Entered into a medical record or used to make treatment decisions
- Is used in connection with a standard electronic transaction as defined by HIPAA (e.g., billing for health care services provided)

RHI

- Individually identifiable health information collected during a research study that is not held by a covered entity
- Not subject to the HIPAA Privacy Rule
- Typically involves self-reported health information by the research participant
- The researcher does not review or alter the participant's medical record or make treatment decisions as part of the research
- Not engaged in standard electronic transactions as defined by HIPAA (e.g., billing for health care services provided)

Access to medical records: clinical vs. research purposes – Are they the same?

ACCESS TO MEDICAL RECORDS

Clinical access to medical records

≠

Access for research purposes

HIPAA REGULATIONS

Clinical Access

- Uses and disclosures for treatment, payment, and health care operations

  [45 CFR 164.506]

Access for Research

- Uses and disclosures for which an authorization is required [45 CFR 164.508]
- Uses and disclosures for which an authorization or opportunity to agree or object is not required [45 CFR 164.512]
- Other requirements relating to uses and disclosures of PHI [45 CFR 164.514]

What avenues permit PHI to be accessed for research purposes?

AVENUES THAT PERMIT PHI TO BE ACCESSED FOR RESEARCH

1. Prospective HIPAA authorization from research participants
2. Waiver of HIPAA authorization
3. Creating a de-identified data set
4. Review of PHI preparatory to research
5. Decedent research
6. Use of a limited data set with a data use agreement

Note: Avenues 2 through 6 do NOT require authorization from the individual

Avenue #1:
HIPAA Authorization

HIPAA AUTHORIZATION

See the '*HIPAA Authorization Template for Research Purposes*' available on the UNE IRB website

- Written permission from an individual that allows a covered entity to use or disclose PHI for research
  - Specifies how, why, and to whom the PHI will be used and/or disclosed
- The authorization may be a stand-alone document or embedded within the consent form
- The IRB must approve the language of the authorization
- The researcher retains the original, signed authorization and a copy is provided to the participant

Avenue #2:
Waiver of HIPAA Authorization

WAIVER OF HIPAA AUTHORIZATION

Types of HIPAA waivers requested by researchers:

- Full waiver of HIPAA authorization
  - For retrospective chart review projects

See the '*Request for a Waiver of HIPAA Authorization for Research Purposes*' form available on the UNE IRB website

- Partial waiver of HIPAA authorization
  - For conducting screening/recruitment activities only

Example: A researcher needs to view patient medical records in order to determine who meets study inclusion criteria and can be approached for participation after IRB approval is granted

WAIVER OF HIPAA AUTHORIZATION

The IRB must determine:

1. Only the minimum necessary PHI will be accessed for the research to comply with the HIPAA minimum necessary standard

2. Research could not practicably be conducted without the waiver and access to PHI

3. Research poses no more than minimal risk to participant's privacy

4. Researcher has provided an adequate plan to:

   - Protect the collected HIPAA identifiers from improper use/disclosure
   - Destroy the HIPAA identifiers collected at the earliest opportunity unless retention is justified or required by law

Note: 'Practicably' means possible, NOT convenient

Avenue #3:
Creating a De-Identified Data Set

DE-IDENTIFIED DATA

De-identified data attributes:

- The data set contains no personal identifiers
- No master list or key exists to link the data back to individuals

OR

- If the data is coded, the researcher is NOT given access to the key to the code to re-identify individuals
- The data set cannot be used alone or in combination with other information to identify the individuals

DE-IDENTIFIED DATA

Acceptable de-identification methods:

1. Removal of all 18 HIPAA identifiers from the data set
    - Includes the removal of identifiers related to the individual, the individual's household members, relatives, or employers
2. Determination from a statistician that the risk of re-identification is very small
    - Statistician must document the methods and results of the analysis leading to their determination

DE-IDENTIFIED DATA

A covered entity is able to de-identify PHI without the patient's authorization because de-identification is considered part of routine '*healthcare operations*' under HIPAA

Things to know…

- De-identified data is…
  - Not PHI
  - Not subject to the HIPAA Privacy Rule
  - Not subject to the HIPAA minimum necessary standard

Is IRB approval or exemption required in order to create a de-identified data set?

- No, if the covered entity provides the researcher with a fully de-identified data set
- Yes, if the researcher will access PHI to create the de-identified data set

This scenario would likely require exempt review (exemption category #4). See the '*Application for Exempt Research Projects*' available on the UNE IRB website.

Avenue #4:
Review of PHI Preparatory to Research

REVIEW OF PHI PREPARATORY TO RESEARCH

In order to conduct activities preparatory to research, the researcher may need to review PHI in order to…

- Design the research study
- Determine study feasibility
- Assess participant eligibility for the research study

Is IRB approval required in order to conduct activities preparatory to research?

- No. However, the researcher must provide notice to the covered entity that they wish to review PHI in order to conduct activities preparatory to research.

See the '*Review of PHI Preparatory to Research Notification Form*' available on the UNE IRB website

REVIEW OF PHI PREPARATORY TO RESEARCH

Things to know…

- Only the minimum amount of PHI necessary should be reviewed
- The PHI cannot leave the covered entity
- The information accessed cannot be used for any other purpose – including presentation or publication
- PHI or other identifiable private information cannot be written down or recorded until:
  - IRB approval or exemption is obtained; and
  - The research participant has signed a HIPAA authorization and/or consent form *(where necessary)*

Avenue #5:
Decedent Research

DECEDENT RESEARCH

See the '*Research Involving PHI of Deceased Individuals Attestation Form*' available on the UNE IRB website

What is decedent research?

- Research that involves the access to, use, or disclosure of PHI belonging to deceased individuals; and
- The entire project or a distinct part of the project is directed at decedents

Note: A retrospective chart review project that only involves the *incidental collection* of PHI on deceased individuals would NOT be considered decedent research

Does decedent research require IRB approval or exemption?

- Yes, if the project involves BOTH living and deceased individuals
- When the entire project consists of deceased individuals, the researcher only needs to provide notice to the covered entity that they wish to conduct decedent research

DECEDENT RESEARCH

Things to know…

- HIPAA protects PHI for 50 years after an individual's death
- Only the minimum amount of PHI necessary should be reviewed/collected
- The information accessed cannot be used for any other purpose
- The covered entity can request documentation of the death of any individuals whose PHI will be used or disclosed in the research

Note: Decedent research involving subjects who have been deceased for > 50 years is not subject to the HIPAA Privacy Rule

Avenue #6:
Limited Data Set with Data Use Agreement

LIMITED DATA SET WITH DATA USE AGREEMENT

What is a limited data set (LDS)?

- A data set comprised of health information that only contains the following HIPAA identifiers:
  - Dates (e.g., admission, discharge, service, date of birth, date of death);
  - City, state, zip code; and
  - Age in years, months, days, or hours

These are deemed *indirect* identifiers

Things to know…

- A LDS is still considered PHI and is subject to the HIPAA minimum necessary standard
- A fully executed data use agreement is typically required before a LDS can be sent outside of the covered entity to a 3rd party (external researcher)

LIMITED DATA SET WITH DATA USE AGREEMENT

What is a data use agreement (DUA)?

- A formal, written contract signed by two or more parties that outlines specific ways the LDS may be used or disclosed, and how it must be protected
- Review and signature are required by a responsible party authorized to act on behalf of the institution

  (the researcher typically does not sign the DUA)

Is IRB approval or exemption required in order to create a limited data set?

- Yes. This will likely require exempt review (exemption category #4).

See the '*Application for Exempt Research Projects*' available on the UNE IRB website

QUESTIONS?

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