DATA USE IN RESEARCH: LIMITATIONS, OBLIGATIONS, MYTHS AND MYSTERIES

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DISCLAIMER

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- This presentation is for general informational purposes. Nothing in this presentation should be construed as legal advice. The opinions expressed are those of the presenter and do not represent the views of her organizations.

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AGENDA

- Privacy, HIPAA, and research
- Organizational structure and the impact on research
- Common challenges
- Information Blocking
- Questions

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PRIVACY, HIPAA, AND RESEARCH

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BACKGROUND AND COMMON IMPLICATIONS

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- Nature of research involving health information
- Privacy is not just HIPAA
- The life cycle of a research study and the privacy implications

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THE DIVIDE IN CLINICAL RESEARCH

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Prospective studies

- Enrolls subjects who receive services according to a schedule of events
- Anticipates interaction with the subject

Retrospective studies

- Uses existing information, often the medical record of the subject
- Does not anticipate any interaction with the subject

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PRIVACY IS NOT JUST HIPAA

- Common Rule
- GDPR and other international laws
- SAMSHA regulations
- State laws

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THE RESEARCH STUDY CYCLE AND PRIVACY

- There are privacy implications at every stage of a research study
  - Protocol drafting
  - Grant submission
  - Negotiating the clinical trial agreement
  - How data is collected, shared, and retained through all stages of the study
  - Data transmission and storage
  - IRB submission
  - Closing out the study

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IMPLICATIONS OF THE ORGANIZATIONAL STRUCTURE ON RESEARCH

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- What is the organizational structure?
- Nature of other relationships for the organization

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WHAT IS THE ORGANIZATIONAL STRUCTURE?

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- Single covered entity
  - Where is research data stored?
    - EHR
    - Research record
- Hybrid covered entity
  - Is the nature of the hybrid entity properly designated
  - Do researcher understand the impact on data?

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WHAT IS THE ORGANIZATIONAL STRUCTURE?

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- Multiple affiliated entities
  - Who "owns" research data
  - Where is it stored?
    - EHR
    - Research record

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OTHER RELATIONSHIPS – Academic Medical Center

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- Health care entity and research entity are all part of one legal entity
- Health care entity is a separate legal entity but part of the overall enterprise under one umbrella

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OTHER RELATIONSHIPS – Academic Medical Center

- Health care entity is a separate legal entity affiliated with a university
  - Research activity is only performed by university
  - Research activity by multiple parties
    - University and
    - Affiliated party under the same corporate umbrella and/or
    - Affiliated party but legally separate from the university and each other

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COMMON CHALLENGES

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CHALLENGES

- Laws and regulations other then HIPAA
- Using a single IRB
- Auditing compliance

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LAWS OTHER THAN HIPAA-COMMON RULE

Common Rule

- Protect the rights and welfare of human subjects.
- Obligations triggered upon recording identifiable information

HIPAA

- Protects the privacy and security of information
- Obligations triggered when identifiable information is looked at which is earlier then Common Rule

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LAWS OTHER THAN HIPAA-GDPR

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LAWS OTHER THAN HIPAA- GDPR

GDPR

- Anonymization –
  - direct and indirect identifiers removed
  - Technical safeguards added
  - Zero risk of re-identification

HIPAA

- De-identification
  - Safe harbor – data set is de-identified if all 18 identifiers regarding the individual, their family members and household members is removed

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LAWS OTHER THEN HIPAA -GDPR

- PSEUDONYMIZATION
  - Processing of personal data in a way that it cannot be linked to a specific subject without the use of additional information
    - Honest Broker concept
  - Coded data is identifiable personal data under GDPR
  - Coded data where the research team does not have access to the code is not PHI under HIPAA

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LAWS OTHER THEN HIPAA -SAMSHA

- Compliance considerations
  - Ensuring appropriate protections
  - Compliance with re-disclosure requirements
  - Contract language if contractors are used
  - Breach notification obligations

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LAWS OTHER THEN HIPAA -SAMSHA

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- Appropriate protections
  - Evaluate the security measures for research involving Part 2 information
  - Reassess the incident response plan to encompass obligations for Part 2 data

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LAWS OTHER THEN HIPAA -SAMSHA

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- Re-disclosure, make sure
  - The notice is going with data used for research
  - Researchers are only re-disclosing to appropriate individuals
  - Any authorization used for Part 2 SUD information is very clear about who might be getting the information
  - Any waiver of authorization is clear on the uses and disclosures for the Part 2 SUD information and
    - Has an adequate plan to protect the information

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LAWS OTHER THEN HIPAA -SAMSHA

- Use of contractors
  - Do agreements include language regarding the need to protect Part 2 information shared with the contractor
  - While a BAA is uncommon in research, make sure your BAA specifically mentions Part 2 data if applicable

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LAWS OTHER THEN HIPAA -SAMSHA

- Breach notifications obligations
  - While not yet clear that the regulatory criteria will be there may be obligations to notify SAMSHA regarding any breach of Part 2 information similar to the requirement to notify OCR of the breach of PHI.

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LAWS OTHER THEN HIPAA –STATE LAWS

- Additional protections of certain data
  - STI
  - Behavioral health
  - Genetic
  - Substance use disorders
  - Biometric
- Different laws if research crosses state boundaries

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USE OF SINGLE IRB

- What happens if your IRB did not approve the study
- Researchers want to use the single IRB approval
  - What is no waiver of authorization was done by the IRB?
  - What is the IRB approved with a statement that an authorization is required if PHI will be used?
  - What if the approval letter only states a waiver of authorization was granted but does not indicate what data elements can be shared?
  - What is approval letter only includes the 18 identifiers as the data elements that can be shared?

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AUDITING AND MONITORING

- Reviewing requests for data
  - Do data requests match to approval?
  - Is IRB or privacy board following minimum necessary for waiver of authorization
- Reviewing the documents being used
  - Do authorizations include your covered entity as party?

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AUDITING AND MONITORING

- Evaluating access to PHI to determine if research staff is following the rules
- Looking at signature dates of authorization to see if access was obtained before it was signed.

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INFORMATION BLOCKING IMPACT ON RESEARCH

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DATA REQUESTS

- Information blocking changes the question from "Can we share the data?" to "Can we not share the data?"
- Data subject to the IB Rule is EHI
  - Essentially equivalent to the designated record set as of 10/6/22
  - Subset of information that is part of the DRS between 4/5/21 and 10/6/22

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DATA REQUESTS

- IB Rule prohibits any "***actor***" – a health information technology developer, health information networks, health information exchanges, and/or health care provider.
- Requisite knowledge standard: whether the provider ***actor*** "knows that such practice is unreasonable and is likely to interfere with access, exchange or use of EHI"

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DATA REQUESTS

- Organizations may see increased requests from
  - Outside unaffiliated researchers
  - Other outside parties
- Requests for data for research and implications.
  - Is research data part of the designated record set?
    - Research data integrated in to the EHR
    - Individually identifiable health information on a research subject held by the covered entity

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Thank You!

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