



# Challenges with Biorepositories, Databases, and Future Research

**Institute of Medicine**

**Committee on Health Research and the Privacy of  
Health Information**

**Presenter: Kristen Rosati, Esq.**

# HIPAA Challenge 1

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- n HIPAA authorization may not seek permission to use PHI in a repository for future research
  - n HIPAA Privacy Rule requires an authorization to describe each purpose of the requested use or disclosure
  - n DHHS has concluded that a HIPAA authorization:
    - n May not seek permission to use or disclose PHI for future unspecified research; and
    - n Must be protocol-specific or seek permission to *store* PHI only
- n Conflicts with the Common Rule

# Solution to HIPAA Challenge

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- n Problems created
  - n Cannot combine HIPAA authorization with informed consent to store PHI for future research
  - n Creates inequity between covered entities and non-covered entities that hold repositories
- n Potential change in DHHS interpretation
  - n Regulatory requirement that an authorization describe “each purpose of the requested use or disclosure” is met if the authorization describes the type or category of research that may be conducted with the PHI stored in the repository (consistent with the Common Rule)

# HIPAA Challenge 2

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- n Cannot combine authorizations to store PHI in a repository and to use PHI for a clinical trial
  - n HIPAA Privacy Rule:
    - n Permits combining an authorization with other documents in the “same research study”
    - n Prohibits combining authorizations where covered entity has conditioned the provision of treatment on only one of the authorizations
    - n Permits conditioning research-related treatment on signing authorization to use or disclosure of PHI for “such research”

# HIPAA Challenge 2

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- n DHHS has concluded that collection of PHI for a clinical trial and a repository are separate research activities
  - n Therefore cannot condition participation in clinical trial on signing authorization to include PHI in repository
  - n Authorizations therefore cannot be combined into a “compound authorization”
- n Problems created
  - n Cannot combine HIPAA authorization for clinical trial with HIPAA authorization to collect PHI for repository—confusing!

# Solution to HIPAA Challenge

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- n Regulatory change to remove prohibition against combining authorizations where covered entity has conditioned the provision of treatment on only one of the authorizations—at least in the research context
- n Potential change in DHHS interpretation
  - n A clinical trial and any related research repository could be treated as the “same research”
  - n HIPAA would thus permit conditioning participation in clinical trial on authorization to disclose PHI in clinical trial and to the repository, and would therefore permit combining those authorizations

# HIPAA Challenge 3

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- n HIPAA de-identification
  - n Remove or code HIPAA identifiers
    - n Includes month and day of dates directly related to an individual, such as dates of service and dates of tissue collection
    - n Code cannot be derived from identifiers (e.g. no initials)
  - n Document that there is a statistically “very small” risk that information could be used to identify a participant
- n Common Rule de-identification: investigator cannot reasonably determine identity of participant

# Solution to HIPAA Challenge

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## n Problems created:

- n Researchers often miss tissue collection dates and initials as HIPAA identifiers
- n Dates and initials can be released as a limited data set, but requires a data use agreement
  - n Data use agreement requires agreement that recipient will not use or further disclose the information in a manner that would violate HIPAA if done by the covered entity; this means that, if a non-covered entity receives the limited data set for its repository, the non-covered entity cannot access that limited data set without complying the HIPAA Privacy Rule
  - n Lack of coordination between IRBs and HIPAA offices regarding data use agreements

# Solution to HIPAA Challenge

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- n Solution: Harmonize HIPAA research rules with Common Rule and permit release of non-direct identifiers without a data use agreement

# HIPAA Challenge 4

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- n Is genetic information accompanying biospecimens “individually identifiable information” under HIPAA?
  - n DHHS has concluded that “neither blood nor tissue, in and of itself, is considered individually identifiable health information...” but that “results from an analysis of blood and tissue, if containing or associated with individually identifiable information, would be PHI”
  - n Problems created: Uncertainty and potential disruption of genetic research with strict interpretation

# Solution to HIPAA Challenge

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- n More express DHHS guidance that genetic information is not PHI unless the recipient has access to a databank that holds genetic information with identifiers
  - n Information is not “individually identifiable” unless it identifies the individual or there is a reasonable basis to believe the information can be used to identify the individual
  - n If genetic information is not “individually identifiable,” it is not necessary to determine whether the information meets the “safe harbor” for de-identification by removing biometrics or other unique identifying characteristics

# Thank You!

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Kristen B. Rosati

Coppersmith Gordon Schermer & Brockelman PLC

2800 North Central Avenue, Suite 1000

Phoenix, Arizona 85004

[krosati@cgsblaw.com](mailto:krosati@cgsblaw.com)

602-381-5464; krosati@cgsblaw.com