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HIPAA Compliance in Research

The continuing challenges



AGENDA

- ❑ How is your organization deal with the challenges of using and disclosing PHI for research?
- ❑ How will EMR/EHR impact research and what are the compliance issues
- ❑ The HIPAA security rule and the implications for research
- ❑ The impact of the HIPAA enforcement rule on research
- ❑ Q & A



The challenges continue

- Use and disclosures of PHI in research
 - Under the waiver of authorization
 - Tissue with identifiers attached
 - For multiple research purposes
- Continuing discussion of combined versus separate authorization and informed consent
- RHI versus PHI
- Have you checked your NPP lately?



Waiver of authorization

- The University of Louisville has a privacy board that reviews all waiver requested
 - A check list has been created for the Privacy Board members to evaluate a waiver request
 - A check list has been created for researchers preparing a waiver request
 - Researchers still don't understand requirements
 - Privacy Board is just now getting the obligation they have to approve the waiver request



Tissue with identifiers

- ❑ Researchers still struggle with the concept that tissue plus identifiers is PHI not “waste tissue”
- ❑ Ownership of tissue can be an issue
- ❑ Collection of the tissue for the underlying clinical research project
- ❑ Retention of tissue for a future research use



Using data for multiple purposes

- ❑ Separation of the clinical trial from a research database and/or bio-repository
- ❑ Is a separate authorization needed?
- ❑ Do you have “old” databases and/or bio-repositories that need to be evaluated?

Together or separate

- Should the informed consent and the authorization be combined?
- Pros
 - Easier for the subject to sign one document
 - Helps with compliance
 - IRB will generally review
- Cons
 - Requirements of CTA regarding proprietary information
 - Storage of documents in medical record
 - Subject may not be clear that documents serve to different purposes
 - May have to present authorization to multiple sites that don't require informed consent document



RHI versus PHI

- ❑ Some institutions have defined health information used for research purposes as “Research Health Information” or RHI
- ❑ RHI is distinguished from PHI because it is collected for a research purpose
- ❑ CAUTION: this definition works if the RHI is not collected by a covered entity

RHI versus PHI

- If RHI is collected by a covered entity it is PHI
- The HIPAA definitions
 - **PHI** - Individually identifiable health information that is transmitted by electronic media; maintained in electronic media; or transmitted or maintained in any other form or medium.
 - **Individually identifiable health information** - is information that is a subset of health information, including demographic information collected from an individual, and: Is created or received by a health care provider, health plan, employer or health care clearinghouse; and relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for health care to an individual; and that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.



RHI versus PHI

- ❑ Many hybrid entities designate the research component as outside the health care component.
- ❑ Thus the information collected by its researcher is not PHI but RHI.
- ❑ However, if research is not separated then RHI equals PHI
- ❑ Even if research is separated it can be complex if the data is collected in a clinical/research setting.



Impact of EMR/EHRs on research

- ❑ EMR and EHRs are becoming more popular
- ❑ Covered entities struggle with the control of PHI when these systems are implemented
- ❑ Researchers can effectively using these systems for data by understanding the privacy and security rules.



Covered entities concerns over EMRs

- Covered entities are concerned that access to EMRs will reduce their ability to control data
 - What process will be in place for determine the reason someone access a record?
 - How can access be controlled before the use or disclosure?
 - How can information be controlled once it has been removed from the covered entity?



Benefiting from EMRs

- ❑ EMRs and EHRs can provide access to a lot of data in an efficient and timely manner
- ❑ Researchers need to understand the restrictions on using and disclosing PHI for research
- ❑ Think about the ways data might be accessed when setting up an EMR/HER
- ❑ Asked to be involved in selection of EMR/EHR so that you can help define the input



Involvement in development

- Can the necessary forms be automate?
 - Preparatory to research
 - Check boxes for waiver of authorizations and authorizations
 - Online request for LDS and DUA
 - Online request for de-identified data set



Benefiting from EMRs

□ Remember-

- Under HIPAA each and every time PHI is looked at or shared a HIPAA exception must be met or an authorization must be in place
- The HIPAA exception to be met will depend on the purpose for which the information is being looked at or shared.
- Educate researchers on the exceptions that apply to looking at or sharing data for research



Have you checked your NPP lately?

- Does your NPP delineate the potential uses and disclosures of PHI for research.
 - Does the language cover all the HIPAA exceptions for research?
 - Did you include research in the original NPP?
 - Are your new patients getting a copy of the NPP?



The HIPAA security rule

- ❑ Is PHI used in research being appropriately protected?
- ❑ Where is the data being stored?
- ❑ Is minimum necessary being applied?
- ❑ Who has access to the data?



Storage of research data

□ Paper records

- Are paper records stored so that only individuals with a need to access can?
- Is the researcher following the storage outlined in his/her protocol and/or waiver of authorization form?
- How are paper records destroyed?



Storage of research data

- Electronic records
 - Are electronic records stored in an encrypted format?
 - Are electronic records stored on the personal computers of faculty, residents, students, research coordinators, etc?
 - Are your electronic research records stored on a device owned by another entity?
 - Are research records properly backed-up?



Enforcement rule and research

- Still not much active enforcement by OCR
- Things to think about under HIPAA
 - Accessing records without an authorization or waiver of authorization could be a violation
 - Violation would potentially be \$100 X every patient record accessed
 - Example: research looks at 100 patients in his/her own practice for a retrospective chart review with authorization or waiver of authorization. Potential violation is \$100 x 100 or \$10000



Enforcement rule and research

- A covered entity releases a limited data set to a Pharma company without a data use agreement.
 - Is it one violation for not have a DUA?
 - Is it one violation each patient?
 - Is it a violation for every day a DUA is not in place?



Enforcement rule and research

- A covered entity has a laptop stolen with research data on it that is identifiable and the data is not encrypted.
 - Is password protection enough?
 - If not, is it one violation or multiple?

QUESTIONS

