Research Privacy and Security Considerations Beyond HIPAA: What are the Compliance Concerns

Presented by:

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CynergisTek won the 2017 Best in KLAS Award for Cyber Security Advisory Services

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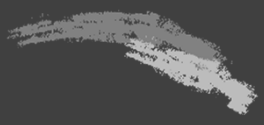
Today's Agenda

1. GDPR Overview
2. HIPAA & GDPR comparison
3. GDPR & Common Rule Comparison
4. Revisions to the Common Rule
5. Privacy Implications
6. Questions

GDPR Overview



General Data Protection Regulations

- Standardizes data protection for all 28 EU countries
- Covered “processing” of personal information by an individual or legal entity.
  - Broad term that covers virtually everything done to and with personal data

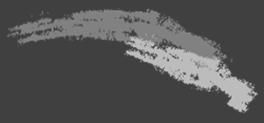
General Data Protection Regulations

- GDPR applies to any entity
  - operating within the EU
  - Outside of the EU that processes personal information of an individual physically in the EU if it
    - Offers goods or services to such individual
    - Monitors the behavior of such individual

General Data Protection Regulations

- Two types of data handlers GDPR applies to:
  - Controllers
    - Entity or person that determines the purpose and means of processing of personal data
    - This might include a sponsor, PI, or primary research site
  - Processors
    - Covered by GDPR when engaged by a controller to provide data processing services.
- GDPR has special rule for transferring personal information outside the EU

GDPR and HIPAA Comparison



Comparing HIPAA and GDPR

- De-identification versus anonymization
- Requirement for notice
- Breach notification
- Fines for non-compliance

Comparing GDPR and HIPAA

HIPAA	GDPR
• De-identification – Safe harbor – data set is de-identified if all 18 identifiers regarding the individual, their family members and household members is removed	• Anonymization – direct and indirect identifiers removed – Technical safeguards added – Zero risk of re-identification

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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

Comparing GDPR and HIPAA

HIPAA	GDPR
• Notice requirement – Must be provided at the first episode of care by a covered entity – No obligation specific to the research team	• Notice requirement – Must be provided by the controller prior to collection of personal information direct and indirect identifiers removed – Likely built into the consent document for research

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Comparing GDPR and HIPAA

HIPAA	GDPR
• Breach reporting – Must report a breach without undue delay but not more than 60 days after breach discovered. – Must notify the individual and OCR	• Breach reporting – Must notify regulator without undue delay o Notice should be no later than 72 hours after awareness of incident – Notice to the individual only if likely to be high risk to the individual's rights and freedoms

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Comparing GDPR and HIPAA

HIPAA	GDPR
• Fines – Tiered approach between $100 to $50000 per violation of each individual standard – Max fine per standard violated is between $25,000 and $1.5 million per standard violated per year	• Fines – Tiered approach o The higher of 10 million euro 2% of global turnover (revenue) or o The higher of 20 million euro 4% of global turnover (revenue)

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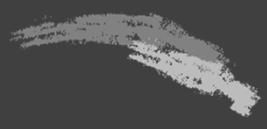
GDPR and Common Rule Comparison



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Comparing GDPR and the Common Rule

Common Rule	GDPR
• Consent – Informed consent required from research participants – Waiver of informed consent permitted.	• Consent – Use of data is permitted if there is freely given, specific, informed, unambiguous, express written consent

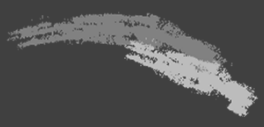
Comparing GDPR and the Common Rule

Common Rule	GDPR
• Withdrawing consent – Individual is no longer a participant – Data already collected can be used for the study.	• Withdrawing consent – Required deletion or anonymization of data unless the informed consent expressly states the data can continue to be used

Comparing GDPR and the Common Rule

Common Rule	GDPR
• Broad consent – Intent to make use of information for research easier – Can use information or biospecimen consistent with consent	• Broad consent – Required deletion or anonymization of data unless the informed consent expressly states the data can continue to be used – Unclear if additional processing of the collected data requires re-consent

Revisions to the Common Rule



Relevant changes to the Common Rule

- Changes to the Federal Wide Assurance
- Provisions for broad consent
- Changed and new exempt categories

Changes to the FWA

- Before the revised rule institutions could elect to have all studies covered by their FWA
- Post 1/21/19 this is no longer an option
- Non-exempt non-federally funded research thus is not covered by the Common Rule requirements

Changes to the FWA

- Without IRB oversight, who will assure protection of human subjects?
- It is technically easier to not require IRB review of these studies
- Increased concern regarding the lack of protections

Changes to the FWA

- Treating non-federally funded, non-exempt research by different rules
- Are there state law provisions that make IRB oversight a requirement?
- How would research be tracked if there was a decision that IRB oversight is not required?

Provisions for broad consent

- One time consent
- Permits the storage, maintenance and secondary research of identifiable information or biospecimen.
  - No additional consent required if future research is within the scope of broad consent
- If subject refused broad consent, IRB cannot later waive informed consent

Mandatory elements of broad consent

- General description of types of research
- Description of types of identifiable information or biospecimens that might be used for research
- Whether data or specimens might occur
- Who might conduct research with the data or specimens
- Time frame for storage and maintenance of data or biospecimens (this can be indefinite)

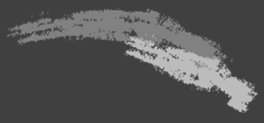
Mandatory elements of broad consent

- Description of any benefits to subject
- Description of how subject confidentiality will be maintained
- Statement that participation is voluntary and there are not adverse consequences of not participating or withdrawing
- Statement regarding possible commercial profits & subject's right to share (if applicable)
- Statement regarding know or anticipated whole genome sequencing

Changed and new exempt categories

- Revises certain existing categories
- Creates new categories of exempt research
  - Use of broad consent
  - Limited IRB review

Privacy Implications



GDPR

- Do you know when a subject's information is governed by GDPR?
- Can you handle the differences in regulatory obligations between GDPR governed data and other data?
- What if a subject withdraws from the study?

GDPR

- Would you consent meet the requirements of GDPR?
- Can you make the required notification within 72 hours of a data compromise?
- What do you do if you learn your study has data covered by the GDPR and you are non-compliant?

Common Rule Changes - FWA issues

- If the IRB does not need to see the study for Common Rule purposes, what about HIPAA waivers?
  - Will the study still come to the IRB?
  - Will the organization establish a separate structure for a Privacy Board?
- If research is not tracked by IRB, how would a study be audited for privacy and security compliance?
- What about ensure appropriate authorization is obtain for studies without IRB oversight?

Common Rule Changes - FWA issues

- For studies that no longer require ongoing review is there a need for any HIPAA oversight?
  - If so who is responsible?
  - Will covered entities start putting more stringent terms in clinical trial agreements?
- Is there an increased risk that sponsors may have data they are not legally entitled to receive?

Thank You!

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