AGENDA

- Research on the rise
- HIPAA issues in research
- Other privacy issues in research

Research – not just an academic issue anymore

- Historically, most clinical research has been done in academic medical centers
- Research has been moving to the community setting and private practice office
- Estimates suggest 40% of clinical research is now done in a non-academic setting

Privacy and Research
It’s 10 pm, do you know where your data is?

Ryan Meade, JD, CHC-F, CHRC
Director, Regulatory Compliance Studies
Loyola University Chicago School of Law

Marti Arvin, JD, CHC-F, CCEP-F, CHPC, CHRC
Chief Compliance Officer
UCLA Health System and David Geffen School of Medicine
Research – Specialties

• The most common specialty areas in Schools of Medicine:
  • Cancer
  • Cardiology
  • Neurology
  • Orthopedics
  • Psychiatry

• Other areas rapidly on the rise:
  • Nursing research
  • Dental research
  • Psychology
  • Public Health
  • Social Work

Research – A fork in the road

• The “big divide” in clinical research:
  • Prospective study: enrolls subjects who receive services according to a schedule of events
  • Retrospective study: uses medical record information that has already been collected

Terminology – Getting on the same page

• “Subject” – a patient enrolled in a research study
• “IRB” – Institutional Review Board, charged with approving and annual review of a research study
• “Research Informed Consent Form” – written document describing the risks and benefits of the research study along with acknowledging subject’s voluntary participation
• “Principal Investigator” – the individual (usually a physician, but sometimes nurse or other clinician) who conducts the research study
Terminology – Getting on the same page

- **“Privacy Board”** –
  - A review body that may be established to act upon requests for a waiver or an alteration of the authorization requirement under the Privacy Rule for uses and disclosures of PHI for a particular research study.
  - A Privacy Board may waive or alter all or part of the authorization requirements for a specified research project or protocol.

- **Use** –
  - The sharing, employment, application, utilization, examination, or analysis of individually identifiable health information within an entity that maintains such information.

- **Disclosure** –
  - The release, transfer, provision of access to, or divulging in any manner of individual identifiable health information outside the entity that maintains such information.
HIPAA Issues in research

- Authorization issues
- Waiver of authorization issues
- Research on decedents
- Reviews preparatory to research
- De-identified data and data use agreements
- The nature of the organization as a covered entity and whether research is considered in or out of the covered component

Authorization issues

- No authorization
  - It is important to understand your organization's HIPAA construct
  - If information is provided to the researcher without an authorization or the authorization is not valid and it is a **use** - no accounting of disclosure obligation
  - If information is provided to the researcher without an authorization or the authorization is not valid and it is a **disclosure** - there is an accounting of disclosure obligation

Authorization issues

- No authorization
  - A researcher obtaining information from your health system without a valid authorization could trigger breach notification obligations
  - Having the discussion with the researcher that is does not matter under HIPAA what is in the informed consent regarding the data to be collected, how it will be used, etc. unless the ICF meets the criteria for a valid authorization.
Authorization issues

- No valid authorization
  - Authorization criteria that if not defined or present would lead to an invalid authorization
    1. Information to be used or disclosed
    2. Who can use or disclose
    3. To whom the information can be used or disclosed
    4. Purpose(s) of uses and disclosures
    5. Required statements
    6. Re-disclosure by third parties
    7. Participation
    8. Revocation
    9. Expiration date
    10. Access to information during study
    11. Individual's signature and date

Authorization issues

- Authorization not fully completed
  - No one filled in the blank regarding the covered entity
  - No one checked the box(es) or the right boxes for the PHI they wanted to obtain
  - No one checked the special boxes for sensitive information
    - Example: the study indicates all subjects will get an HIV test and state law has specific criteria for who can get the HIV test results.
      - If the box is not checked
        - Can you provide the information to the study team?
        - What does this mean if you find the study team already has the data?

Authorization issues

- Authorization does not cover PHI the researcher wants or has actually acquired
  - Example: the researcher and/or the research team has direct access to your EHR so they have acquired data directly but the data is not covered by the authorization

- Inconsistencies with research informed consent
  - Example: the authorization states the research team can access the entire medical record. The ICF indicates only certain information about the subject will be viewed and recorded.
Waiver of the Authorization

- The criteria for waiver of an authorization is the same for both the complete and partial waiver.
- The rule makes it the responsibility of the Institutional Review Board or a Privacy Board of the organization to ensure the criteria for the waiver is met.
  - Even though the IRB or Privacy Board approves a waiver of authorization the covered entity must still be able to clearly distinguish what PHI the covered entity can give to the researchers or allow the research team to access.

Waiver of the Authorization

- An authorization can be waived if the IRB/Privacy Board determines
  
  A. The use or disclosure of the PHI involves no more than minimal risk to the privacy of the subject based on at least ALL of the following:
  1. An adequate plan to protect the identifiers
  2. An adequate plan to destroy the identifiers at the earliest possible time
Waiver of Authorization (cont.)

iii. Adequate written assurance the PHI will not be reused or re-disclosed except under very limited circumstances
   • Required by law
   • Oversight of the research
   • Other research after additional IRB approval

Waiver of Authorization (cont.)

B. The research cannot practicably be done without the waiver of authorization.
   i. Why won't other recruitment methods be effective?
   ii. Why is obtaining an authorization impractical?
   iii. Example: retrospective records review of clinical database for ER visits for patients with gunshot wound to the head
      i. The subjects might be deceased
      ii. Hard to locate
      iii. So numerous that location is impractical

Waiver of Authorization (cont.)

C. The research cannot practicably be done without access to the PHI.
   i. Why must the researcher use identifiable information for his/her study?
   ii. If the study can be done with de-identified information and there is an adequate process to obtain the de-identified information from the covered entity then the use of a waiver of authorization to allow the research team to access identifiable information may not be appropriate.
Waiver of Authorization (cont.)

D. Protected health information needed.

- Brief description of the PHI needed for which the use or access has been determined to be necessary by the IRB or Privacy Board

The researcher must provide the IRB or Privacy Board with sufficient information to determine that the PHI the researcher wishes to look at is really necessary for the research project.

- The means the researcher should identify the specific PHI she wishes to look at and/or record for her project in the application to the IRB or Privacy Board.
  - If the research team only needs to look at the demographic information about a subject in order to gain access to things like lab results, diagnostic test results, etc. the researcher should indicate both the demographic information they need to see as well as the information they need to record in the research record.

How should this be done?

- The researcher must specify the information needed for the specific purpose of the waiver.
  - Examples
    - Recruitment – What information will the researcher be required to look at to determine if the individual is a potential subject for his or her research project?
    - Retrospective records review – What PHI does the researcher need to look at for the project and what information does the researcher need to record for the project?
Waiver of authorization issues

- The IRB or Privacy Board approval
  - What do you expect from your IRB or Privacy Board to meet the required elements for approval
    - Example: the protocol indicates certain data elements are needed for the study but the waiver application is asking for more information. Has your IRB/Privacy Board evaluated if the PHI is necessary?

Waiver of authorization issues

- What if the researcher asks the covered entity for more PHI than what was approved by the IRB/Privacy Board?
- Understanding the difference between when HIPAA is applicable to data and when the Common Rule is applicable to data.

Reminder

- If a researcher needs to access identifiable information of subjects but does not need to record any of the 18 HIPAA delineated identifiers it is not appropriate to state the research will be using de-identified information.
  - The fact that the researcher is looking at identified information, even if no identifiers are recorded, means the researcher must fit a HIPAA exception before looking at the information for his or her research project, even information for his or her own patients.
De-identified data set

- If the research team can obtain a de-identified data set from the covered entity, meaning a data set from which all 18 of the HIPAA delineated identifiers have been removed for the subject, the subject’s family and any household members; and
- No one on the research team has the means to use a linking code to identify the subject then
- The research team can perform the research activity.

HIPAA Delineated Identifiers

- (i) Names (including initials);
- (2) Street address, city, county, precinct, zip code, and equivalent geo-codes;
- (3) All elements of dates (except year) for dates directly related to an individual and all ages over 89 (this would include procedure dates, date of admission, date of lab work, etc.);
- (4) Telephone numbers;
- (5) Fax numbers;
- (6) Electronic mail addresses;
- (7) Social security numbers;
- (8) Medical record numbers;
- (9) Health plan ID numbers;
- (10) Account numbers;
- (11) Certificate/license numbers;
- (12) Vehicle identifiers and serial numbers, including license plate numbers;
- (13) Device identifiers/serial numbers;
- (14) Web addresses (URLs);
- (15) Internet IP addresses;
- (16) Biometric identifiers, including fingerprints and voice prints;
- (17) Full face photographic images and any comparable images; and
- (18) Any other unique identifying number, characteristic, or code.

Another option

If the research project cannot be done if all 18 of the identifiers are removed another option is the limited data set which removes all "direct" identifiers.

Direct identifiers include

- Names (including initials)
- Street address
- Not city, state, zip code, etc
- Telephone and fax numbers
- Email addresses
- Social Security & medical record numbers
- Health plan ID number
- Other account numbers
- Certificate/license or license plate numbers
- Other identifiers and serial numbers
- Web or IP addresses
- Biometric identifiers like fingerprint and voice prints
- Full face photos
Limited Data Set (LDS)

- Before a LDS can be shared for research, a Data Use Agreement (DUA) must be entered between the covered entity and the recipient.
  - Who signs the agreement?
  - Who is the covered entity?
  - Who is the recipient?

Preparatory to Research

- This HIPAA exception is used to review identifiable health information to prepare a research protocol
- The research must attest to the covered component, BEFORE any information is accessed, that
  - The identifiable information is necessary to prepare the research protocol
  - The information will be used only to prepare the research protocol
  - No identifiable information will be recorded or removed from the covered entity
  - If the researcher is not a member of your workforce but directly views the information from your EHR has the PHI been "removed" from the covered entity?

Research on Decedent Information

- HIPAA protects PHI of a decedent held by the covered entity who has been deceased for less than 50 years.
- To conduct research on the PHI of decedents requires the researcher to submit an attestation to the covered entity indicating:
  - The information is sought solely for research on decedents
  - The information is necessary for the research purpose
  - If requested by the covered entity, documentation of the death of the individual(s)
Accounting for Disclosures

- When a researcher looks at a medical record and/or a billing record for research this can be a disclosure of PHI.
- The disclosure must be accounted for by the covered entity if it is
  - done without an authorization,
  - is not a de-identified data set, and
  - is not in a limited data set
- How do you accomplish this?

Other Privacy Issues in Research

- Use and understanding of Certificates of Confidentiality
- Desire of researcher to further protect data
  - Handling information in the EHR that the researcher wants to have additional protection

Certificate of Confidentiality

- What it is
  - Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project.
  - They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.
Certificate of Confidentiality

• When it is used
  • Used generally to protect sensitive information collected in the research
    • genetic information;
    • information on psychological well-being of subjects;
    • information on subjects’ sexual attitudes, preferences or practices;
    • data on substance abuse or other illegal risk behaviors;
    • Studies where subjects may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures).

Certificate of Confidentiality

• What it is not
  • Prohibition against internal use of the information for administrative and billing activity
  • An absolute protection or guarantee that the information will never be disclosed
  • Prohibition the release of otherwise mandated reporting such as
    • Child abuse
    • Communicable diseases
    • Threat of violence against self or others

Desire of researcher to further protect data

• Language in the Research Informed Consent and promises made
  • Promise only the research team will know a subject is a participant in research
  • What is services are performed and billed by your health system billing office?
  • What about the modifiers you might send to the payor for routine costs?
  • What about compliance activities?
  • Would you consider this part of the research team?
  • Do you think the subject would?
Desire of researcher to further protect data

- Promise that certain information will have higher protections without assuring the capabilities are present to meet the promise
  - Genetic information
  - Other Sensitive information
- Promise of complete confidentiality
  - Can we ever assure this?
- Handling information in the EHR that the researcher wants to have additional protections around
  - Can your EHR handle blinding certain data but not all the research data?
  - What is the impact on the connection between you EHR and your CRMS?

Questions